

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	14	16-25 Years/C4591001 1007 10071082 (2)
			16-25 Years/C4591001 1007 10071556
			12-15 Years/C4591001 1007 10071593
			16-25 Years/C4591001 1080 10801019
			16-25 Years/C4591001 1080 10801055
			16-25 Years/C4591001 1085 10851244
			16-25 Years/C4591001 1091 10911122
			16-25 Years/C4591001 1094 10941169
			16-25 Years/C4591001 1121 11211067
			16-25 Years/C4591001 1128 11281177
			16-25 Years/C4591001 1167 11671132
			16-25 Years/C4591001 1169 11691014
			16-25 Years/C4591001 1231 12312528
			16-25 Years/C4591001 1269 12691047
			Subject received systemic corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Inclusion/exclusion	Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	3	16-25 Years/C4591001 1247 12471244
			16-25 Years/C4591001 1120 11201038
	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	3	16-25 Years/C4591001 1161 11611023
			16-25 Years/C4591001 1231 12311088
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	1	16-25 Years/C4591001 1006 10061246
			12-15 Years/C4591001 1006 10061272
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	4	12-15 Years/C4591001 1009 10091320
			16-25 Years/C4591001 1231 12311191
	Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	3	16-25 Years/C4591001 1133 11331207
			16-25 Years/C4591001 1156 11561015
16-25 Years/C4591001 1161 11611016			
16-25 Years/C4591001 1254 12541142			
			16-25 Years/C4591001 1112 11121058
			16-25 Years/C4591001 1161 11611008

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
Investigational product Blind compromised	Dosing/administration error, subject did not receive correct dose of vaccine	1	16-25 Years/C4591001 1161 11611018
		16	16-25 Years/C4591001 1096 10961195
			16-25 Years/C4591001 1068 10681002
			16-25 Years/C4591001 1068 10681010
			16-25 Years/C4591001 1068 10681018
			16-25 Years/C4591001 1068 10681037
			16-25 Years/C4591001 1068 10681047
			16-25 Years/C4591001 1141 11411065
			16-25 Years/C4591001 1141 11411139
			16-25 Years/C4591001 1231 12313467
			16-25 Years/C4591001 1231 12313498
			16-25 Years/C4591001 1231 12313505
			16-25 Years/C4591001 1231 12313515
			16-25 Years/C4591001 1231 12313519
16-25 Years/C4591001 1231 12313533			

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
			16-25 Years/C4591001 1231 12313542
			16-25 Years/C4591001 1231 12313546
			16-25 Years/C4591001 1231 12313553
	IP administered that was deemed not suitable for use by Almac	4	16-25 Years/C4591001 1024 10241091
			16-25 Years/C4591001 1044 10441034
			16-25 Years/C4591001 1096 10961027
			16-25 Years/C4591001 1096 10961245
	Other IP deviation	3	16-25 Years/C4591001 1096 10961195
			16-25 Years/C4591001 1126 11261053
			16-25 Years/C4591001 1161 11611015
	Subject was vaccinated despite being ineligible	1	16-25 Years/C4591001 1092 10921158
	Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (<14 days) systemic corticosteroids, IP administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days.	2	16-25 Years/C4591001 1028 10281294
			16-25 Years/C4591001 1247 12471244
Other	Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	8	16-25 Years/C4591001 1161 11611007
			16-25 Years/C4591001 1161 11611008

16.2.2.1 Listing of Important Protocol Deviations – Subjects 12 Through 25 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Age Group/Subject (Number of Deviations if >1)
			16-25 Years/C4591001 1161 11611009
			16-25 Years/C4591001 1161 11611010
			16-25 Years/C4591001 1161 11611023
			16-25 Years/C4591001 1161 11611024
			16-25 Years/C4591001 1161 11611026
			16-25 Years/C4591001 1161 11611028
	Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	5	16-25 Years/C4591001 1161 11611006
			16-25 Years/C4591001 1161 11611015
			16-25 Years/C4591001 1161 11611016
			16-25 Years/C4591001 1161 11611018
			16-25 Years/C4591001 1161 11611019
Procedures/tests	Subject had a vaccination diary activated, but was not part of the reactogenicity subset	2	16-25 Years/C4591001 1219 12191004
			16-25 Years/C4591001 1235 12351153

