

### 16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
Action - Study Vaccine Dose	NA	Not applicable
	P	Investigational product withdrawn
Action - Subject	TC	Concomitant drug treatment given
	TCN	Concomitant non-drug treatment given
	W	Withdrawn from study
Cause of AE	CD	Concomitant drug treatment
	CND	Concomitant non-drug treatment
	O	Other
Outcome	F	Fatal
	N	Not recovered/not resolved
	R	Recovered/resolved
	RS	Recovered/resolved with sequelae
	RG	Recovering/resolving
	UNK	Unknown
Toxicity Grade	1	Mild
	2	Moderate
	3	Severe
	4	Life-threatening
System Organ Class	BLOOD	Blood and lymphatic system disorders
	CARD	Cardiac disorders
	CONG	Congenital, familial and genetic disorders
	EAR	Ear and labyrinth disorders
	ENDO	Endocrine disorders
	EYE	Eye disorders
	GASTR	Gastrointestinal disorders
	GENRL	General disorders and administration site conditions
HEPAT	Hepatobiliary disorders	

### 16.2.7.1 Adverse Events Legend Page

Category	Abbreviation	Text
	IMMUN	Immune system disorders
	INFEC	Infections and infestations
	INJ&P	Injury poisoning and procedural complications
	INV	Investigations
	METAB	Metabolism and nutrition disorders
	MUSC	Musculoskeletal and connective tissue disorders
	NEOPL	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
	NERV	Nervous system disorders
	PREG	Pregnancy, puerperium and perinatal conditions
	PSYCH	Psychiatric disorders
	RENAL	Renal and urinary disorders
	REPRO	Reproductive system and breast disorders
	RESP	Respiratory, thoracic and mediastinal disorders
	SKIN	Skin and subcutaneous tissue disorders
	SOCCI	Social circumstances
	SURG	Surgical and medical procedures
	VASC	Vascular disorders

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**16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>	
					1	2	3	4	5	6	7			
12-15	C4591001 1009 10091288	1	04DEC2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	06DEC2020	3	
	C4591001 1009 10091396	2	26JAN2021	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	28JAN2021	3	
	C4591001 1013 10131845	1	03DEC2020	Pain at the injection site	Sev	Mod		N				04DEC2020	2	
	C4591001 1057 10571438	1	04JAN2021	Pain at the injection site	N	Sev	Mild	Mild	N	N	N	07JAN2021	3	
	C4591001 1066 10661408	1	08DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	11DEC2020	4	
	C4591001 1091 10911406	2	28DEC2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	30DEC2020	3	
	C4591001 1091 10911428	1	16DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild		N	N	19DEC2020	4	
	C4591001 1140 11401359	1	23DEC2020	Pain at the injection site	N	Sev	N	N	N	N	N	24DEC2020	1	
	C4591001 1140 11401376	1	29DEC2020	Pain at the injection site	Mild	Sev	Mild	Mild	N	N	N	01JAN2021	4	
			2	20JAN2021	Pain at the injection site	Mild	Sev	Mod	Mild	N	N	N	23JAN2021	4
	C4591001 1142 11421340	2	28DEC2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	30DEC2020	3	
	C4591001 1142 11421369	2	15JAN2021	Pain at the injection site	Mod	Sev	N	N	N	N	N	16JAN2021	2	
	C4591001 1147 11471320	2	27JAN2021	Pain at the injection site	Mod	Sev	Mod				Mild	Mild	06FEB2021	11
	C4591001 1150 11501124	2	10NOV2020	Pain at the injection site	Mod	Sev	Mod	Mild	N	N			13NOV2020	4

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**16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
16-25	C4591001 1150 11501250	1	29DEC2020	Pain at the injection site	Mod	Sev	Mild	N	N	N	N	31DEC2020	3
	C4591001 1152 11521697	1	18DEC2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	21DEC2020	4
	C4591001 1156 11561249	1	16OCT2020	Redness (cu)		21						17OCT2020	1
				Redness (svt)	N	Sev		N	N	N	N		
	C4591001 1156 11561310	1	01DEC2020	Pain at the injection site	N	Sev	Mild	Mild		N		04DEC2020	3
	C4591001 1235 12351253	1	08JAN2021	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	10JAN2021	3
	C4591001 1008 10081782	2	30DEC2020	Redness (cu)			21	21				02JAN2021	2
				Redness (svt)	N	N	Sev	Sev	N	N			
	C4591001 1057 10571368	1	23NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	24NOV2020	2
	C4591001 1090 10901043	2	24AUG2020	Pain at the injection site	Sev	Sev	Mild	N		N	Mild	01NOV2020	70
	C4591001 1120 11201130	2	03SEP2020	Pain at the injection site	Sev	Mod	Mild	Mild	Mild		N	07SEP2020	5
	C4591001 1125 11251243	1	08DEC2020	Pain at the injection site	Mild	Sev	Sev	Mild	N	N		11DEC2020	4
	C4591001 1142 11421316	1	24NOV2020	Pain at the injection site	Mild	Sev	N	N	N	N	N	25NOV2020	2
	C4591001 1150 11501152	2	23DEC2020	Pain at the injection site	Sev	Mod	Mild				N	25DEC2020	3
	C4591001 1162 11621019	1	03AUG2020	Pain at the injection site	N	Sev	N	N	N		N	04AUG2020	1

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**16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
	C4591001 1194 11941069	1	20OCT2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	22OCT2020	3
	C4591001 1194 11941091	1	22OCT2020	Pain at the injection site	Mod	Sev	Mild	Mild	Mild	N		26OCT2020	5
	C4591001 1205 12051079	1	11NOV2020	Pain at the injection site	Sev	Mod	Mild	N	N	N	N	13NOV2020	3
		2	02DEC2020	Pain at the injection site	Mod	Sev	Mod	Mild	Mild	Mild	Mild	09DEC2020	8
	C4591001 1212 12121007	2	17NOV2020	Pain at the injection site	Mod	Sev	Mild	Mild	N	N	N	20NOV2020	4
	C4591001 1217 12171012	1	23OCT2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	25OCT2020	3
	C4591001 1226 12261096	1	11AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	Mild	N	16AUG2020	6
	C4591001 1230 12301018	1	24SEP2020	Pain at the injection site	Sev	Sev	Mild	N	N	N	N	26SEP2020	3
	C4591001 1230 12301133	1	05OCT2020	Redness (cu)		2	21					07OCT2020	1
				Redness (svt)		N	Sev	N	N	N	N		
	C4591001 1231 12311018	2	27AUG2020	Pain at the injection site	N	Sev	Mild	Mild	Mild	N	N	31AUG2020	4
	C4591001 1231 12311055	1	11AUG2020	Pain at the injection site	Mild	Sev	Mod	Mild	Mild	Mild	Mild	17AUG2020	7
	C4591001 1231 12311162	1	13AUG2020	Pain at the injection site	Mild	Sev	Mild	N	N	N	N	15AUG2020	3
	C4591001 1247 12471033	2	15OCT2020	Pain at the injection site	N			Sev	Sev	N	N	19OCT2020	2

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### 16.2.7.2.1.1 Listing of Severe and Grade 4 Local Reactions – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	Dose No.	Dose Date	Local Reaction <sup>b</sup>	Rel Day <sup>a</sup>							Stop Date <sup>c</sup>	Dur (Days) <sup>d</sup>
					1	2	3	4	5	6	7		
	C4591001 1247 12471199	1	06OCT2020	Redness (cu)	21	21						07OCT2020	2
				Redness (svt)	Sev	Sev		N			N		
				Swelling (cu)	21							06OCT2020	1
				Swelling (svt)	Sev	N		N			N		

Abbreviations: cu = caliper units; Dur = duration; Mod = moderate; N = none; Sev = severe; svt = severity.

a. Relative day (Rel Day) = date of reaction - date of last vaccination + 1.

b. The maximum measurable size for redness and swelling in the electronic diary (e-diary) was 21 caliper units. Redness and swelling exceeding 21 caliper units are reported as >21. Study sites recorded injection site redness or swelling in centimeters. These were converted to caliper units (1 caliper unit = 0.5 centimeters).

c. Stop date is the date the reaction was last reported.

d. Duration (days) was calculated as the difference from the start of the first reported reaction to resolution of the last reported reaction, inclusive. If the reaction continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the reaction was ongoing at the time of the subsequent vaccination, the end date/day for the reaction is the date/day that the next vaccine was administered, which was used for the duration calculation.

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
12-15	C4591001 1005 10051317	2	12NOV2020	Oral temperature (°C)	36.7	39.1	37.5	37.1	36.6	36.8	36.6	13NOV2020	1
	C4591001 1005 10051328	2	11NOV2020	Headache	N	Sev	N	N	N	N	N	12NOV2020	1
	C4591001 1006 10061189	1	01DEC2020	Oral temperature (°C)	37.1	39.9	36.8	36.9	35.8	37.1	37.4	02DEC2020	1
		2	22DEC2020	Oral temperature (°C)	37.3	39.3	37.3		37.1		36.9	23DEC2020	1
	C4591001 1006 10061220	2	28DEC2020	Headache	N	Sev	Mild	N	N		N	30DEC2020	2
	C4591001 1006 10061297	1	29DEC2020	Oral temperature (°C)	36.7	39.4	37.1	37.1	36.8	37.1	36.8	30DEC2020	1
				Fatigue	N	Sev	N	N	N	N	N	30DEC2020	1
	C4591001 1007 10071544	2	30DEC2020	Fatigue	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1007 10071546	2	30DEC2020	Chills	Sev	N	N	N	N	N	N	30DEC2020	1
	C4591001 1007 10071620	2	20JAN2021	Fatigue	N	Sev	Mod	Mod	Mod	Mod	Mod		
				Headache	N	Sev	Mod	Sev	Mild	Mod	Mod		
				Chills	N	Sev	N	Mod	N	N	Mod	27JAN2021	7
				New or worsened muscle pain	N	Sev	Mod	Sev	Mod	Mod	Mod		
				New or worsened joint pain	N	Sev	Mod	Sev	Mod	Mod	Mod		
	C4591001 1007 10071626	2	20JAN2021	Oral temperature (°C)	36.8	39.1	36.7	36.6		36.7	36.9	21JAN2021	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1007 10071639	2	25JAN2021	Fatigue	Mild	Sev	Mild	N	N	N	N	27JAN2021	3
	C4591001 1007 10071642	1	04JAN2021	Fatigue	N	Sev	N	N	N	Mild	Mild	01FEB2021	28
	C4591001 1007 10071659	2	27JAN2021	Fatigue	N	Sev	Mild	N	N	N	N	29JAN2021	2
	C4591001 1008 10081802	1	17DEC2020	Oral temperature (°C)	36.6	39.1	36.3	36.4	35.7	36.9	35.8	18DEC2020	1
	C4591001 1008 10081809	1	18DEC2020	Headache	Sev			N	N		N	18DEC2020	1
	C4591001 1008 10081827	1	21DEC2020	Fatigue	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1008 10081846	2	11JAN2021	Headache	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1008 10081908	2	27JAN2021	Oral temperature (°C)	37.3	39.3	36.4	36.2	36.1		36.2	12JAN2021	1
	C4591001 1008 10081908	2	27JAN2021	Oral temperature (°C)	36.8	39.7	37.3	37.1	36.9	37	37.1	28JAN2021	1
	C4591001 1009 10091220	1	19OCT2020	Fatigue	Mod		Sev	N		Mod	N	24OCT2020	6
	C4591001 1009 10091221	1	19OCT2020	New or worsened joint pain	Sev	N		N	N			19OCT2020	1
	C4591001 1009 10091288	2	23DEC2020	Chills	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1009 10091310	2	29DEC2020	Headache	Mild	Sev		N	N	N		30DEC2020	2
	C4591001 1009 10091317	1	10DEC2020	Oral temperature (°C)	37.3	39	36.6	37.4	36.9	36.8	36.9	11DEC2020	1
				Headache	N	Sev	N	N	N	N	N	11DEC2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1009 10091318	2	29DEC2020	Oral temperature (°C)	36.6	39	37.1	37	36.6	36.3	36.9	30DEC2020	1
	C4591001 1009 10091321	2	30DEC2020	Fatigue	N	Sev	Mild	N	N	N	N	01JAN2021	2
				Chills	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1009 10091326	1	11DEC2020	Headache	N	Sev	N	N	N	N	N	12DEC2020	1
	C4591001 1009 10091328	2	30DEC2020	Headache	N	Sev	N	Mild	N	N	N	02JAN2021	3
	C4591001 1009 10091355	2	08JAN2021	Headache		Sev	N	N	N		N	09JAN2021	1
	C4591001 1009 10091358	1	17DEC2020	Headache	N	N	N	N	N	N	Sev	23DEC2020	1
	C4591001 1009 10091361	1	17DEC2020	Fatigue	Mod	Mod	Sev	Mild	N	N	N	20DEC2020	4
				Headache	Mild	Sev	Mod	Mild	Mild	Mild	N	22DEC2020	6
	C4591001 1009 10091362	1	17DEC2020	Chills	Sev	Mod	N	N		Mod	Mild	24DEC2020	8
	C4591001 1013 10131841	1	02DEC2020	Fatigue		Sev			N			03DEC2020	1
				Headache		Sev			N			03DEC2020	1
	C4591001 1013 10131859	1	09DEC2020	Fatigue	N	Sev	N	N	N	N	N	10DEC2020	1
				Headache	N	Sev	N	N	N	N	N	10DEC2020	1
	C4591001 1013 10131866	2	06JAN2021	Fatigue	N	Sev	N	N	N	N		07JAN2021	1
				Chills	N	Sev	N	N	N	N		07JAN2021	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1013 10131871	1	21DEC2020	Oral temperature (°C)	36.8	39	36.7	36.7	38.9		37.2	25DEC2020	4
				Fatigue	Mild	Sev	N	N	N		N	22DEC2020	2
	C4591001 1016 10161307	1	15OCT2020	Fatigue	Mod	Sev	Mild	Mod	Mild	N	Mild	22OCT2020	8
	C4591001 1016 10161326	2	10NOV2020	New or worsened joint pain	N	Sev	N	N		N	N	11NOV2020	1
	C4591001 1016 10161330	1	20OCT2020	Headache	N	N	N	N	N	N	Sev	27OCT2020	2
	C4591001 1016 10161373	2	27JAN2021	Headache	N	Sev	N	N	N	N	N	28JAN2021	1
				Chills	N	Sev	N	N	N	Mild	N	01FEB2021	5
	C4591001 1039 10391304	2	19JAN2021	Fatigue	N	Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1039 10391318	2	29JAN2021	Fatigue	Mod		Sev	Mild	Mild		Mild	04FEB2021	7
	C4591001 1044 10441266	1	08DEC2020	Fatigue	Mod	Sev	N	Mild	N	N	N	11DEC2020	4
		2	28DEC2020	Chills		Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1044 10441291	2	06JAN2021	Oral temperature (°C)	36.1	39.6	37.2	36.1	36.9	36.4	36.6	07JAN2021	1
	C4591001 1044 10441300	2	18JAN2021	Fatigue		Sev	N	N	N	N		19JAN2021	1
	C4591001 1044 10441316	1	04JAN2021	Chills	N	Sev	N	N	N	N	N	05JAN2021	1
	C4591001 1044 10441322	2	27JAN2021	Headache	N	Sev	N	N	N	N	N	28JAN2021	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1044 10441331	2	27JAN2021	Fatigue	N	Sev	N	N	N	N	N	28JAN2021	1
	C4591001 1044 10441343	2	29JAN2021	Oral temperature (°C)	37.3	39.5	37.7	37.5	36.2	36.6	36.5	30JAN2021	1
				Fatigue	Mod	Sev	Mod	Mod	Mod	Mod	Mod		
				Chills	N	Sev	Mod	N	N	N	N	31JAN2021	2
	C4591001 1044 10441355	2	29JAN2021	Headache	N	Sev	Mild	Mild	N	Mild	N	03FEB2021	5
	C4591001 1044 10441379	2	04FEB2021	Fatigue	Mild	Sev	N	N	N	N	N	05FEB2021	2
	C4591001 1057 10571382	1	08DEC2020	Oral temperature (°C)	35.9	39.1	36.9	36.8	37.4	37.1	36.5	09DEC2020	1
				Fatigue	N	Sev	N	N	N	N	N	09DEC2020	1
	C4591001 1057 10571411	2	06JAN2021	Fatigue	N	Sev	Mod	Mild	N	N	N	09JAN2021	3
	C4591001 1057 10571424	1	24DEC2020	Chills	N	Mod	Sev		Mod	Mod	Mild	01JAN2021	8
	C4591001 1057 10571428	1	24DEC2020	Fatigue	N		N	N	N	Sev	Sev	31DEC2020	3
				Headache	N		N	N	N	Mod	Sev	31DEC2020	3
				Chills	N		N	N	Mod	Sev	N	29DEC2020	2
	C4591001 1057 10571438	2	25JAN2021	Oral temperature (°C)	36.8	39.2	36.6	36.7		36.9	37.1	26JAN2021	1
	C4591001 1057 10571451	1	12JAN2021	Oral temperature (°C)	36.5	39.2	38.1	37.1	37.3	36.3	36.6	14JAN2021	2
	C4591001 1066 10661408	2	28DEC2020	Headache	Mild	Sev	Mild			N	N	30DEC2020	3

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1077 10771280	2	04JAN2021	Fatigue	Sev	Sev	N	N		N		05JAN2021	2
				New or worsened muscle pain	Sev	Sev	Mild	N		N		06JAN2021	3
	C4591001 1084 10841546	1	18DEC2020	Fatigue	Mild	Sev	Mild	Mild	N	N	N	21DEC2020	4
				Headache	Mild	Sev	Mild	Mild	N	N	Mild	24DEC2020	7
	C4591001 1084 10841571	1	30DEC2020	Fatigue		Mild		Mild		Sev		05JAN2021	6
	C4591001 1084 10841580	1	06JAN2021	Oral temperature (°C)	37.5	39.9	37.7	36.4	36.8	36.8	37	07JAN2021	1
	C4591001 1084 10841593	2	29JAN2021	Headache	N	Sev	Mild		N	N	N	31JAN2021	2
	C4591001 1091 10911457	1	29DEC2020	Fatigue	Sev	Mod	Mod	Sev	Mod	N	Mod	05JAN2021	8
		2	18JAN2021	Fatigue		Sev	Mod	Mod	Mild	N	N	22JAN2021	4
				Headache		Sev	Mod	Mild	N	N	N	21JAN2021	3
	C4591001 1123 11231440	2	28DEC2020	Headache	N	Sev	N	N		N	N	29DEC2020	1
	C4591001 1123 11231442	1	09DEC2020	Oral temperature (°C)	39.7	33.4		33.4	34.6	34.1	34.1	09DEC2020	1
	C4591001 1123 11231461	2	05JAN2021	Oral temperature (°C)	37.8	39.3	37.6	37.1		36.4	36.7	06JAN2021	1
	C4591001 1123 11231475	2	11JAN2021	Oral temperature (°C)	36.8	39.4	36.8		36.8	37.5	37.1	12JAN2021	1
	C4591001 1123 11231481	2	12JAN2021	Headache	N	Sev	Mild	N	N		N	14JAN2021	2

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1123 11231484	2	12JAN2021	Oral temperature (°C)		39.4	37.5	37.1	36.6		36.3	13JAN2021	1
				Headache		Sev	Mild	Mod	Mod		N	16JAN2021	4
	C4591001 1123 11231495	2	13JAN2021	Fatigue	Mod	Sev	N		N	N	N	14JAN2021	2
	C4591001 1123 11231513	1	30DEC2020	Headache	N	N	N	N	Sev	Mild	N	04JAN2021	2
	C4591001 1124 11241251	2	08JAN2021	Oral temperature (°C)	37.6	39	36.9	36.7			36.7	09JAN2021	1
	C4591001 1125 11251248	1	11DEC2020	Fatigue	Mod	Sev	Mod	Mod	Mild	Mild	Mild	17DEC2020	7
	C4591001 1125 11251252	1	16DEC2020	Fatigue		Sev	N					17DEC2020	1
	C4591001 1126 11261263	1	04DEC2020	Chills	N	Sev	N	N	N	N		05DEC2020	1
	C4591001 1126 11261273	2	06JAN2021	Headache	N	Sev	Mild	Mild	N	N	N	09JAN2021	3
	C4591001 1126 11261281	1	16DEC2020	Headache	N	Mild	Sev	N	N	N	N	18DEC2020	2
	C4591001 1126 11261286	1	16DEC2020	Oral temperature (°C)	37.2	39	36.8	36.9	36.6	36.8	36.4	17DEC2020	1
	C4591001 1126 11261299	2	12JAN2021	New or worsened muscle pain	N	N	Sev	N	N	N	N	14JAN2021	1
	C4591001 1126 11261307	1	04JAN2021	Chills	N	Sev	N	N	N	N	N	05JAN2021	1
	C4591001 1126 11261309	1	04JAN2021	New or worsened muscle pain	N	Sev	N	N	N		N	05JAN2021	1
		2	25JAN2021	Fatigue	Mild	Sev	N	N	N	N	N	26JAN2021	2

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
				Chills	Mild	Sev	N	N	N	N	N	26JAN2021	2
	C4591001 1126 11261310	2	26JAN2021	Headache	N	Sev	N		N	N	N	27JAN2021	1
	C4591001 1126 11261315	1	06JAN2021	Oral temperature (°C)	36.9	39.3	36.3	36.8	36.6	36.9	36.8	07JAN2021	1
	C4591001 1126 11261324	2	28JAN2021	Oral temperature (°C)	36.4	39.2	36.6	36.2	36.5	36.3	35.8	29JAN2021	1
	C4591001 1131 11311290	2	20JAN2021	Fatigue	Mod	Sev		N	N	N	N	21JAN2021	2
				Headache	N	Sev		N	N	N	N	21JAN2021	1
	C4591001 1131 11311302	2	01FEB2021	Oral temperature (°C)	36.2	39.6	36.5	36.4	36.3		36.3	02FEB2021	1
	C4591001 1139 11391155	2	28DEC2020	Fatigue	N	Sev	Mild	N	N	N	N	30DEC2020	2
	C4591001 1139 11391238	1	07JAN2021	Headache	Mild	Sev	Mod	Mild	Mild	N	Mild	14JAN2021	8
	C4591001 1140 11401328	2	05JAN2021	Oral temperature (°C)	36.7	39.5	37.1	37	37.1	37	37	06JAN2021	1
	C4591001 1140 11401329	2	05JAN2021	Oral temperature (°C)	36.8	40	36.9	36.5	36.6	36.7	36.7	06JAN2021	1
	C4591001 1140 11401343	1	21DEC2020	Headache	N	N	Sev	N	N	N	N	23DEC2020	1
				Vomiting	N	N	Sev	N	N	N	N	23DEC2020	1
	C4591001 1140 11401345	2	11JAN2021	Oral temperature (°C)	36.2	38.9	36.4	35.7			36.8	12JAN2021	1
	C4591001 1140 11401352	2	13JAN2021	Headache	Mild	Sev	N	N	N	N	Mild	17FEB2021	36

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1140 11401359	1	23DEC2020	Fatigue	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1140 11401378	2	20JAN2021	Fatigue	Mod	Sev		N		N	N	21JAN2021	2
	C4591001 1140 11401380	2	19JAN2021	Chills		Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1140 11401391	2	28JAN2021	Headache			Sev	N	Mod	N	N	01FEB2021	3
	C4591001 1140 11401400	1	08JAN2021	Headache		N	N	N	Mod	N	Sev	20JAN2021	9
	C4591001 1142 11421340	1	07DEC2020	Fatigue	N	Sev	N	N	N	N	N	08DEC2020	1
				Headache	N	Sev	N	N	N	N	N	08DEC2020	1
		2	28DEC2020	Headache	Mod	Sev	N	N	N	N	N	29DEC2020	2
	C4591001 1142 11421369	2	15JAN2021	Fatigue	Mod	Sev	Mild	N	N	N	N	17JAN2021	3
				Chills	Mild	Sev	Mild	N	N	N	N	17JAN2021	3
				New or worsened muscle pain	N	Sev	N	N	N	N	N	16JAN2021	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	16JAN2021	1
	C4591001 1142 11421375	1	22DEC2020	Fatigue	Sev	N		N	N	N	N	22DEC2020	1
	C4591001 1142 11421392	2	29JAN2021	Chills		Sev	N	N	N	N	N	30JAN2021	1
	C4591001 1147 11471277	2	28DEC2020	New or worsened muscle pain		N	N	N	N	Sev	Sev	07JAN2021	6

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1147 11471285	2	04JAN2021	Fatigue						Sev	N	09JAN2021	1
	C4591001 1147 11471301	1	19DEC2020	Fatigue	N	Sev	Mild	N	N		N	21DEC2020	2
	C4591001 1147 11471312	2	09JAN2021	Fatigue	Mild	N	N	N	N	Sev	N	14JAN2021	6
	C4591001 1147 11471327	1	05JAN2021	Oral temperature (°C)	35.6	40.4	38	35.8	35.9		36.4	07JAN2021	2
	C4591001 1147 11471334	2	27JAN2021	Chills	Sev	Mild	N	N	N	N	N	28JAN2021	2
	C4591001 1147 11471337	2	27JAN2021	Chills	N	Sev	N	N	N	N	N	28JAN2021	1
				New or worsened muscle pain	N	Sev	N	N	N	N	N	28JAN2021	1
	C4591001 1147 11471347	2	28JAN2021	Chills	N	Sev	Mild	N	N	N		30JAN2021	2
	C4591001 1150 11501198	2	30DEC2020	Fatigue	N	Sev						31DEC2020	1
	C4591001 1150 11501245	1	28DEC2020	Headache	N	Sev		N	N	N	N	29DEC2020	1
		2	19JAN2021	Headache	N	Sev	N	N	N	N	N	20JAN2021	1
	C4591001 1150 11501260	2	20JAN2021	Oral temperature (°C)	37.2	39.1	37.2	36.7	37.1	37	36.4	21JAN2021	1
	C4591001 1150 11501274	2	25JAN2021	New or worsened muscle pain		Sev	N					26JAN2021	1
				New or worsened joint pain		Sev	N					26JAN2021	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1150 11501297	1	11JAN2021	Oral temperature (°C)	37.2	39.1	37.4	37.1	36.9	36.9	37.1	12JAN2021	1
		2	02FEB2021	Oral temperature (°C)	36.8	39.7	38.4	36.8		37.1		04FEB2021	2
				Fatigue	N	Sev	Mod	N		N		04FEB2021	2
				Chills	N	Sev	N	N		N		03FEB2021	1
	C4591001 1150 11501299	1	12JAN2021	Chills	N	Sev	Mild	N	N	N	N	14JAN2021	2
		2	01FEB2021	Chills	N	Sev	Mild	N		N	N	03FEB2021	2
	C4591001 1152 11521619	2	22DEC2020	Oral temperature (°C)	36.7	39.3	37.9	37.2	36.9	37	36.8	23DEC2020	1
	C4591001 1152 11521670	2	30DEC2020	Chills	N	Sev	N	N	N	N	N	31DEC2020	1
	C4591001 1152 11521706	1	21DEC2020	Fatigue	Mod	Mod	Mild	N		Sev	Mild	27DEC2020	7
				Headache	N	N	N	N		Sev	Mod	27DEC2020	2
	C4591001 1156 11561340	2	19JAN2021	Fatigue	Sev	Mod		N	N	N		20JAN2021	2
	C4591001 1156 11561342	2	19JAN2021	Oral temperature (°C)	36.8	39.9	37.1	37	37	37	37	20JAN2021	1
	C4591001 1156 11561349	2	26JAN2021	Chills	N	Sev	N	N	N	N	N	27JAN2021	1
	C4591001 1156 11561356	1	07JAN2021	Fatigue	Mild	Sev	Mod	Mild	N	N	N	10JAN2021	4
				New or worsened muscle pain	N	Sev	N	N	N	N	N	08JAN2021	1
	C4591001 1156 11561358	2	29JAN2021	Fatigue	N	Sev	Mild	N	N	N	N	31JAN2021	2