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16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
	Dosing/administration error, subject did not receive correct dose of vaccine	1	C4591001 1231 12313428
Concomitant medications	Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	259	C4591001 1003 10031166 C4591001 1006 10061078 (2) C4591001 1006 10061109 (2) C4591001 1007 10071082 (2) C4591001 1007 10071110 C4591001 1007 10071186 C4591001 1007 10071212 C4591001 1007 10071218 C4591001 1007 10071225 C4591001 1007 10071243 C4591001 1007 10071250 C4591001 1007 10071266 C4591001 1007 10071269 C4591001 1007 10071276

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1007 10071286
			C4591001 1007 10071295
			C4591001 1007 10071339
			C4591001 1007 10071380
			C4591001 1007 10071387
			C4591001 1007 10071402
			C4591001 1007 10071556
			C4591001 1009 10091133
			C4591001 1009 10091185
			C4591001 1012 10121083
			C4591001 1012 10121110
			C4591001 1015 10151116
			C4591001 1016 10161087
			C4591001 1016 10161280
			C4591001 1018 10181009

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1018 10181027
			C4591001 1018 10181039
			C4591001 1018 10181058
			C4591001 1018 10181105
			C4591001 1018 10181111
			C4591001 1018 10181113
			C4591001 1018 10181127
			C4591001 1018 10181141
			C4591001 1018 10181164
			C4591001 1018 10181170
			C4591001 1018 10181191
			C4591001 1018 10181204
			C4591001 1018 10181214
			C4591001 1018 10181223
			C4591001 1018 10181302

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1018 10181306
			C4591001 1018 10181319
			C4591001 1019 10191063
			C4591001 1028 10281162 (2)
			C4591001 1037 10371219
			C4591001 1039 10391124
			C4591001 1039 10391153
			C4591001 1042 10421028
			C4591001 1042 10421262
			C4591001 1044 10441056
			C4591001 1048 10481027
			C4591001 1048 10481070
			C4591001 1048 10481085
			C4591001 1052 10521121
			C4591001 1054 10541110

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1054 10541161
			C4591001 1055 10551145
			C4591001 1055 10551152
			C4591001 1056 10561009 (2)
			C4591001 1056 10561197 (2)
			C4591001 1056 10561477 (2)
			C4591001 1057 10571050
			C4591001 1057 10571198
			C4591001 1057 10571201
			C4591001 1057 10571222
			C4591001 1057 10571236 (2)
			C4591001 1066 10661121
			C4591001 1071 10711234
			C4591001 1072 10721012
			C4591001 1072 10721029

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1072 10721058
			C4591001 1072 10721077
			C4591001 1072 10721084
			C4591001 1079 10791177 (2)
			C4591001 1080 10801019
			C4591001 1080 10801055
			C4591001 1081 10811094
			C4591001 1081 10811114
			C4591001 1081 10811186
			C4591001 1083 10831154
			C4591001 1083 10831162
			C4591001 1083 10831242
			C4591001 1083 10831252
			C4591001 1083 10831284
			C4591001 1084 10841017

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1084 10841061
			C4591001 1084 10841137
			C4591001 1084 10841156
			C4591001 1084 10841241
			C4591001 1084 10841358
			C4591001 1084 10841439 (2)
			C4591001 1084 10841456
			C4591001 1084 10841480
			C4591001 1085 10851064
			C4591001 1085 10851069
			C4591001 1085 10851136
			C4591001 1085 10851137
			C4591001 1085 10851237
			C4591001 1085 10851244
			C4591001 1085 10851286 (2)

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1085 10851287
			C4591001 1087 10871066
			C4591001 1089 10891103 (2)
			C4591001 1091 10911091
			C4591001 1091 10911122
			C4591001 1091 10911215
			C4591001 1093 10931216
			C4591001 1094 10941167
			C4591001 1094 10941169
			C4591001 1095 10951031
			C4591001 1096 10961026
			C4591001 1096 10961109
			C4591001 1096 10961216
			C4591001 1096 10961256
			C4591001 1096 10961318