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>	
					1	2	3	4	5	6	7			
16-25	C4591001 1223 12231280	2	28JAN2021	Oral temperature (°C)		39.2	38.4						30JAN2021	2
	C4591001 1235 12351236	2	22DEC2020	New or worsened muscle pain	Mod	Sev	N	N	N			N	23DEC2020	2
	C4591001 1235 12351249	1	15DEC2020	Headache	Sev	Mod	Mod			Sev	Mod	Mild	04JAN2021	21
		2	04JAN2021	Headache	Sev	Sev	Sev	Sev	Sev				09JAN2021	6
	C4591001 1235 12351254	2	28JAN2021	Fatigue		Sev	Mild	N	N	N	N		30JAN2021	2
				Chills		Sev	N	N	N	N	N		29JAN2021	1
	C4591001 1270 12701191	2	23DEC2020	Fatigue	N	Sev	Mild	N	N	N	N		25DEC2020	2
	C4591001 1270 12701207	2	05JAN2021	Oral temperature (°C)	37.4	39.5	37.4	37.1	37.2	36.8	37.4		06JAN2021	1
				Fatigue	N	Sev	Mod	Mod	N	Mod	N		10JAN2021	5
	C4591001 1270 12701220	2	08JAN2021	Oral temperature (°C)	37.2	39.1	37.4	37.1	36.2	36.4			09JAN2021	1
	C4591001 1270 12701239	2	28JAN2021	Oral temperature (°C)	36.2	39	36.1	36.1	36.3	36.1	36.2		29JAN2021	1
	C4591001 1001 10011125	1	04AUG2020	Fatigue	Mod	Mod	Sev	Mild				N	07AUG2020	4
				Headache	Mod	Mod	Sev	Mod				N	07AUG2020	4
				New or worsened muscle pain	N	N	Sev	N				N	06AUG2020	1
				New or worsened joint pain	N	Mild	Sev	N				N	06AUG2020	2
C4591001 1005 10051024	2	31AUG2020	Fatigue		Sev	N	N	N			N	01SEP2020	1	

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1005 10051434	2	12JAN2021	Chills	N	Sev	N		N	N		13JAN2021	1
	C4591001 1005 10051442	1	22DEC2020	Fatigue	N	Sev	Mild	Mild	N	Mild	N	27DEC2020	5
	C4591001 1006 10061185	2	21DEC2020	Chills	N	Sev	N	N	N	N	N	22DEC2020	1
	C4591001 1006 10061192	2	22DEC2020	Headache	N	Sev	N	Mild	N	N	N	25DEC2020	3
	C4591001 1006 10061210	2	23DEC2020	Headache	N	Sev	N	N	N	N	N	24DEC2020	1
	C4591001 1006 10061246	1	10DEC2020	Fatigue	N	N	Sev	N	N	N	N	12DEC2020	1
	C4591001 1007 10071487	1	01DEC2020	Headache	N	Sev	Mild		N	N		03DEC2020	2
	C4591001 1007 10071503	1	03DEC2020	New or worsened muscle pain	Sev	Mod		N			N	04DEC2020	2
	C4591001 1009 10091028	2	31AUG2020	New or worsened muscle pain	N	Sev	N	N	N	N	N	01SEP2020	1
	C4591001 1013 10131005	1	28JUL2020	Headache	N	N	N	N	Sev		N	01AUG2020	1
	C4591001 1013 10131059	2	25AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	27AUG2020	2
	C4591001 1015 10151035	2	04SEP2020	Fatigue		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened muscle pain		Sev	N	N	N	N	N	05SEP2020	1
				New or worsened joint pain		Sev	N	N	N	N	N	05SEP2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1016 10161349	2	25NOV2020	Headache	Mod	Sev	Mild	N	N	N	N	27NOV2020	3
	C4591001 1044 10441244	2	14DEC2020	Fatigue	N	Sev	Mild	Mild	Mild	Mild	N	19DEC2020	5
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	16DEC2020	2
	C4591001 1044 10441245	2	14DEC2020	Fatigue		Sev	Mild	N	N		N	16DEC2020	2
	C4591001 1044 10441287	1	11DEC2020	Fatigue	Mod	Sev	Mild	Mild	N	Mild	Mild		
	C4591001 1071 10711039	2	04SEP2020	Headache	N	N	Mod	Sev		Mild	Mild	21SEP2020	16
	C4591001 1073 10731064	2	01SEP2020	Fatigue	Mod	Mod	Mod	Sev	N	N	N	04SEP2020	4
				Headache	N	Mod	N	Sev	N	N	N	04SEP2020	3
	C4591001 1073 10731083	2	02SEP2020	Fatigue	Mod	Sev	N	N	N		N	03SEP2020	2
				Chills	N	Sev	N	N	N		N	03SEP2020	1
	C4591001 1080 10801009	2	03SEP2020	Headache		Sev	Mod	N			N	05SEP2020	2
	C4591001 1082 10821036	1	04AUG2020	Headache	Mod	N	Mild	N	N	N	Sev	11AUG2020	8
		2	25AUG2020	Headache	N	Sev	Sev	N	N	N	Mod	31AUG2020	6
	C4591001 1090 10901043	2	24AUG2020	Headache	Mild	Sev	N	N		N	Mild	30AUG2020	7
				Chills	N	Sev	N	N		N	N	25AUG2020	1
	C4591001 1107 11071010	2	18AUG2020	Headache	Mod	N		Mod	Sev	Mod		23AUG2020	6

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1107 11071055	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1
	C4591001 1109 11091020	2	18AUG2020	Headache	Mod	Sev	N	N		N	N	19AUG2020	2
	C4591001 1112 11121045	1	03AUG2020	Oral temperature (°C)	36.9	39	37	37.1	36.9	36.8	36.6	04AUG2020	1
	C4591001 1120 11201172	1	13AUG2020	Fatigue	N	Sev	Mild	N	N	N	N	15AUG2020	2
	C4591001 1120 11201250	2	11SEP2020	Headache	N	Sev	N	N	N	N	N	12SEP2020	1
				New or worsened joint pain	N	Sev	N	N	N	Mod	Mild		
	C4591001 1125 11251243	1	08DEC2020	Fatigue	N	Mod	Sev	N	N	N		10DEC2020	2
				Headache	N	Sev	Sev	N	N	N		10DEC2020	2
	C4591001 1126 11261208	2	04DEC2020	Headache	N	Sev	N	N	N	N	N	05DEC2020	1
	C4591001 1129 11291261	2	14DEC2020	Headache	Sev	Sev	N	N	N	N	N	15DEC2020	2
	C4591001 1129 11291262	2	14DEC2020	Fatigue	Sev	Mild	Mild	N	N	N	N	16DEC2020	3
	C4591001 1135 11351088	2	28AUG2020	Fatigue	Mild	Sev	N	N	N	N	N	29AUG2020	2
	C4591001 1139 11391160	2	29DEC2020	Oral temperature (°C)	36.3	38.9	36.2			36.8		30DEC2020	1
	C4591001 1140 11401316	2	14DEC2020	Headache	Mild	Sev	N	N	N	N	N	15DEC2020	2
				Chills	N	Sev	N	N	N	N	N	15DEC2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1140 11401320	2	23DEC2020	Fatigue	Mild	Sev	N	N	N	N	N	24DEC2020	2
	C4591001 1140 11401321	1	04DEC2020	Fatigue	Mod	Sev	Mod	N	N	N	N	06DEC2020	3
	C4591001 1140 11401322	2	23DEC2020	Fatigue	Mod	Sev	Mod	Mild	N			26DEC2020	4
				Headache	Mod	Sev	Mild	N	N			25DEC2020	3
	C4591001 1141 11411081	1	14AUG2020	Fatigue	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1142 11421336	2	23DEC2020	Headache		N	N	N	N	Sev	N	28DEC2020	1
	C4591001 1147 11471255	2	05DEC2020	Oral temperature (°C)	37.1	39.5	37.1	37.1	37.2	37.1	37	06DEC2020	1
				Chills	N	Sev	N	N	N	N	N	06DEC2020	1
	C4591001 1152 11521072	2	01SEP2020	Diarrhea	N	N	Sev	Mild		N	N	04SEP2020	2
	C4591001 1152 11521600	2	15DEC2020	Oral temperature (°C)	36.8	37.3	39	36.7	36.6	36.8	36.9	17DEC2020	1
	C4591001 1152 11521630	2	28DEC2020	Headache	N	Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1152 11521632	1	07DEC2020	Chills	Mod	Sev	Mild	N			N	09DEC2020	3
		2	28DEC2020	Fatigue	N	Sev	Mild	N	N		N	30DEC2020	2
				Headache	N	Sev	Mild	N	N		N	30DEC2020	2
	C4591001 1156 11561299	1	11NOV2020	Fatigue	N	Mild	Mod	N	N	Sev	N	16NOV2020	5
	C4591001 1156 11561300	1	17NOV2020	Oral temperature (°C)	36.9	38.9	35.4	36.5	37.1		36.4	18NOV2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1162 11621044	1	06AUG2020	Oral temperature (°C)			36.1			40	37.6	11AUG2020	1
				Fatigue			N			Sev	Sev	13AUG2020	3
				Headache			N			Sev	Sev	13AUG2020	3
				Chills			Mild			Sev	Mod	13AUG2020	6
				New or worsened muscle pain			N			Sev	N	11AUG2020	1
	C4591001 1162 11621080	2	02SEP2020	Headache	N	Sev	Mod	N	N	N		04SEP2020	2
				Chills	N	Sev	Mod	N	N	N		04SEP2020	2
	C4591001 1162 11621110	2	02SEP2020	Fatigue		Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1171 11711027	1	14AUG2020	Chills	N	Sev	N	N	N	N	N	15AUG2020	1
	C4591001 1194 11941062	2	11NOV2020	Fatigue	Mod	Sev	Mild	Mild	N	N	N	14NOV2020	4
	C4591001 1194 11941069	2	11NOV2020	Fatigue	Sev	Sev	Mild	N	N	N	N	13NOV2020	3
	C4591001 1195 11951100	1	18OCT2020	Vomiting	Sev	N	N		N	N	N	18OCT2020	1
	C4591001 1205 12051079	1	11NOV2020	Headache	Mild	Sev	N	N	Mild	N	Mod	18NOV2020	8
		2	02DEC2020	Headache	Mod	Sev	N	N	N	N	N	03DEC2020	2
				Chills	Mild	Sev	N	N	N	N	N	03DEC2020	2
				New or worsened muscle pain	N	Sev	N	N	N	N	N	03DEC2020	1
				New or worsened joint pain	N	Sev	N	N	N	N	N	03DEC2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1208 12081051	2	01DEC2020	Fatigue	Mod	Sev	Mod	N		N	N	03DEC2020	3
	C4591001 1212 12121007	2	17NOV2020	Oral temperature (°C)	36.9	39.5	37.5	36.9	36.8	36.6	37	18NOV2020	1
				Fatigue	Mod	Sev	Mod	N	N	N	N	19NOV2020	3
				New or worsened muscle pain	N	Sev	Mod	N	N	N	N	19NOV2020	2
	C4591001 1214 12141053	2	02DEC2020	Headache	N	N	N	N	N	N	Sev	08DEC2020	1
	C4591001 1217 12171053	1	06NOV2020	Fatigue	N	Sev		N	N	N	N	07NOV2020	1
		2	26NOV2020	Fatigue	N	Sev	N	N	N	N		27NOV2020	1
	C4591001 1223 12231057	1	01SEP2020	Headache	N	Sev	Mild	N	N	N	N	03SEP2020	2
	C4591001 1224 12241168	2	10DEC2020	Chills	Mod	Sev	N	N	N	N	N	11DEC2020	2
	C4591001 1224 12241171	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1
				Headache	N	Sev	N	N	N	N	N	24NOV2020	1
	C4591001 1224 12241173	2	21DEC2020	New or worsened muscle pain	N	Sev		N	N		N	22DEC2020	1
	C4591001 1224 12241176	1	30NOV2020	Chills	N	Sev	N	N	N	N	N	01DEC2020	1
	C4591001 1224 12241178	1	30NOV2020	Fatigue	Mild	Sev	N	N	N	N	N	01DEC2020	2
				Chills	N	Sev	N	N	N	N	N	01DEC2020	1
		2	29DEC2020	Chills	Mild	Sev	Mild	N	N	N	N	31DEC2020	3

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1226 12261001	2	25AUG2020	New or worsened muscle pain	Mod	Sev		N	N	N		26AUG2020	2
	C4591001 1226 12261096	1	11AUG2020	Fatigue	N	Sev	Mod	N	N	N	N	13AUG2020	2
				Headache	N	Sev	Mod	N	N	N	N	13AUG2020	2
				New or worsened muscle pain	N	Sev	Mild	N	N	N	N	13AUG2020	2
				New or worsened joint pain	N	Sev	Mild	Mild	N	N	N	14AUG2020	3
		2	01SEP2020	Fatigue	N	Sev	N	N	N	N	N	02SEP2020	1
	C4591001 1226 12261124	2	04SEP2020	Fatigue	N	Sev	N	N	N	N		05SEP2020	1
	C4591001 1229 12291065	1	30SEP2020	Chills	Mod	Mild	Mild	Mod	Sev	N	N	04OCT2020	5
		2	21OCT2020	Fatigue	Mild	N	Mod	N	N	Sev	N	26OCT2020	6
				New or worsened muscle pain	N	Mild	N	N	N	Sev	Mod	27OCT2020	6
	C4591001 1230 12301018	1	24SEP2020	New or worsened muscle pain	Mod	Sev	N	N	N	N	N	25SEP2020	2
				New or worsened joint pain	N	Sev	N	N	N	N	N	25SEP2020	1
	C4591001 1230 12301094	1	01OCT2020	Headache	N	Sev	Sev	N	N	N	N	03OCT2020	2
	C4591001 1230 12301102	2	23OCT2020	Headache	N	Mod	N	Mod	N	Sev	N	28OCT2020	5
	C4591001 1231 12311018	2	27AUG2020	Headache	N	Sev	N	N	N	N	N	28AUG2020	1

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1231 12311055	2	01SEP2020	Oral temperature (°C)	36.7	39	37.2	36.7		36.5	36.6	02SEP2020	1
				Fatigue	N	Sev	N	N		Mod	N	06SEP2020	5
				Chills	N	Sev	N	N		N	N	02SEP2020	1
	C4591001 1231 12311164	2	02SEP2020	Fatigue	N	Sev	Mild	Mild	N	Mild	Mild	09SEP2020	7
				Chills	N	Sev	N	N	N	N	N	03SEP2020	1
	C4591001 1231 12311266	2	02SEP2020	Oral temperature (°C)	37.4	39.1	37.9	36.2	36.4	36.3	36.2	03SEP2020	1
	C4591001 1231 12311281	2	04SEP2020	New or worsened muscle pain	Mild	Sev	N	N	N	N	N	05SEP2020	2
	C4591001 1231 12311306	1	15AUG2020	Headache	N	Mod	N	Sev	N	N	N	18AUG2020	3
	C4591001 1231 12311368	2	04SEP2020	Oral temperature (°C)	36	39.1	39.2	35.8	35.9	36.6	35.9	06SEP2020	2
	C4591001 1231 12311432	1	15AUG2020	Headache	N	Sev	Mild	Mild	Mild	N	N	19AUG2020	4
	C4591001 1231 12311454	2	03SEP2020	Fatigue	Mild	Sev	N	N	N	N	N	04SEP2020	2
	C4591001 1231 12311463	1	15AUG2020	Fatigue	Mild	Mod	Mild	N	N	Sev	Mild	23AUG2020	9
	C4591001 1235 12351237	2	28DEC2020	New or worsened joint pain	N	Sev	N	N	N	N	N	29DEC2020	1
	C4591001 1235 12351241	2	28DEC2020	Headache	Mild	Sev	Mild	Mild	Mild	N	N	01JAN2021	5
	C4591001 1246 12461038	2	20OCT2020	Diarrhea	N	Sev	Mild			N	N	22OCT2020	2

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**16.2.7.3.1.1 Listing of Severe and Grade 4 Systemic Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	Dose No.	Dose Date	Systemic Event	Rel Day <sup>a</sup>							Stop Date <sup>b</sup>	Dur (Days) <sup>c</sup>
					1	2	3	4	5	6	7		
	C4591001 1247 12471010	1	23SEP2020	Headache	Mild	Mild	Mod	N	Mod	Mild	Sev	29SEP2020	7
	C4591001 1247 12471033	2	15OCT2020	New or worsened muscle pain	N			Sev	Sev	N	N	19OCT2020	2
	C4591001 1247 12471121	1	30SEP2020	Oral temperature (°C)	39.2	39.8	39.1	39.2	39	38.8	38.9	06OCT2020	7
				Fatigue	Mod	Mod	Mod	Sev	Mod	Mod	Mod	06OCT2020	7
				Headache	Mod	Sev	Mod	Mod	Mod	Mild	Mod	06OCT2020	7
		2	21OCT2020	Oral temperature (°C)	38.9	40	39.6	39.3	38.2	38.9	38.8		
				Fatigue	Mod	Mod	Mod	Mod	Mod	Mod	Sev		
	C4591001 1247 12471145	2	22OCT2020	Headache		Mild	N		Sev	N	N	26OCT2020	4
	C4591001 1270 12701165	1	23NOV2020	Fatigue	N	Sev	N	N	N	N	N	24NOV2020	1

Abbreviations: Dur = duration; Mod = moderate; N = none; Sev = severe.

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this listing.

a. Relative day (Rel Day) = date of event - date of last vaccination + 1.

b. Stop date is the date the event was last reported.

c. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive. If the event continued beyond Day 7, the calculation includes all days from the last e-diary day until the date of resolution collected on the case report form. If the event is ongoing at the time of the subsequent vaccination, the end date/day for the event is the date/day that the next vaccine was administered, which was used for the duration calculation.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adce\_1004\_sevse\_ped

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12-15	C4591001 1005 10051317	GENRL	Chills/ CHILLS	1	21OCT2020	2/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	C4591001 1005 10051328	GASTR	Nausea/ NAUSEA	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	C4591001 1005 10051424	GASTR	Nausea/ NAUSEA	2	08JAN2021	1/4	1	Yes		NA/TC	R (11JAN2021)	N/N
		GENRL	Fatigue/ FATIGUE	2	08JAN2021	1/4	2	Yes		NA	R (11JAN2021)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	08JAN2021	1/4	2	Yes		NA	R (11JAN2021)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	2	08JAN2021	1/4	2	Yes		NA	R (11JAN2021)	N/N
		NERV	Headache/ HEADACHE	2	08JAN2021	1/4	2	Yes		NA/TC	R (11JAN2021)	N/N
	C4591001 1006 10061203	GASTR	Nausea/ Nausea	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
			Injection site pain/ Injection site pain	1	04DEC2020	2/5	1	Yes		NA	R (08DEC2020)	N/N
		NERV	Headache/ Headache	1	04DEC2020	2/2	1	Yes		NA	R (05DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	2	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ Injection Site Pain	2	22DEC2020	1/3	2	Yes		NA	R (24DEC2020)	N/N
		NERV	Headache/ Headache	2	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/N
	C4591001 1006 10061209	NERV	Syncope/ Syncope Vasovagal response	2	12MAR2021	80/1	1	No	O	NA/TCN	R (12MAR2021)	N/N
	C4591001 1006 10061245	SKIN	Urticaria/ Hives face	1	12DEC2020	3/20	1	Yes		NA/TC	R (31DEC2020)	N/N
			Urticaria/ Hives trunk	1	12DEC2020	3/4	1	Yes		NA/TC	R (15DEC2020)	N/N
	C4591001 1006 10061266#	GENRL	Chills/ CHILLS	3	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
		INJ&P	Contusion/ Contusion left elbow	1	05FEB2021	52/C	1	No	O	NA	RG	N/N
	C4591001 1006 10061286	GENRL	Fatigue/ FATIGUE	2	16JAN2021	6/4	2	Yes		NA	R (19JAN2021)	N/N
	C4591001 1006 10061290	INJ&P	Concussion/ Concussion	1	12JAN2021	22/C	2	No	O	NA/TC	RG	N/N
	C4591001 1006 10061292	EAR	Cerumen impaction/ Earwax Impaction Left Ear	2	24JAN2021	13/5	2	No	O	NA/TCN	R (28JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071476	NERV	Syncope/ Vasovagal syncope without collapse*		30NOV2020	1/1	1	No	O	NA/TC/TCN	R (30NOV2020)	N/N
		NERV	Dizziness/ lightheadness after vaccination	2	21DEC2020	1/1	1	No	O	NA	R (21DEC2020)	N/Y
	C4591001 1007 10071497	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	2	25DEC2020	4/C	1	Yes		NA	RG	N/N
	C4591001 1007 10071500	PSYCH	Sleep terror/ Night Terror	2	23DEC2020	2/1	1	No	O	NA	R (23DEC2020)	N/N
	C4591001 1007 10071524	INFEC	Candida infection/ thrush	2	01FEB2021	35/2	2	No	CD	NA	R (02FEB2021)	N/N
	C4591001 1007 10071533	MUSC	Myalgia/ abdominal muscle pain	2	06JAN2021	8/2	1	No	O	NA/TC	R (07JAN2021)	N/N
	C4591001 1007 10071563	NERV	Dizziness/ lightheadness	1	14DEC2020	1/1	1	Yes		NA/TCN	R (14DEC2020)	N/Y
	C4591001 1007 10071568	GENRL	Injection site pain/ injection site soreness	1	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y
		SKIN	Rash maculo-papular/ maculopapular rash	2	05JAN2021	1/29	1	Yes		NA	R (02FEB2021)	N/Y
	C4591001 1007 10071575	MUSC	Mobility decreased/ Altered Mobility of Left upper extremity	1	03JAN2021	19/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1007 10071581	INFEC	Appendicitis/ Appendicitis	2	11MAR2021	64/C	3	No	O	NA/TC	RG	Y/N
	C4591001 1007 10071584	GENRL	Injection site pain/ Soreness at injection site	2	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/Y
	C4591001 1007 10071585	SKIN	Urticaria/ hives; trunk, abdomen, back	2	16JAN2021	10/C	2	Yes		NA/TC	RG	N/N
	C4591001 1007 10071593	INJ&P	Ligament sprain/ left Ankle sprain	1	30DEC2020	3/17	2	No	O	NA/TCN	R (15JAN2021)	N/N
	C4591001 1007 10071613	GENRL	Injection site pain/ Pain at injection site	1	29DEC2020	1/1	1	Yes		NA	R (29DEC2020)	N/N
	C4591001 1007 10071615	BLOOD	Lymphadenopathy/ left axillary lymph node swelling	2	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N
	C4591001 1007 10071618	GENRL	Injection site pain/ Pain at injection nsite	1	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/Y
	C4591001 1007 10071620	GASTR	Abdominal pain/ Abdominal pain	2	21JAN2021	2/20	2	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Neuralgia/ generalized Functional neurologic pain	2	21JAN2021	2/C	2	No	O	NA/TC	RG	Y/N
		INFEC	Vulval abscess/ Vulvar boil	2	24JAN2021	5/3	1	No	O	NA/TC	R (26JAN2021)	N/N
		GASTR	Gastritis/ Gastritis	2	30JAN2021	11/C	2	No	CD	NA/TC	RG	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		SKIN	Dermatitis contact/contact dermatitis bilateral arms	2	12FEB2021	24/C	1	No	O	NA/TC	RG	N/N
		GASTR	Abdominal pain/Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
			Constipation/Constipation	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
	C4591001 1007 10071623	GASTR	Toothache/teeth pain	2	27JAN2021	7/2	2	No	CND	NA/TC	R (28JAN2021)	N/N
	C4591001 1007 10071632	GENRL	Injection site pain/tenderness at injection site	1	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/Y
			Vessel puncture site pain/pain at blood draw site	1	30DEC2020	1/2	1	No	O	NA	R (31DEC2020)	N/Y
		NERV	Headache/headache	1	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/Y
		SKIN	Rash/rash to chest and back	2	22JAN2021	2/5	2	Yes		NA	R (26JAN2021)	N/N
	C4591001 1007 10071634	RESP	Rhinorrhoea/Rhinorrhea	2	18FEB2021	25/C	1	No	O	NA	RG	N/N
		NERV	Presyncope/vasovagal response	2	22FEB2021	29/1	1	No	O	NA	R (22FEB2021)	N/N
	C4591001 1007 10071648	GENRL	Injection site pain/Injection site pain	2	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/Y
	C4591001 1007 10071651	BLOOD	Lymphadenopathy/Left deep cervical chain lymph node swelling	1	12JAN2021	8/29	1	Yes		NA	R (09FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		BLOOD	Lymphadenopathy/ left Cervical lymphadenopathy	2	23FEB2021	29/C	1	No	O	NA	RG	N/N
	C4591001 1008 10081928	SKIN	Urticaria/ urticaria multiple sites	1	10JAN2021	3/13	1	Yes		NA/TC	R (22JAN2021)	N/N
	C4591001 1009 10091220	INJ&P	Procedural pain/ POST SURGICAL PAIN, ORAL	2	20NOV2020	14/11	2	No	O	NA/TC	R (30NOV2020)	N/N
	C4591001 1009 10091221	MUSC	Arthralgia/ worsening right ankle pain	1	19OCT2020	1/1	3	No	O	NA/TCN	R (19OCT2020)	N/N
	C4591001 1009 10091231	BLOOD	Lymphadenopathy/ left swollen axillary lymph node	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	C4591001 1009 10091267	RESP	Rhinorrhoea/ RUNNY NOSE	2	27DEC2020	6/6	1	No	O	NA/TC	R (01JAN2021)	N/N
	C4591001 1009 10091294	MUSC	Arthralgia/ bilateral shoulder pain	1	22DEC2020	16/3	1	No	O	NA	R (24DEC2020)	N/N
	C4591001 1009 10091319	NERV	Headache/ headache	2	22JAN2021	25/1	2	No	O	NA	R (22JAN2021)	N/N
	C4591001 1009 10091323	GASTR	Nausea/ nausea	2	08JAN2021	10/1	1	No	O	NA	R (08JAN2021)	N/N
		GENRL	Fatigue/ fatigue	2	08JAN2021	10/1	1	No	O	NA	R (08JAN2021)	N/N