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1098 10981224
			C4591001 1107 11071013
			C4591001 1109 11091275
			C4591001 1109 11091352
			C4591001 1110 11101053
			C4591001 1110 11101177
			C4591001 1110 11101234
			C4591001 1110 11101244
			C4591001 1111 11111051
			C4591001 1112 11121062
			C4591001 1112 11121083
			C4591001 1112 11121135
			C4591001 1112 11121243
			C4591001 1114 11141015
			C4591001 1114 11141054

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1116 11161008
			C4591001 1116 11161012 (2)
			C4591001 1120 11201096
			C4591001 1121 11211029 (2)
			C4591001 1121 11211057 (2)
			C4591001 1121 11211059
			C4591001 1121 11211067
			C4591001 1121 11211087
			C4591001 1122 11221003
			C4591001 1122 11221038
			C4591001 1123 11231104
			C4591001 1123 11231145
			C4591001 1123 11231249
			C4591001 1124 11241025
			C4591001 1124 11241052

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1124 11241103
			C4591001 1124 11241120 (2)
			C4591001 1125 11251043
			C4591001 1126 11261045
			C4591001 1126 11261080
			C4591001 1126 11261135
			C4591001 1126 11261151
			C4591001 1128 11281026
			C4591001 1128 11281083
			C4591001 1128 11281112
			C4591001 1128 11281132
			C4591001 1128 11281177
			C4591001 1128 11281227
			C4591001 1128 11281265
			C4591001 1129 11291064

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1129 11291072
			C4591001 1130 11301028
			C4591001 1130 11301094 (2)
			C4591001 1133 11331130
			C4591001 1133 11331406
			C4591001 1133 11331438 (2)
			C4591001 1133 11331555
			C4591001 1135 11351241 (2)
			C4591001 1135 11351555
			C4591001 1139 11391042
			C4591001 1140 11401176
			C4591001 1142 11421112
			C4591001 1147 11471001
			C4591001 1147 11471007 (3)
			C4591001 1147 11471047

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1149 11491025 (2)
			C4591001 1149 11491040
			C4591001 1149 11491307
			C4591001 1152 11521137
			C4591001 1152 11521192 (2)
			C4591001 1152 11521347 (2)
			C4591001 1167 11671071 (2)
			C4591001 1167 11671132
			C4591001 1169 11691014
			C4591001 1169 11691023
			C4591001 1169 11691034
			C4591001 1169 11691057
			C4591001 1169 11691069
			C4591001 1170 11701026
			C4591001 1170 11701045

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1170 11701081
			C4591001 1170 11701110
			C4591001 1170 11701171
			C4591001 1170 11701209
			C4591001 1170 11701231 (2)
			C4591001 1170 11701296
			C4591001 1170 11701413
			C4591001 1171 11711071
			C4591001 1171 11711181
			C4591001 1171 11711183
			C4591001 1171 11711186
			C4591001 1171 11711247
			C4591001 1171 11711250
			C4591001 1171 11711261
			C4591001 1177 11771076

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1177 11771157
			C4591001 1177 11771369
			C4591001 1178 11781065
			C4591001 1204 12041094
			C4591001 1204 12041176†
			C4591001 1204 12041280
			C4591001 1207 12071045
			C4591001 1208 12081012
			C4591001 1226 12261080
			C4591001 1226 12261085
			C4591001 1226 12261455
			C4591001 1226 12262132
			C4591001 1226 12262138
			C4591001 1231 12311081
			C4591001 1231 12311145

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12311230
			C4591001 1231 12311237
			C4591001 1231 12311647
			C4591001 1231 12311975 (2)
			C4591001 1231 12312528
			C4591001 1231 12312856
			C4591001 1231 12313059
			C4591001 1231 12314046
			C4591001 1231 12314324
			C4591001 1231 12314974
			C4591001 1231 12315286
			C4591001 1231 12315386
			C4591001 1231 12315578
			C4591001 1232 12321054
			C4591001 1232 12321202