**16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1009 10091334	RESP	Rhinorrhoea/ runny nose	2	11JAN2021	12/1	1	No	O	NA	R (11JAN2021)	N/N
	C4591001 1009 10091342	BLOOD	Lymphadenopathy/ swollen cervical lymph nodes bilateral	2	31JAN2021	28/3	1	No	O	NA	R (02FEB2021)	N/N
	C4591001 1009 10091361	INJ&P	Ligament sprain/ sprained right thumb	1	02JAN2021	17/30	2	No	O	NA	R (31JAN2021)	N/N
	C4591001 1009 10091363	NERV	Presyncope/ Vasovagal Reaction	1	09FEB2021	55/1	1	No	O	NA	R (09FEB2021)	N/N
	C4591001 1009 10091366	GENRL	Injection site pain/ Mild Injection Site Pain	2	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
	C4591001 1009 10091370	NERV	Headache/ headache	1	06JAN2021	20/1	3	No	O	NA/TC	R (06JAN2021)	N/N
	C4591001 1009 10091379	INJ&P	Fall/ GROUND LEVEL FALL	2	26FEB2021	44/1	2	No	O	NA	R (26FEB2021)	N/N
	C4591001 1009 10091380	INJ&P	Clavicle fracture/ Right Clavicle Fracture	1	18JAN2021	21/C	2	No	O	NA/TC	N	N/N
		INJ&P	Procedural pain/ pain after wisdom teeth removal	2	11FEB2021	24/5	1	No	O	NA/TC	R (15FEB2021)	N/N
	C4591001 1009 10091382	MUSC	Arthralgia/ RIGHT KNEE PAIN	1	10JAN2021	7/16	2	No	O	NA	R (25JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1009 10091399	INJ&P	Foot fracture/ Left Fifth Metatarsal Fracture	2	23FEB2021	26/C	2	No	O	NA/TC	RG	N/N
	C4591001 1009 10091403	RESP	Rhinorrhoea/ runny nose	1	10JAN2021	3/4	1	Yes		NA	R (13JAN2021)	N/N
	C4591001 1009 10091406	MUSC	Joint swelling/ Swilling in bilateral knees	1	25JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1009 10091410	GENRL	Fatigue/ FATIGUE	2	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	C4591001 1013 10131824	GENRL	Peripheral swelling/ SWELLING LEFT ARM	1	05DEC2020	5/2	1	Yes		NA	R (06DEC2020)	N/N
	C4591001 1013 10131839	INJ&P	Concussion/ CONCUSSION	2	01MAR2021	69/C	2	No	O	NA	RG	N/N
	C4591001 1016 10161316#	GENRL	Chills/ chills	3	26FEB2021	2/1	2	Yes		NA	R (26FEB2021)	N/N
		MUSC	Myalgia/ muscle pain	3	26FEB2021	2/1	2	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1016 10161344	BLOOD	Lymphadenopathy/ enlarged lymph nodes, right anterior cervical nodes	2	25NOV2020	15/43	1	No	O	NA	R (06JAN2021)	N/N
		INFEC	Infectious mononucleosis/ infectious mononucleosis	2	25NOV2020	15/43	1	No	O	NA	R (06JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1039 10391246#	GENRL	Fatigue/ fatigue	3	27FEB2021	2/3	2	Yes		NA	R (01MAR2021)	N/N
			Pain/ generalized achiness	3	27FEB2021	2/4	2	Yes		NA	R (02MAR2021)	N/N
			Pyrexia/ fever	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		NERV	Headache/ headache	3	27FEB2021	2/3	1	Yes		NA	R (01MAR2021)	N/N
	C4591001 1039 10391250	PSYCH	Tic/ exacerbation of tic disorder	2	09JAN2021	13/C	1	No	O	NA	RG	N/N
	C4591001 1039 10391314	NEOPL	Fibroadenoma of breast/ Exacerbation of fibroadenoma of right breast	2	06FEB2021	10/C	1	No	O	NA	RG	N/N
	C4591001 1039 10391326	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N
	C4591001 1039 10391337	SKIN	Urticaria/ urticaria, both hands	2	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	C4591001 1044 10441275	MUSC	Myalgia/ myalgia	2	04JAN2021	7/1	1	Yes		NA/TC	R (04JAN2021)	N/N
	C4591001 1044 10441292	GENRL	Oedema peripheral/ Edema Toes (Bilateral)	1	17DEC2020	1/3	1	No	O	NA/TC	R (19DEC2020)	N/N
	C4591001 1044 10441304	SKIN	Rash/ rash	2	25FEB2021	38/3	1	No	O	NA/TC	R (27FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1044 10441335	SKIN	Acne/ Worsening of acne	2	27FEB2021	30/C	1	No	O	NA/TC	RG	N/N
	C4591001 1044 10441337	INJ&P	Humerus fracture/ Broken humerus (right arm)	1	10JAN2021	3/C	2	No	O	NA/TC	RG	N/N
	C4591001 1044 10441338	NEOPL	Skin papilloma/ Wart on second toe (left)	2	01FEB2021	4/7	1	No	O	NA/TC	R (07FEB2021)	N/N
	C4591001 1044 10441351	INJ&P	Muscle strain/ Left hip flexor strain	2	11FEB2021	11/17	2	No	O	NA/TC	R (27FEB2021)	N/N
	C4591001 1044 10441361	INJ&P	Concussion/ Concussion	1	23JAN2021	13/22	1	No	O	NA	R (13FEB2021)	N/N
	C4591001 1044 10441373	SKIN	Urticaria/ hives forehead	1	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
		PSYCH	Anxiety/ Worsening of Anxiety	2	05MAR2021	30/C	2	No	O	NA/TC	RG	N/N
	C4591001 1057 10571451	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	13JAN2021	2/C	2	No	O	NA/TC	N	N/N
	C4591001 1066 10661422	SKIN	Rash/ rash on torso	1	24DEC2020	3/C	1	No	O	NA	N	N/N
	C4591001 1077 10771278	GASTR	Diarrhoea/ DIARRHEA	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Vomiting/ VOMITING	2	23DEC2020	1/1	1	Yes		NA	R (23DEC2020)	N/N
		GENRL	Fatigue/ FATIGUE	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N
			Injection site pain/ RIGHT ARM INJECTION SITE PAIN	2	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
			Injection site swelling/ INJECTION SITE SWELLING	2	23DEC2020	1/2	2	Yes		NA	R (24DEC2020)	N/N
			Pyrexia/ FEVER	2	23DEC2020	1/2	3	Yes		NA/TC	R (24DEC2020)	N/N
		PSYCH	Disorientation/ DISORIENTATION	2	23DEC2020	1/1	2	Yes		NA	R (23DEC2020)	N/N
	C4591001 1077 10771279	GASTR	Oral mucosal blistering/ ORAL/BUCCAL BLISTERS	2	07JAN2021	4/4	2	Yes		NA	R (10JAN2021)	N/N
	C4591001 1084 10841556	INFEC	Ear infection/ L Ear infection	2	28JAN2021	11/9	2	No	O	NA/TC	R (05FEB2021)	N/N
	C4591001 1084 10841558	INJ&P	Ligament sprain/ left sprained ankle	2	27JAN2021	10/2	2	No	O	NA/TC	R (28JAN2021)	N/N
	C4591001 1091 10911422	INFEC	Ear infection/ left ear infection	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N
			Otitis externa/ outer ear infection left ear	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N
			Otitis media/ middle ear infection left ear	1	23DEC2020	10/8	1	No	O	NA/TC	R (30DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1091 10911433	SKIN	Rash/ intermittent rash on wrist	1	19DEC2020	3/C	1	No	O	NA	N	N/N
	C4591001 1123 11231442	PSYCH	Depression/ Depression	1	23DEC2020	15/C	2	No	O	NA/TC	N	N/N
	C4591001 1123 11231448	GASTR	Diarrhoea/ Diarrhea	1	16DEC2020	6/3	1	Yes		NA	R (18DEC2020)	N/N
	C4591001 1123 11231472	INFEC	Tinea capitis/ Tinea capitis	1	01JAN2021	12/43	1	No	O	NA/TC	R (12FEB2021)	N/N
		SKIN	Acne/ worsening of acne vulgaris	1	07JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1123 11231507	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N
	C4591001 1123 11231520	INFEC	Conjunctivitis/ Bilateral conjunctivitis	1	12JAN2021	14/6	1	No	O	NA/TC	R (17JAN2021)	N/N
	C4591001 1123 11231523	EYE	Retinal haemorrhage/ INTRA RETINAL HEMORRHAGE OD	2	16FEB2021	22/C	2	No	O	NA	RG	N/N
	C4591001 1124 11241251	GENRL	Pyrexia/ Fever (102.2 degrees F)	2	09JAN2021	2/1	3	Yes		NA/TC	R (09JAN2021)	N/N
	C4591001 1125 11251248	GENRL	Fatigue/ Fatigue	2	05JAN2021	7/4	1	Yes		NA/TC	R (08JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	C4591001 1126 11261246	MUSC	Pain in extremity/ Right leg pain	2	31DEC2020	9/C	1	No	O	NA	N	N/N
		GASTR	Aphthous ulcer/ Canker sore under tongue	2	12JAN2021	21/4	1	No	O	NA	R (15JAN2021)	N/N
		GENRL	Nodule/ Red bump on right index finger at cuticle	2	13JAN2021	22/C	1	No	O	NA	N	N/N
	C4591001 1126 11261254	IMMUN	Food allergy/ Allergic reaction, nuts	1	09DEC2020	7/1	2	No	O	NA/TC	R (09DEC2020)	N/N
	C4591001 1126 11261262#	GENRL	Injection site pain/ Left upper arm injection site pain	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261263	BLOOD	Lymphadenopathy/ LEFT AXILLA LYMPH NODE SWELLING	1	10DEC2020	7/4	1	Yes		NA	R (13DEC2020)	N/N
		INJ&P	Fall/ Mechanical Fall	1	20DEC2020	17/1	2	No	O	NA	R (20DEC2020)	N/N
			Radius fracture/ RIGHT DISTAL RADIUS TORUS FRACTURE	1	20DEC2020	17/32	2	No	O	NA/TC	R (20JAN2021)	N/N
	C4591001 1126 11261268	SKIN	Urticaria/ Facial Urticaria, worsening	1	18DEC2020	5/14	1	No	O	NA	R (31DEC2020)	N/N
		MUSC	Osteochondrosis/ Juvenile Osteochondrosis of bilateral fifth metatarsals	1	28DEC2020	15/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1126 11261275#	GENRL	Injection site pain/ Left upper arm injection site pain	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Chills/Chills	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Headache/Headache	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
	C4591001 1126 11261276#	GENRL	Injection site pain/ Left upper arm injection site pain	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
		GENRL	Pyrexia/ Fever	3	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
		NERV	Headache/ Headache	3	09FEB2021	2/1	2	Yes		NA/TC	R (09FEB2021)	N/N
	C4591001 1126 11261290	SKIN	Pityriasis rosea/ Worsening Pityriasis Rosea	1	23DEC2020	7/28	2	No	O	NA/TC	R (19JAN2021)	N/N
	C4591001 1126 11261296	INJ&P	Accident/ Dirt bike nontraffic accident	2	24JAN2021	17/1	2	No	O	NA/TC/TCN	R (24JAN2021)	N/N
			Contusion/ Left elbow contusion	2	24JAN2021	17/8	1	No	O	NA/TCN	R (31JAN2021)	N/N
			Lip injury/ Lower lip laceration	2	24JAN2021	17/13	1	No	O	NA/TC/TCN	R (05FEB2021)	N/N
			Tooth fracture/ Three teeth fractures	2	24JAN2021	17/1	2	No	O	NA/TC/TCN	R (24JAN2021)	N/N
	C4591001 1126 11261301	GASTR	Nausea/ Nausea	1	24DEC2020	3/2	2	Yes		NA	R (25DEC2020)	N/N
	C4591001 1126 11261305#	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain	3	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261307	NERV	Migraine/ Migraine headache, worsening	1	24JAN2021	21/C	2	No	O	NA/TC	RG	N/N
	C4591001 1126 11261309	GASTR	Lip swelling/ Swollen lips	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
			Mouth swelling/ Swollen mouth	2	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	C4591001 1126 11261312	NERV	Headache/ Headache	1	17JAN2021	13/5	2	No	O	NA	R (21JAN2021)	N/N
	C4591001 1126 11261314	SKIN	Rash/ Skin rash L side of neck to L scapula	2	01FEB2021	4/3	1	Yes		NA/TC	R (03FEB2021)	N/N
	C4591001 1131 11311280	NERV	Presyncope/ vasovagal reaction secondary to vaccine	1	17DEC2020	1/1	2	Yes		NA	R (17DEC2020)	N/N
	C4591001 1131 11311283	INFEC	Pilonidal cyst/ pilonidal cyst	1	29DEC2020	8/52	2	No	O	NA/TC	R (18FEB2021)	N/N
	C4591001 1131 11311287	RESP	Rhinorrhoea/ rhinorrhea	1	17JAN2021	20/18	1	No	O	NA	R (03FEB2021)	N/N
		BLOOD	Lymphadenopathy/ enlarge lymph nodes- neck(bilateral)	2	27JAN2021	10/8	1	Yes		NA	R (03FEB2021)	N/N
	C4591001 1131 11311301	MUSC	Arthralgia/ sacroiliac joint pain	1	15JAN2021	5/C	2	No	O	NA	N	N/N
		INJ&P	Accident/ skiing accident	2	18FEB2021	14/C	2	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		INJ&P	Clavicle fracture/ broken collar bone	2	19FEB2021	15/C	1	No	O	NA/TC	RG	N/N
			Clavicle fracture/ right clavicle fracture	2	19FEB2021	15/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1139 11391225	INJ&P	Concussion/ concussion	2	01FEB2021	5/9	2	No	O	NA/TC	R (09FEB2021)	N/N
	C4591001 1139 11391246	MUSC	Arthralgia/ Bilateral knee pain	1	11JAN2021	4/C	2	No	O	NA/TC	RG	N/N
	C4591001 1139 11391248	INJ&P	Muscle strain/ Muscle Strain	2	10MAR2021	41/C	1	No	O	NA	RG	N/N
	C4591001 1140 11401343	NERV	Migraine/ complex migraine	1	23DEC2020	3/1	3	Yes		NA/TC/TCN	R (23DEC2020)	N/N
	C4591001 1140 11401353	MUSC	Neck pain/ neck pain	2	03FEB2021	23/3	2	No	O	NA/TC	R (05FEB2021)	N/N
	C4591001 1140 11401357	GENRL	Chills/ Mild Chills	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
			Fatigue/ Mild Fatigue	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
			Injection site pain/ mild injection site pain	2	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
	C4591001 1142 11421352	INJ&P	Patella fracture/ Fracture of left patella	2	31JAN2021	28/C	3	No	O	NA	RG	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	C4591001 1142 11421385	BLOOD	Lymphadenopathy/ left supraclavicular lymph node swelling	1	07JAN2021	8/C	1	Yes		NA	RG	N/N
	C4591001 1142 11421394	NERV	Paraesthesia/ transient feeling of pins and needles to torso	1	18JAN2021	8/C	1	No	O	NA	RG	N/N
	C4591001 1147 11471262	PSYCH	Generalised anxiety disorder/ Generalized anxiety disorder (worsening)	2	25JAN2021	22/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471263	MUSC	Limb mass/ Arm mass	1	2020	1/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471270#	INV	Body temperature increased/ Increased body temperature	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		MUSC	Myalgia/ Myalgia	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		NERV	Headache/ Headache	3	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	C4591001 1147 11471281	INFEC	Appendicitis/ Acute appendicitis	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
			Focal peritonitis/ localized peritonitis, without perforation or gangrene	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
	C4591001 1147 11471292	SKIN	Acne/ Acne vulgaris (new diagnosis)	2	25JAN2021	17/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1147 11471310	RESP	Nasal congestion/ Nasal congestion	1	02JAN2021	13/8	1	No	O	NA/TC	R (09JAN2021)	N/N
		EAR	Ear pain/ Left ear pain	2	JAN2021	1/C	1	No	O	NA/TC	RG	N/N
	C4591001 1147 11471322	EAR	Ear pain/ Right ear pain	1	25JAN2021	21/7	1	No	O	NA/TC	R (31JAN2021)	N/N
		INFEC	Conjunctivitis/ Acute conjunctivitis, left	2	25FEB2021	30/C	1	No	O	NA/TC	RG	N/N
	C4591001 1147 11471323	SKIN	Dermatitis contact/ Allergic reaction to surgical dressings.	2	09FEB2021	14/C	2	No	O	NA/TC	RG	N/N
	C4591001 1147 11471327	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N
	C4591001 1147 11471331	INJ&P	Hand fracture/ Fracture of middle phalanx of left index finger	2	24FEB2021	28/C	1	No	O	NA	RG	N/N
	C4591001 1150 11501127	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	C4591001 1150 11501129	INJ&P	Concussion/ Concussion	2	11JAN2021	63/60	2	No	O	NA	R (11MAR2021)	N/N
	C4591001 1150 11501130	GASTR	Nausea/ Nausea	2	09NOV2020	1/3	2	Yes		NA	R (11NOV2020)	N/N
		NERV	Dizziness/ Dizziness	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501131#	GENRL	Fatigue/ Fatigue	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
			Injection site pain/ Pain at injection site	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
			Pain/ Generalized Body Aches	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		NERV	Headache/ Headache	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	C4591001 1150 11501132	GASTR	Diarrhoea/ Diarrhea	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N
	C4591001 1150 11501182#	GENRL	Injection site pain/ Injection Site Pain	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	C4591001 1150 11501193	PSYCH	Attention deficit hyperactivity disorder/ ADHD	1	DEC2020	1/C	1	No	O	NA	RG	N/N
	C4591001 1150 11501287	GENRL	Injection site pain/ Injection Site Pain	1	08JAN2021	2/1	1	Yes		NA/TC	R (08JAN2021)	N/N
	C4591001 1152 11521615	SKIN	Rash/ generalized rash upper body	1	03DEC2020	1/8	1	No	O	NA	R (10DEC2020)	N/N
	C4591001 1152 11521640	INFEC	Ear infection/ right ear infection, NFI	1	20DEC2020	14/7	2	No	O	NA/TC	R (26DEC2020)	N/N
	C4591001 1152 11521641	EYE	Eyelid rash/ rash right eyelid	1	07DEC2020	1/2	1	Yes		NA	R (08DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		SKIN	Rash/ rash bilateral extremities	1	08DEC2020	2/1	1	Yes		NA	R (08DEC2020)	N/N
	C4591001 1152 11521654	PSYCH	Depression/ Worsened Depression	1	26DEC2020	18/C	2	No	O	NA/TC	N	N/N
	C4591001 1152 11521683	BLOOD	Lymphadenopathy/ Swollen Lymph Node (Left Clavicle)	1	26DEC2020	12/C	1	No	O	NA	N	N/N
	C4591001 1152 11521704	BLOOD	Lymphadenopathy/ swollen lymph node left axilla	1	26DEC2020	6/10	2	Yes		NA	R (04JAN2021)	N/N
	C4591001 1152 11521706	GENRL	Fatigue/ Fatigue	1	21DEC2020	1/7	3	Yes		NA/TC	R (27DEC2020)	N/N
		NERV	Headache/ HEADACHE	1	26DEC2020	6/2	3	Yes		NA/TC	R (27DEC2020)	N/N
	C4591001 1152 11521740	INJ&P	Tooth fracture/ Chipped baby tooth	2	17FEB2021	22/1	1	No	O	NA	R (17FEB2021)	N/N
	C4591001 1152 11521749	GASTR	Abdominal pain/ ABDOMINAL CRAMPS	1	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	C4591001 1152 11521756	GASTR	Diarrhoea/ Diarrhea	2	06FEB2021	6/3	1	No	O	NA	R (08FEB2021)	N/N
	C4591001 1156 11561310	INFEC	Body tinea/ TINEA CORPORIS	1	08DEC2020	8/18	1	No	O	NA	R (25DEC2020)	N/N
	C4591001 1223 12231267	GENRL	Fatigue/ fatigue	2	27JAN2021	1/3	2	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pyrexia/fever	1	27JAN2021	21/3	1	Yes		NA/TC	R (29JAN2021)	N/N
		MUSC	Myalgia/generalized muscle aches	2	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	C4591001 1223 12231271	GENRL	Injection site pain/injection site pain	1	29JAN2021	22/4	1	Yes		NA	R (01FEB2021)	N/N
	C4591001 1223 12231281	GENRL	Pyrexia/fever	2	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		MUSC	Myalgia/muscle ache generalized	2	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
		NERV	Headache/headache	2	03FEB2021	2/3	1	Yes		NA/TC	R (05FEB2021)	N/N
	C4591001 1223 12231286	NERV	Headache/headache	2	05FEB2021	3/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	C4591001 1270 12701205	INFEC	Subcutaneous abscess/Subcutaneous Tissue Abscess Right Earlobe	1	19DEC2020	5/17	1	No	O	NA/TCN	R (04JAN2021)	N/N
	C4591001 1270 12701222	PSYCH	Suicidal ideation/SUICIDAL IDEATION	2	16FEB2021	40/C	3	No	O	NA/TCN	N	Y/N
	C4591001 1270 12701233	GASTR	Rectal prolapse/Rectal Prolapse	2	22FEB2021	28/C	1	No	O	NA/TC	RG	N/N
	C4591001 1270 12701236	PSYCH	Anxiety/Anxiety	1	11JAN2021	6/C	1	No	O	NA	RG	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-25	C4591001 1270 12701237	MUSC	Musculoskeletal chest pain/ Rib pain on right side	1	10FEB2021	35/29	1	No	O	NA	R (10MAR2021)	N/N
	C4591001 1001 10011125	NERV	Dizziness/ dizziness*		04AUG2020	1/1	1	Yes		NA	R (04AUG2020)	N/N
		NERV	Migraine/ migraine headache	1	05AUG2020	2/5	3	Yes		NA	R (09AUG2020)	N/N
		MUSC	Myalgia/ diffuse myalgias	1	06AUG2020	3/2	3	Yes		NA	R (07AUG2020)	N/N
		PSYCH	Disorientation/ disorientation	1	08AUG2020	5/2	1	No	O	NA	R (09AUG2020)	N/N
	C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N
	C4591001 1005 10051024	METAB	Decreased appetite/ DECREASED APPETITE	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	C4591001 1005 10051071#	GENRL	Chills/ CHILLS	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
			Fatigue/ FATIGUE	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ HEADACHE	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N	