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1241 12411211
			C4591001 1241 12411449
			C4591001 1241 12411465 (2)
			C4591001 1241 12411569 (2)
			C4591001 1241 12412120
			C4591001 1254 12541007
			C4591001 1254 12541167
			C4591001 1264 12641159
			C4591001 1265 12651153 (2)
			C4591001 1269 12691014
			C4591001 1269 12691026
			C4591001 1269 12691047
			C4591001 1269 12691088
			C4591001 1270 12701003
			C4591001 1270 12701008

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1270 12701069
			C4591001 1270 12701118
			C4591001 1270 12701137
			C4591001 4444 44441327
			C4591001 4444 44442088
	Receipt of blood/plasma products or immunoglobulins within 60 days before enrollment through conclusion of the study.	8	C4591001 1091 10911241
			C4591001 1096 10961012
			C4591001 1096 10961305
			C4591001 1107 11071065
			C4591001 1170 11701482
			C4591001 1218 12181027
			C4591001 1231 12313697
			C4591001 1231 12313895
	Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study.	6	C4591001 1028 10281059
			C4591001 1046 10461261

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1128 11281241
			C4591001 1140 11401020 (2)
			C4591001 1226 12262078
			C4591001 1254 12541144
	Subject received systemic corticosteroids (≥ 20 mg/day of prednisone or equivalent) for ≥ 14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	7	C4591001 1003 10031101
			C4591001 1007 10071276
			C4591001 1028 10281026
			C4591001 1220 12201029
			C4591001 1221 12211002 (2)
			C4591001 1247 12471244
			C4591001 1261 12611054
Inclusion/exclusion	Participant failed to meet inclusion criterion #01 (Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase).	1	C4591001 1142 11421084
	Participant failed to meet inclusion criterion #02 (Participants who are willing and able to comply with all scheduled visits, vaccination plan, laboratory tests, lifestyle considerations, and other study procedures).	1	C4591001 1229 12291135†
	Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	9	C4591001 1044 10441152†

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1096 10961036
			C4591001 1117 11171036
			C4591001 1117 11171186
			C4591001 1120 11201038
			C4591001 1161 11611023
			C4591001 1203 12031048
			C4591001 1231 12311088
			C4591001 1231 12313140
	Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	4	C4591001 1006 10061246
			C4591001 1096 10961036
			C4591001 1117 11171036
			C4591001 1117 11171186
	Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	6	C4591001 1098 10981155
			C4591001 1098 10981168†
			C4591001 1098 10981169†

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Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1170 11701457†
			C4591001 1224 12241158†
			C4591001 1226 12262255†
	Participant met exclusion criterion #05 (previous clinical or microbiological diagnosis of COVID-19)	4	C4591001 1054 10541033
			C4591001 1231 12311191
			C4591001 1231 12313211
			C4591001 1235 12351167
	Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	23	C4591001 1003 10031186
			C4591001 1015 10151071
			C4591001 1047 10471301
			C4591001 1133 11331207
			C4591001 1136 11361082
			C4591001 1152 11521450
			C4591001 1156 11561015
			C4591001 1161 11611016

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1162 11621128
			C4591001 1166 11661078
			C4591001 1170 11701365 (2)
			C4591001 1178 11781061
			C4591001 1185 11851055
			C4591001 1204 12041280
			C4591001 1220 12201020
			C4591001 1226 12261313
			C4591001 1231 12312378
			C4591001 1231 12313998
			C4591001 1241 12411679
			C4591001 1241 12412369
			C4591001 1241 12412411
			C4591001 1254 12541142
			C4591001 1254 12541145

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
	Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	1	C4591001 1038 10381061
	Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	3	C4591001 1006 10061099 C4591001 1081 10811114 C4591001 1081 10811186
	Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	6	C4591001 1112 11121058 C4591001 1161 11611002 C4591001 1161 11611008 C4591001 1161 11611011 C4591001 1161 11611014 C4591001 1161 11611018
Investigational product	Blind compromised	2	C4591001 1096 10961195 C4591001 1096 10961197
	Dosing/administration error, subject did not receive correct dose of vaccine	96	C4591001 1068 10681002 C4591001 1068 10681003 C4591001 1068 10681006

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Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681010
			C4591001 1068 10681011
			C4591001 1068 10681012
			C4591001 1068 10681013
			C4591001 1068 10681016
			C4591001 1068 10681017
			C4591001 1068 10681018
			C4591001 1068 10681021
			C4591001 1068 10681024
			C4591001 1068 10681025
			C4591001 1068 10681026
			C4591001 1068 10681027
			C4591001 1068 10681028
			C4591001 1068 10681031
			C4591001 1068 10681034

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681035
			C4591001 1068 10681036
			C4591001 1068 10681037
			C4591001 1068 10681038
			C4591001 1068 10681042
			C4591001 1068 10681046
			C4591001 1068 10681047
			C4591001 1068 10681052
			C4591001 1068 10681053
			C4591001 1068 10681058
			C4591001 1068 10681060
			C4591001 1068 10681061
			C4591001 1068 10681064
			C4591001 1068 10681066
			C4591001 1068 10681071

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1068 10681072
			C4591001 1068 10681073
			C4591001 1068 10681074
			C4591001 1068 10681076
			C4591001 1068 10681077
			C4591001 1068 10681080
			C4591001 1068 10681081
			C4591001 1068 10681083
			C4591001 1091 10911005
			C4591001 1091 10911008
			C4591001 1091 10911014
			C4591001 1091 10911015
			C4591001 1136 11361027
			C4591001 1136 11361039
			C4591001 1136 11361083

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1136 11361084
			C4591001 1136 11361109
			C4591001 1141 11411011
			C4591001 1141 11411014
			C4591001 1141 11411023
			C4591001 1141 11411065
			C4591001 1141 11411068
			C4591001 1141 11411080
			C4591001 1141 11411093
			C4591001 1141 11411139
			C4591001 1169 11691033
			C4591001 1231 12313429
			C4591001 1231 12313449
			C4591001 1231 12313456
			C4591001 1231 12313459

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313467
			C4591001 1231 12313469 (2)
			C4591001 1231 12313479
			C4591001 1231 12313483
			C4591001 1231 12313486
			C4591001 1231 12313487
			C4591001 1231 12313492
			C4591001 1231 12313497
			C4591001 1231 12313498
			C4591001 1231 12313501
			C4591001 1231 12313505
			C4591001 1231 12313506
			C4591001 1231 12313508
			C4591001 1231 12313509
			C4591001 1231 12313512

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313514
			C4591001 1231 12313515
			C4591001 1231 12313517
			C4591001 1231 12313518
			C4591001 1231 12313519
			C4591001 1231 12313528
			C4591001 1231 12313533
			C4591001 1231 12313534
			C4591001 1231 12313537
			C4591001 1231 12313541
			C4591001 1231 12313542
			C4591001 1231 12313546
			C4591001 1231 12313551
			C4591001 1231 12313553
			C4591001 1231 12313554

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1231 12313556
			C4591001 1231 12313564
			C4591001 1231 12313567
	IP administered that was deemed not suitable for use by Almac	68	C4591001 1024 10241002
			C4591001 1024 10241004
			C4591001 1024 10241006
			C4591001 1024 10241014
			C4591001 1024 10241023
			C4591001 1024 10241032
			C4591001 1024 10241033
			C4591001 1024 10241039
			C4591001 1024 10241040
			C4591001 1024 10241042
			C4591001 1024 10241044
			C4591001 1024 10241046

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241054
			C4591001 1024 10241055
			C4591001 1024 10241061
			C4591001 1024 10241066
			C4591001 1024 10241067
			C4591001 1024 10241071
			C4591001 1024 10241072
			C4591001 1024 10241074
			C4591001 1024 10241078
			C4591001 1024 10241084
			C4591001 1024 10241085
			C4591001 1024 10241091
			C4591001 1024 10241094
			C4591001 1024 10241100
			C4591001 1024 10241102

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1024 10241104
			C4591001 1024 10241108
			C4591001 1044 10441001
			C4591001 1044 10441015
			C4591001 1044 10441028
			C4591001 1044 10441029
			C4591001 1044 10441031
			C4591001 1044 10441034
			C4591001 1044 10441037
			C4591001 1044 10441045
			C4591001 1044 10441048
			C4591001 1044 10441050
			C4591001 1044 10441052
			C4591001 1044 10441054
			C4591001 1044 10441060