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1005 10051442	GENRL	Fatigue/ FATIGUE	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
			Injection site swelling/ INJECTION SITE SWELLING (1 INCH)	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
		MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
			Myalgia/ GENERALIZED MYALGIA	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
		NERV	Headache/ WORSENING OF HEADACHE	2	14JAN2021	2/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	C4591001 1006 10061031	INFEC	Oral fungal infection/ ORAL YEAST INFECTION	1	16AUG2020	4/11	2	No	O	NA/TC	R (26AUG2020)	N/N
	C4591001 1006 10061194	INFEC	Otitis externa/ Otitis Externa Left	2	15JAN2021	24/13	3	No	O	NA/TC/TCN	R (27JAN2021)	N/N
	C4591001 1006 10061194#	INJ&P	Mouth injury/ Oral laceration	2	15FEB2021	55/10	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N
	C4591001 1006 10061202	NERV	Headache/ Headache	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1006 10061204	GENRL	Injection site bruising/ 1 MM BRUISING AT INJECTION SITE LEFT DELTOID	2	22DEC2020	1/25	1	Yes		NA	R (15JAN2021)	N/Y
	C4591001 1006 10061205	INJ&P	Foot fracture/ Left Great Toe Fracture	2	29JAN2021	37/C	2	No	O	NA/TC	RG	N/N
	C4591001 1006 10061208	GENRL	Pain/ Body Aches	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
		NERV	Headache/ Headache	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
		RESP	Oropharyngeal pain/ Sore Throat	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	C4591001 1006 10061215	INJ&P	Ligament sprain/ Knee sprain Right	1	10DEC2020	7/3	1	No	O	NA/TC	R (12DEC2020)	N/N
		MUSC	Arthralgia/ right shoulder pain	2	23JAN2021	2/C	3	No	O	NA/TC/TCN	RG	N/N
	C4591001 1006 10061216#	GENRL	Chills/ Chills	3	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1006 10061240	GENRL	Injection site pain/ Injection site pain	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
			Pyrexia/ Fever	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
	C4591001 1006 10061246#	GENRL	Chills/ Chills	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/Headache	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	C4591001 1007 10071154#	GENRL	Injection site pain/ Injection Site Arm Soreness	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		GENRL	Chills/ chills	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
			Pyrexia/ fever	4	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N
	C4591001 1007 10071463#	EYE	Lacrimation increased/ Watery Eyes	3	03MAR2021	3/3	1	No	O	NA	R (05MAR2021)	N/N
	C4591001 1007 10071464	GASTR	Nausea/ nausea	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
	C4591001 1007 10071470#	GENRL	Injection site pain/ Injection site pain	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		NERV	Headache/ Headache	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1007 10071493#	GENRL	Injection site pain/ Injection site pain	2	22FEB2021	63/3	1	Yes		NA	R (24FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	23FEB2021	2/8	1	No	O	NA	R (02MAR2021)	N/N
		NERV	Headache/ Headache	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1007 10071502	GENRL	Injection site discomfort/ Weighted feeling in injection site arm	1	03DEC2020	1/3	1	Yes		NA	R (05DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup>	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		INFEC	Cellulitis/ Right axillary cellulitis	2	01JAN2021	11/8	2	No	O	NA/TC	R (08JAN2021)	N/N
			Folliculitis/ Right axillary folliculitis	2	01JAN2021	11/8	2	No	O	NA	R (08JAN2021)	N/N
	C4591001 1007 10071510#	GENRL	Injection site pain/ Injection Site Pain	3	22FEB2021	1/2	1	Yes		NA/TC/TCN	R (23FEB2021)	N/N
	C4591001 1007 10071538#	GENRL	Fatigue/ Fatigue	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	C4591001 1007 10071548#	NERV	Presyncope/ Vasovagal response with venipuncture	2	11MAR2021	72/1	2	No	O	NA	R (11MAR2021)	N/N
	C4591001 1007 10071553	GENRL	Injection site pain/ injection site pain	1	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/Y
		NERV	Dizziness/ Lightheaded*		10DEC2020	1/1	1	No	O	NA	R (10DEC2020)	N/N
	C4591001 1007 10071553#	GENRL	Chills/ Chills	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
			Injection site pain/ Injection site pain	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
			Pain/ Body aches	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		NERV	Headache/ Headache	3	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	C4591001 1008 10081776#	GENRL	Pain/ body aches	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pyrexia/ Fever	3	27FEB2021	2/3	2	Yes		NA/TC	R (01MAR2021)	N/N
		NERV	Headache/ Headache	3	27FEB2021	2/C	2	Yes		NA/TC	RG	N/N
	C4591001 1009 10091261	INJ&P	Skin laceration/ left index finger laceration	2	10FEB2021	71/C	2	No	O	NA/TC/TCN	RG	N/N
	C4591001 1009 10091278	EAR	Ear pain/ ear ache	2	21JAN2021	31/8	1	No	O	NA	R (28JAN2021)	N/N
	C4591001 1009 10091285	GENRL	Injection site pain/ pain at injection site	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		INFEC	Impetigo/ impetigo on face	2	12JAN2021	22/9	1	No	O	NA/TC	R (20JAN2021)	N/N
	C4591001 1009 10091286#	GENRL	Chills/ chills	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
			Pain/ body aches	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
		NERV	Headache/ Headache	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
	C4591001 1013 10131005	MUSC	Arthropathy/ CYST, WRIST, LEFT	2	SEP2020	14/	1	No	O	NA/TCN	R	N/N
	C4591001 1013 10131059	GENRL	Fatigue/ FATIGUE	2	26AUG2020	2/1	3	Yes		NA	R (26AUG2020)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	2	26AUG2020	2/1	2	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1015 10151006#	GENRL	Chills/ Chills	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
			Fatigue/ Fatigue	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
			Injection site pain/ Injection site pain	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		INV	Body temperature increased/ Increased body temperature 99F	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/ Headache	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
			Injection site pain/ Injection site pain	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
		MUSC	Myalgia/ Myalgias	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1015 10151029#	GENRL	Injection site pain/ Injection site pain	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y
		GENRL	Injection site pain/ Injection site pain	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
	C4591001 1015 10151035	BLOOD	Lymphadenopathy/ Swollen lymph node - left armpit axillary	2	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
	C4591001 1016 10161003#	GASTR	Nausea/ nausea	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Chills/ chills	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
			Pain/ generalized body aches	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
			Pyrexia/ subjective fever	3	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
	C4591001 1016 10161028	SKIN	Dermatitis contact/ Contact dermatitis	1	08AUG2020	6/8	2	No	O	NA/TC	R (15AUG2020)	N/N
	C4591001 1016 10161349	SKIN	Rash erythematous/ rash, top ten toes(red rash)	1	09NOV2020	4/C	1	No	O	NA	N	N/N
	C4591001 1018 10181133	SURG	Wisdom teeth removal/ Wisdom tooth extraction	1	20AUG2020	9/1	1	No	O	NA/TC	R (20AUG2020)	N/N
	C4591001 1039 10391243#	GENRL	Injection site pain/ Injection Arm Soreness	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1039 10391254#	GENRL	Injection site pain/ injection site pain	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	C4591001 1044 10441234	RESP	Reflux laryngitis/ Laryngopharyngeal Reflux	2	DEC2020	1/C	1	No	O	NA/TC	RG	N/N
	C4591001 1044 10441237#	GENRL	Injection site pain/ injection site pain	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
		NERV	Headache/ headache	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1044 10441240	GASTR	Nausea/ nausea	1	09DEC2020	17/1	1	No	O	NA/TC	R (09DEC2020)	N/N
	C4591001 1044 10441242	NERV	Dizziness/ dizziness	1	24NOV2020	1/1	1	Yes		NA	R (24NOV2020)	N/N
	C4591001 1044 10441242#	SKIN	Eczema/ Worsening of eczema (face)	2	26FEB2021	74/3	1	No	O	NA/TC	R (28FEB2021)	N/N
	C4591001 1044 10441244	GENRL	Injection site pain/ injection site pain	1	24NOV2020	1/4	1	Yes		NA	R (27NOV2020)	N/N
	C4591001 1044 10441246	INFEC	Otitis media/ otitis media (Left ear)	1	02JAN2021	6/6	1	No	O	NA/TC	R (07JAN2021)	N/N
	C4591001 1054 10541012	GASTR	Diarrhoea/ diarrhea - 1 episode	2	17SEP2020	7/1	1	Yes		NA	R (17SEP2020)	N/N
	C4591001 1057 10571373#	GENRL	Injection site pain/ INJECTION SITE PAIN ON LEFT ARM	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
	C4591001 1066 10661396#	GENRL	Injection site pain/ pain at injection site	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
		GENRL	Fatigue/ fatigue	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		MUSC	Myalgia/ muscle pain	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		NERV	Headache/ headache	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1071 10711039	GENRL	Fatigue/ FATIGUE	2	09SEP2020	6/13	2	Yes		NA	R (21SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	09SEP2020	6/13	1	Yes		NA	R (21SEP2020)	N/N
	C4591001 1081 10811012#	GENRL	Injection site pain/ pain at site of injection (left deltoid)	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		GASTR	Diarrhoea/ diarrhea (one episode)	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
		GENRL	Chills/ chills	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
			Pyrexia/ fever (101.9)	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N
	C4591001 1083 10831001	INJ&P	Fall/ Fall	2	26AUG2020	6/1	2	No	O	NA	R (26AUG2020)	N/N
			Fibula fracture/ Fibula fracture	2	26AUG2020	6/C	2	No	O	NA/TC	RG	N/N
	C4591001 1083 10831084	INJ&P	Meniscus injury/ Torn Meniscus-Right	1	17AUG2020	7/C	1	No	O	NA/TC/TCN	RG	N/N
	C4591001 1087 10871064	INFEC	Tooth infection/ Wisdom Teeth Infection - Right lower quadrant	2	15JAN2021	136/15	2	No	O	NA/TC	R (29JAN2021)	N/N
	C4591001 1087 10871078	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	02FEB2021	156/C	1	No	O	NA/TC	N	N/N
	C4591001 1087 10871078#	EYE	Blepharitis/ Blepharitis - Right Eye	2	19FEB2021	173/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1089 10891015	INFEC	Tonsillitis/ Tonsillitis	2	14SEP2020	28/1	2	No	O	NA/TCN	R (14SEP2020)	N/N
		PSYCH	Depression/ worsening depression	2	02NOV2020	77/30	2	No	O	NA/TC	R (01DEC2020)	N/N
	C4591001 1090 10901038	RESP	Oropharyngeal pain/ sore throat	1	20AUG2020	17/4	2	No	O	NA	R (23AUG2020)	N/N
	C4591001 1090 10901044#	GENRL	Fatigue/ Fatigue	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
			Injection site pain/ Injection site pain-right arm	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
	C4591001 1090 10901201#	GENRL	Chills/ Chills	3	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		MUSC	Myalgia/ Myalgia	3	03MAR2021	1/3	2	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1091 10911067#	GENRL	Injection site pain/ injection pain	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y
		GENRL	Chills/ chills	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
			Fatigue/ fatigue	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		MUSC	Arthralgia/ generalized arthralgia	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
			Myalgia/ Myalgia	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1091 10911088	GASTR	Crohn's disease/ Crohn's Disease	2	NOV2020	62/C	2	No	O	NA/TC	RG	N/N
	C4591001 1091 10911095#	MUSC	Myalgia/ myalgia	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	C4591001 1091 10911392	GENRL	Oedema peripheral/ left foot edema	1	01DEC2020	2/37	2	No	O	NA/TC	R (06JAN2021)	N/N
		MUSC	Arthralgia/ right knee joint pain	2	24DEC2020	3/14	2	No	O	NA/TC	R (06JAN2021)	N/N
	C4591001 1091 10911398	RESP	Asthma/ asthma attack	1	14DEC2020	12/1	1	No	O	NA	R (14DEC2020)	N/N
	C4591001 1092 10921223	GENRL	Injection site pain/ Injection Site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	1	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N
	C4591001 1095 10951055	REPRO	Cervical dysplasia/ ASCUS of cervix	1	10AUG2020	7/18	1	No	O	NA/TC	R (27AUG2020)	N/N
	C4591001 1095 10951106	MUSC	Arthralgia/ polyarthralgia	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
	C4591001 1095 10951308	PSYCH	Depression/ worsening of depression	2	DEC2020	1/C	1	No	O	NA/TC	N	N/N
	C4591001 1095 10951310	PSYCH	Attention deficit hyperactivity disorder/	2	25JAN2021	42/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			ADHD diagnosed by Psychiatrist									
	C4591001 1095 10951317	GENRL	Fatigue/ Fatigue	2	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y
	C4591001 1095 10951319	INJ&P	Joint dislocation/ L Patellar Dislocation	2	02JAN2021	6/C	1	No	O	NA/TC	RG	N/N
	C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
		RESP	Oropharyngeal pain/ Sore throat	1	05OCT2020	53/3	1	No	O	NA	R (07OCT2020)	N/N
		INFEC	Urinary tract infection/ urinary tract infection	1	22JAN2021	162/C	1	No	O	NA/TC	N	N/N
	C4591001 1107 11071010	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O	NA/TC	R (17AUG2020)	N/N
	C4591001 1107 11071010#	GENRL	Pain/ BODYACHES	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
			Pyrexia/ FEVER	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		NERV	Dizziness/ DIZZINESS	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/Y
			Headache/ HEADACHE	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1109 11091030	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N
	C4591001 1109 11091242#	GENRL	Fatigue/ FATIGUE	4	14FEB2021	2/C	1	Yes		NA	N	N/N
		NERV	Headache/ HEADACHE	4	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
	C4591001 1110 11101057#	GENRL	Injection site pain/ Pain at the site of injection.	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	C4591001 1110 11101379	GENRL	Fatigue/ Fatigue	1	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
		MUSC	Arthralgia/ Joint Pain (Generalized)	1	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	C4591001 1112 11121078	INFEC	Pharyngitis streptococcal/ Strep Throat	1	24AUG2020	20/12	1	No	O	NA/TC	R (04SEP2020)	N/N
	C4591001 1112 11121125	INFEC	Tinea infection/ Ringworm	1	19AUG2020	3/31	2	No	O	NA/TC	R (18SEP2020)	N/N
	C4591001 1112 11121125#	MUSC	Myalgia/ Muscle Aches	3	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N
	C4591001 1114 11141008#	GENRL	Chills/ CHILLS	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
			Injection site pain/ ARM PAIN AT INJECTION SITE	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1114 11141009#	GENRL	Fatigue/ FATIGUE	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
			Injection site pain/ Injection site pain	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	C4591001 1120 11201250	SKIN	Rash/ Rash torso and legs	1	27AUG2020	7/16	1	No	O	NA/TC	R (11SEP2020)	N/N
		NERV	Burning sensation/ Burning sensation in palm of left hand	2	16SEP2020	6/1	2	No	O	NA	R (16SEP2020)	N/N
	C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N
		NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N
	C4591001 1126 11261205	METAB	Decreased appetite/ Decreased appetite	1	23NOV2020	13/C	1	No	O	NA	RG	N/N
		PSYCH	Depressed mood/ Depressed mood	1	23NOV2020	13/C	1	No	O	NA	RG	N/N
	C4591001 1126 11261206#	GENRL	Injection site pain/ Pain, injection site	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	C4591001 1126 11261207#	GENRL	Injection site pain/ Pain Injection Site	3	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1126 11261210#	GENRL	Injection site pain/ Left upper arm injection site pain	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261211#	GENRL	Chills/ Chills	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
			Injection site pain/ Injection site pain	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
		NERV	Headache/ Headache	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	C4591001 1126 11261214#	GENRL	Chills/ Chills	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
			Injection site pain/ Injection site pain	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
			Malaise/ Malaise	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	C4591001 1126 11261215#	GENRL	Injection site pain/ Left arm injection site pain	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	C4591001 1126 11261220#	GENRL	Injection site pain/ Left upper arm injection site pain	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N
		NERV	Headache/ Headache	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		GENRL	Chills/ Chills	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
			Pyrexia/ Fever	3	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	C4591001 1126 11261223#	GENRL	Injection site pain/ Injection site pain	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261224#	GENRL	Malaise/ Malaise	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	C4591001 1126 11261228#	GENRL	Injection site pain/ Injection Site Pain	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		NERV	Headache/ Headache	3	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1126 11261236#	GENRL	Fatigue/ Fatigue	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
			Injection site pain/ Pain, injection site	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	C4591001 1126 11261237#	GENRL	Injection site pain/ Injection Site Pain	3	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1126 11261238#	GENRL	Injection site pain/ Injection site pain	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261244#	BLOOD	Lymphadenopathy/ Lymph node swelling left armpit	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
		GENRL	Injection site pain/ Left upper arm injection site pain	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		GENRL	Chills/ Chills	3	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Pyrexia/ Fever	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1126 11261247#	GENRL	Injection site pain/ Left upper arm injection site pain	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1126 11261248#	GENRL	Injection site pain/ Left upper arm injection site pain	3	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N
		MUSC	Myalgia/ Muscle aches, generalized	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
		GENRL	Pyrexia/ Fever	3	13FEB2021	3/1	2	Yes		NA/TC	R (13FEB2021)	N/N
	C4591001 1126 11261259#	GASTR	Irritable bowel syndrome/ Worsening irritable bowel syndrome	2	14FEB2021	55/C	2	No	O	NA/TC/TCN	N	N/N
	C4591001 1126 11261260#	GENRL	Chills/ Chills	3	12FEB2021	2/1	2	Yes		NA	R (12FEB2021)	N/N
			Fatigue/ Fatigue	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
		MUSC	Myalgia/ Muscle aches, generalized	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
		INFEC	Vulvitis/ Vulvitis	3	16FEB2021	6/7	2	No	O	NA/TC	R (22FEB2021)	N/N
		RENAL	Dysuria/ Dysuria	3	17FEB2021	7/6	2	No	O	NA	R (22FEB2021)	N/N
	C4591001 1126 11261261#	GENRL	Injection site pain/ Left upper arm injection site pain	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1128 11281057	INFEC	Tonsillitis/ tonsillitis	2	19SEP2020	25/C	1	No	O	NA	N	N/N
	C4591001 1128 11281098	SKIN	Macule/ Erythematous, Macule upper anterior thigh	2	13SEP2020	10/27	2	No	O	NA/TC	R (09OCT2020)	N/N
		MUSC	Musculoskeletal chest pain/ chest wall pain	2	08OCT2020	35/5	1	No	O	NA	R (12OCT2020)	N/N
	C4591001 1128 11281098#	GENRL	Chills/ Chills	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
			Injection site pain/ Injection Site Soreness, Left Arm	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	C4591001 1129 11291097	INFEC	Urinary tract infection/ urinary tract infection	2	19DEC2020	110/3	2	No	O	NA/TC	R (21DEC2020)	N/N
	C4591001 1129 11291256#	EYE	Eye pain/ eye pain	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		GENRL	Chills/ chills	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		NERV	Headache/ headache	3	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		MUSC	Back pain/ back pain muscular	3	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		GENRL	Chills/ Chills	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
	C4591001 1129 11291260#	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1129 11291262	GASTR	Lip swelling/ lip swelling	1	23NOV2020	1/12	1	No	O	NA/TC	R (04DEC2020)	N/N
		GASTR	Aphthous ulcer/ worsening canker sore episode of lips	1	27NOV2020	5/8	2	Yes		NA/TC	R (04DEC2020)	N/N
	C4591001 1129 11291263#	GENRL	Injection site pain/ left deltoid injection site soreness	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	C4591001 1131 11311279	GENRL	Fatigue/ fatigue	2	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
			Injection site pain/ injection site pain	2	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
	C4591001 1139 11391089	MUSC	Musculoskeletal discomfort/ Left Shoulder discomfort	1	26AUG2020	15/12	1	Yes		NA	R (06SEP2020)	N/N
	C4591001 1139 11391138	INFEC	Sinusitis/ sinusitis	2	08JAN2021	23/18	2	No	O	NA/TC	R (25JAN2021)	N/N
	C4591001 1140 11401321#	GENRL	Injection site pain/ Pain at injection site	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1141 11411006	MUSC	Back pain/ Back Pain	1	31JUL2020	1/10	3	Yes		NA/TC	R (09AUG2020)	N/N
		INFEC	Gingivitis/ Gum Infection	2	01DEC2020	103/72	1	No	O	NA/TC	R (10FEB2021)	N/N
	C4591001 1141 11411010	PSYCH	Anxiety/ Anxiousness	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Depressed mood/ Low Mood	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N
	C4591001 1141 11411016#	GENRL	Injection site pain/ injection site pain	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
		GASTR	Nausea/ Nausea	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		INV	Body temperature increased/ Elevated Body Temperature T. Max 100.1 F	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		MUSC	Myalgia/ Diffuse Myalgia in vaccinated arm	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	C4591001 1141 11411021	GENRL	Injection site pain/ muscle soreness injection area	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	C4591001 1141 11411029	MUSC	Arthralgia/ Arthralgias	2	17SEP2020	23/12	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N
		PSYCH	Anxiety/ Anxiety Flare up	2	18SEP2020	24/C	1	Yes		NA/TC/TCN	N	N/N
	C4591001 1141 11411032#	GENRL	Fatigue/ Fatigue	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
			Injection site pain/ Injection site pain left deltoid	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	C4591001 1141 11411053	PSYCH	Anxiety/ Worsening Anxiety	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N