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1044 10441063
			C4591001 1044 10441068
			C4591001 1044 10441071
			C4591001 1044 10441076
			C4591001 1044 10441079
			C4591001 1044 10441088
			C4591001 1044 10441089
			C4591001 1096 10961011
			C4591001 1096 10961027
			C4591001 1096 10961059
			C4591001 1096 10961209
			C4591001 1096 10961245
			C4591001 1096 10961246
			C4591001 1163 11631117
			C4591001 1163 11631121

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1163 11631124
			C4591001 1163 11631127
			C4591001 1163 11631136
			C4591001 1163 11631142
			C4591001 1163 11631145
			C4591001 1232 12321354
			C4591001 1232 12321373
			C4591001 1232 12321382
			C4591001 1232 12321385
			C4591001 1232 12321394
			C4591001 1232 12321395
	Incorrect IP assigned to subject due to IRT not being utilized	1	C4591001 1163 11631006 (2)
	Incorrect vaccine allocation/assigned to subject	6	C4591001 1012 10121103 C4591001 1079 10791130 C4591001 1088 10881077 (2)

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1090 10901334
			C4591001 1116 11161226
			C4591001 1169 11691049
	Other IP deviation	10	C4591001 1096 10961195
			C4591001 1096 10961197
			C4591001 1101 11011024
			C4591001 1126 11261053
			C4591001 1161 11611015
			C4591001 1163 11631039
			C4591001 1163 11631064
			C4591001 1163 11631096
			C4591001 1213 12131012
			C4591001 1221 12211079
	Subject was vaccinated despite being ineligible	4	C4591001 1092 10921158
			C4591001 1112 11121270†

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1170 11701334†
			C4591001 1265 12651164†
	Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (<14 days) systemic corticosteroids, IP administration should be delayed until systemic corticosteroid use has been discontinued for at least 28 days.	4	C4591001 1028 10281241
			C4591001 1028 10281294
			C4591001 1231 12311499
			C4591001 1247 12471244
Laboratory	Nasal swab can't be analyzed due to incorrect shipping procedure	1	C4591001 1083 10831154
Other	Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	19	C4591001 1161 11611001
			C4591001 1161 11611004
			C4591001 1161 11611007
			C4591001 1161 11611008
			C4591001 1161 11611009
			C4591001 1161 11611010
			C4591001 1161 11611014
			C4591001 1161 11611017

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611020
			C4591001 1161 11611023
			C4591001 1161 11611024
			C4591001 1161 11611026
			C4591001 1161 11611027
			C4591001 1161 11611028
			C4591001 1161 11611032
			C4591001 1161 11611033
			C4591001 1161 11611034
			C4591001 1161 11611040
			C4591001 1161 11611041
	Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	8	C4591001 1161 11611002
			C4591001 1161 11611005
			C4591001 1161 11611006
			C4591001 1161 11611011

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1161 11611015
			C4591001 1161 11611016
			C4591001 1161 11611018
			C4591001 1161 11611019
Procedures/tests	Procedure/Test not done	1	C4591001 1146 11461010
	Subject had a vaccination diary activated, but was not part of the reactogenicity subset	18	C4591001 1098 10981168† (2)
			C4591001 1098 10981169†
			C4591001 1112 11121174
			C4591001 1133 11331537
			C4591001 1219 12191001
			C4591001 1219 12191002
			C4591001 1219 12191003
			C4591001 1219 12191004
			C4591001 1219 12191013
			C4591001 1219 12191014

16.2.2.2 Listing of Important Protocol Deviations – Phase 2/3 Subjects 16-55 Years of Age

Protocol Deviation Category	Protocol Deviation Subcategory	Number of Subjects	Subject (Number of Deviations if >1)
			C4591001 1219 12191016
			C4591001 1219 12191017
			C4591001 1219 12191042
			C4591001 1219 12191044
			C4591001 1219 12191048
			C4591001 1235 12351152
			C4591001 1235 12351153
			C4591001 1235 12351155

Note: † = Human immunodeficiency virus (HIV)-positive subject.
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