**16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Depression/ Worsening depression	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
	C4591001 1141 11411056	GENRL	Injection site hyperaesthesia/ Hyperesthesia left deltoid region on injection site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
	C4591001 1141 11411067	MUSC	Plantar fasciitis/ worsening of plantar fasciitis left foot	2	14SEP2020	13/C	2	No	O	NA/TC	RG	N/N
	C4591001 1141 11411067#	GENRL	Fatigue/ fatigue	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
			Injection site pain/ injection site pain	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N
		GENRL	Fatigue/ Fatigue	4	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N
		NERV	Headache/ Headache (worse than typical)	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
		GASTR	Nausea/ Nausea	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		GENRL	Pyrexia/ Fever	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		MUSC	Myalgia/ Generalized Myalgia	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
		GENRL	Injection site pain/ Arm Pain (injection)	4	16JAN2021	4/2	1	Yes		NA	R (17JAN2021)	N/N
	C4591001 1141 11411070#	GENRL	Chills/ chills	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N

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## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Fatigue/fatigue	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
			Injection site pain/injection site pain	3	23DEC2020	1/2	2	Yes		NA/TC	R (24DEC2020)	N/N
		GENRL	Pyrexia/Fever	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
	C4591001 1141 11411074#	GASTR	Abdominal discomfort/Stomach discomfort	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Chills/chills	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Malaise/Malaise	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
			Pyrexia/Fever (101 F)	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
		MUSC	Myalgia/myalgia	4	25FEB2021	2/1	3	Yes		NA/TC	R (25FEB2021)	N/N
		NERV	Headache/Headache	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
	C4591001 1142 11421045#	GENRL	Injection site pain/injection site pain	3	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
		SKIN	Ecchymosis/ecchymosis at left antecubital fossa	3	27FEB2021	2/C	1	No	O	NA	RG	N/N
	C4591001 1142 11421059#	GENRL	Injection site pain/injection site pain	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
		GENRL	Fatigue/fatigue	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ injection site pain	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
			Pain/ body aches	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	C4591001 1142 11421078#	GENRL	Injection site pain/ injection site pain	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	C4591001 1147 11471258#	GENRL	Injection site pain/ Pain at injection site	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
	C4591001 1147 11471259	EYE	Eye pain/ Ocular pain, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
			Ocular hyperaemia/ Ocular redness, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
	C4591001 1147 11471272	INJ&P	Ligament sprain/ Sprained Ankle	2	14JAN2021	18/C	1	No	O	NA/TC	N	N/N
	C4591001 1149 11491335†	GENRL	Injection site pain/ mild pain at site of injection (right arm)	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	C4591001 1150 11501148#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
			Pain/ Generalized Body Aches	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		NERV	Dizziness/ Dizziness	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501149#	GENRL	Injection site pain/ Pain at injection site	3	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
			Pain/ Generalized Body Aches	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		NERV	Headache/ Headache	3	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1150 11501151#	GENRL	Injection site pain/ Pain at injection site	3	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	C4591001 1150 11501153#	GENRL	Injection site pain/ Pain at injection site	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
	C4591001 1150 11501155#	GENRL	Injection site pain/ Pain at injection site	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1150 11501158#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
	C4591001 1150 11501159#	GENRL	Injection site pain/ Pain at injection site	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501169#	GENRL	Injection site pain/ Injection Site Pain	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	C4591001 1150 11501170#	GENRL	Injection site pain/ Injection Site Pain	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
	C4591001 1152 11521024#	INJ&P	Upper limb fracture/ broken right arm	2	15JAN2021	136/C	2	No	O	NA/TC/TCN	N	N/N
	C4591001 1152 11521591#	NERV	Headache/ Headache	3	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
	C4591001 1152 11521643	ENDO	Autoimmune thyroiditis/ Hashimoto's disease	2	12FEB2021	47/C	2	No	O	NA	N	N/N
	C4591001 1156 11561300	GENRL	Pyrexia/ FEVER	1	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N
	C4591001 1156 11561329	NERV	Headache/ HEADACHE	2	07JAN2021	2/42	1	Yes		NA/TC	R (17FEB2021)	N/N
	C4591001 1161 11611016	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	17JAN2021	60/C	1	No	O	NA	UNK	N/N
	C4591001 1162 11621019	INFEC	Sinusitis/ sinus infection	2	06OCT2020	42/C	1	No	O	NA/TC	N	N/N
	C4591001 1162 11621583	NERV	Headache/ headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup>	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	C4591001 1170 11701022	GENRL	Pain/ Exercise Induced Body Soreness	1	06SEP2020	21/2	1	No	O	NA/TC	R (07SEP2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	C4591001 1171 11711027	INJ&P	Muscle strain/ Lower back strain	2	18SEP2020	15/11	2	No	O	NA/TC	R (28SEP2020)	N/N
	C4591001 1185 11851060#	GENRL	Fatigue/ Fatigue	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		NERV	Somnolence/ Drowsiness	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1194 11941045#	GENRL	Injection site pain/ Pain at injection site	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	C4591001 1194 11941047#	GENRL	Injection site pain/ Pain at injection site	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N
			Injection site pain/ Pain at injection site	4	15FEB2021	1/5	2	Yes		NA	R (19FEB2021)	N/N
	C4591001 1194 11941067#	GENRL	Fatigue/ Fatigue	3	15JAN2021	1/6	3	Yes		NA	R (20JAN2021)	N/N
			Injection site pain/ Pain at injection site	3	15JAN2021	1/6	2	Yes		NA	R (20JAN2021)	N/N
			Injection site swelling/ Swelling at injection pain	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/Headache	3	16JAN2021	2/3	2	Yes		NA	R (18JAN2021)	N/N
		GENRL	Injection site pain/Pain at injection site	4	05FEB2021	1/7	2	Yes		NA	R (11FEB2021)	N/N
	C4591001 1194 11941086#	GENRL	Injection site pain/Pain at injection site	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/Headache	3	29JAN2021	2/2	2	Yes		NA	R (30JAN2021)	N/N
		NERV	Headache/Headache	4	19FEB2021	2/3	2	Yes		NA	R (21FEB2021)	N/N
	C4591001 1194 11941092#	GENRL	Injection site pain/Pain at the injection site	3	27JAN2021	2/3	2	Yes		NA	R (29JAN2021)	N/N
	C4591001 1194 11941103#	GENRL	Injection site pain/Pain at injection site	3	13JAN2021	2/4	1	Yes		NA	R (16JAN2021)	N/N
	C4591001 1195 11951066#	GENRL	Chills/Chills	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	C4591001 1195 11951100	GASTR	Vomiting/Emesis	1	18OCT2020	1/1	1	No	O	NA	R (18OCT2020)	N/N
	C4591001 1195 11951148	MUSC	Spinal disorder/cervical spine syndrome	1	02NOV2020	14/45	1	No	O	NA/TC	R (16DEC2020)	N/N
	C4591001 1195 11951148#	GENRL	Injection site pain/pain injection site	3	09FEB2021	2/7	2	Yes		NA	R (15FEB2021)	N/N
		GASTR	Nausea/Nausea	3	24FEB2021	17/2	1	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1197 11971031	MUSC	Tenosynovitis/ Tenosynovitis right forearm	2	15JAN2021	71/C	2	No	O	NA/TC	N	N/N
	C4591001 1197 11971031#	NERV	Headache/ headache	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1203 12031026	NERV	Headache/ headache	1	07NOV2020	19/1	2	No	O	NA/TC	R (07NOV2020)	N/N
		GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	C4591001 1203 12031026#	NERV	Headache/ systemic vaccination reaction headache	3	01MAR2021	1/1	2	Yes		NA/TC	R (01MAR2021)	N/N
	C4591001 1203 12031047#	GENRL	Injection site pain/ tenderness at injection site	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		GENRL	Malaise/ Malaise	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		MUSC	Arthralgia/ Arthralgia	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
		GENRL	Pyrexia/ Fever	4	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1213 12131003#	GENRL	Injection site pain/ PAIN AT INJECTION SITE	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		MUSC	Myalgia/ MUSCLE PAIN	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of Vax Rel <sup>c</sup> AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ HEADACHE	4	29JAN2021	1/2	2	Yes	NA/TC	R (30JAN2021)	N/N
		SKIN	Hyperhidrosis/ SWEATING	4	29JAN2021	1/2	2	Yes	NA/TC	R (30JAN2021)	N/N
	C4591001 1213 12131018#	GENRL	Injection site pain/ PAIN AT INJECTION SITE	3	12JAN2021	1/2	2	Yes	NA	R (13JAN2021)	N/N
		NERV	Headache/ HEADACHE	3	12JAN2021	1/2	2	Yes	NA	R (13JAN2021)	N/N
		GENRL	Injection site pain/ PAIN AT INJECTION SITE	4	01FEB2021	1/3	2	Yes	NA	R (03FEB2021)	N/N
		NERV	Headache/ HEADACHE	4	01FEB2021	1/3	3	Yes	NA	R (03FEB2021)	N/N
	C4591001 1214 12141012#	GENRL	Injection site pain/ Pain at injection site	3	02FEB2021	1/2	2	Yes	NA	R (03FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	03FEB2021	2/2	2	Yes	NA	R (04FEB2021)	N/N
		NERV	Headache/ Headache	3	03FEB2021	2/2	2	Yes	NA	R (04FEB2021)	N/N
		GENRL	Injection site pain/ pain at injection site	4	24FEB2021	1/4	2	Yes	NA	R (27FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	4	25FEB2021	2/2	2	Yes	NA	R (26FEB2021)	N/N
		NERV	Headache/ Headache	4	25FEB2021	2/2	2	Yes	NA	R (26FEB2021)	N/N
	C4591001 1214 12141022#	GENRL	Injection site pain/ pain at injection site	3	01FEB2021	1/3	2	Yes	NA	R (03FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GENRL	Injection site pain/pain at injection site	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
		GENRL	Fatigue/fatigue	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
	C4591001 1214 12141027#	GENRL	Injection site pain/pain at injection site	3	01FEB2021	1/2	3	Yes		NA	R (02FEB2021)	N/N
		GENRL	Fatigue/fatigue	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
		MUSC	Pain in extremity/arm pain	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	C4591001 1214 12141053#	MUSC	Pain in extremity/Arm Pain	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		MUSC	Pain in extremity/Arm Pain	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		GENRL	Fatigue/Fatigue	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	C4591001 1217 12171032#	GENRL	Injection site pain/Injection pain (Arm pain)	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		GENRL	Fatigue/Lassitude	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
			Injection site pain/Injection pain(arm pain)	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	C4591001 1217 12171041#	GENRL	Injection site pain/arm pain (injection pain)	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		GENRL	Pyrexia/38 C Fever	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1223 12231005#	GENRL	Injection site pain/ injection site pain	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	C4591001 1223 12231008#	GENRL	Fatigue/ fatigue	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
		MUSC	Back pain/ back pain	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	C4591001 1223 12231025#	GENRL	Injection site pain/ injection site pain	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	C4591001 1223 12231036#	GENRL	Fatigue/ fatigue	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	C4591001 1223 12231057	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
			Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	C4591001 1223 12231073	GASTR	Nausea/ nausea	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
		NERV	Dizziness/ Dizziness	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
	C4591001 1223 12231073#	GENRL	Chills/ chills	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		NERV	Headache/ headache	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	C4591001 1224 12241168	GENRL	Pyrexia/ Fever - 101.0F	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
		SKIN	Rash/ Rash - bilateral upper arms	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
	C4591001 1226 12261049	GENRL	Pyrexia/ fever (38 C)	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	C4591001 1226 12261082	GASTR	Nausea/ nausea	1	19AUG2020	9/1	1	No	O	NA/TC	R (19AUG2020)	N/N
		MUSC	Torticollis/ torticollis	1	24AUG2020	14/1	1	No	O	NA/TC	R (24AUG2020)	N/N
	C4591001 1226 12261100#	GENRL	Fatigue/ Fatigue	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
			Injection site pain/ Pain at injection site	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
		GENRL	Pyrexia/ Fever 39 C	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	C4591001 1226 12261124	MUSC	Pain in extremity/ Pain in legs	1	19AUG2020	8/3	2	No	O	NA/TC	R (21AUG2020)	N/N
	C4591001 1226 12261126	MUSC	Back pain/ acute low back pain	1	20AUG2020	9/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1226 12261126#	GENRL	Fatigue/ tiredness	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
			Injection site pain/ pain at the injection site	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		MUSC	Myalgia/ muscle pain	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		GENRL	Injection site pain/ Pain at the injection site	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
			Injection site swelling/ Swelling at the injection site	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N
		GENRL	Chills/ Chills	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		INV	Body temperature increased/ Increased body temperature 37.6 C	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		MUSC	Arthralgia/ Joint pain	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	C4591001 1226 12261144	NERV	Headache/ Headache	1	27AUG2020	16/1	1	No	O	NA	R (27AUG2020)	N/N
		NERV	Headache/ Headache	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
	C4591001 1226 12261158#	GENRL	Chills/ Chills	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
			Injection site pain/ Pain at the injection site	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MUSC	Myalgia/Myalgia	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		NERV	Headache/Headache	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		GENRL	Chills/chills	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
			Pain/body pain	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	C4591001 1226 12261172#	GENRL	Chills/chills	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		NERV	Headache/headache	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	C4591001 1226 12261207#	GENRL	Pyrexia/Fever 38 C	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	C4591001 1226 12261230#	GENRL	Pain/body pain	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N
	C4591001 1226 12261238#	GENRL	Injection site pain/pain at the injection site	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1226 12261251#	GASTR	Nausea/Nausea	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		GENRL	Injection site pain/Pain at injection site	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		GENRL	Injection site pain/pain at the injection site	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		GASTR	Nausea/ Nausea	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	C4591001 1230 12301057#	MUSC	Myalgia/ New onset of muscle pain.	3	29JAN2021	2/4	3	Yes		NA/TC	R (01FEB2021)	N/N
		GENRL	Injection site pain/ Pain at injection site.	3	07FEB2021	11/14	2	Yes		NA	R (20FEB2021)	N/N
		GENRL	Peripheral swelling/ Swelling left upper arm.	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
		MUSC	Myalgia/ New onset of muscle pain.	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
		MUSC	Arthralgia/ New onset of joint pain left upper wrist	4	19FEB2021	4/15	3	Yes		NA/TC	R (05MAR2021)	N/N
	C4591001 1230 12301114#	GENRL	Chills/ Chills	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		MUSC	Myalgia/ Muscle pain in upper arms and legs.	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
	C4591001 1231 12311141	INFEC	Genital herpes/ exacerbated genital herpes	2	27SEP2020	26/9	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
	C4591001 1231 12311164	GASTR	Abdominal pain/ Abdominal pain	2	02SEP2020	1/2	3	No	O	NA/TC/TCN	R (03SEP2020)	N/N
	C4591001 1231 12311191	INFEC	Cystitis/ Cystitis	1	09OCT2020	57/3	1	No	O	NA/TC	R (11OCT2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1231 12311199	INFEC	Genital herpes simplex/ Genital herpes simplex type 2	2	16SEP2020	14/13	1	No	O	NA/TC	R (28SEP2020)	N/N
	C4591001 1231 12311229	CARD	Tachycardia/ tachycardia	2	06OCT2020	33/39	2	No	O	NA	R (13NOV2020)	N/N
	C4591001 1231 12311281	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
		INV	Electrocardiogram QT prolonged/ QT interval prolongation	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
	C4591001 1231 12311306	GENRL	Chest pain/ Self-limited oppressive chest pain	1	02SEP2020	19/1	1	No	O	NA	R (02SEP2020)	N/N
	C4591001 1231 12311387	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	2	07NOV2020	65/C		No	O	NA	UNK	N/N
		INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
	C4591001 1231 12311388	NERV	Headache/ headache	1	16AUG2020	2/8	1	No	O	NA	R (23AUG2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA	1	18AUG2020	4/7	1	Yes		NA	R (24AUG2020)	N/N
		MUSC	Arthralgia/ ARTHRALGIA	1	21AUG2020	7/4	1	No	O	NA	R (24AUG2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		SURG	Tooth extraction/ Programmed extraction of the right third molar	2	26SEP2020	24/1	1	No	CND	NA/TC/TCN	R (26SEP2020)	N/N
	C4591001 1231 12311436	GASTR	Diarrhoea/ diarrhea	2	30SEP2020	28/2	1	No	O	NA/TCN	R (01OCT2020)	N/N
	C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
	C4591001 1241 12411010	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
	C4591001 1241 12411011	MUSC	Myalgia/ Myalgia	2	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
	C4591001 1241 12411028#	GENRL	Injection site pain/ Injection site pain	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
			Injection site pain/ Injection site pain	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		GENRL	Pyrexia/ Fever	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	C4591001 1241 12411034	SURG	Sclerotherapy/ Sclerotherapy	2	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
	C4591001 1241 12411127#	GENRL	Injection site pain/ Injection site pain	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Pyrexia/ Fever	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
		NERV	Headache/ Headache	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
		GENRL	Injection site pain/ Injection site pain	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
			Pyrexia/ Fever	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		NERV	Headache/ Headache	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1241 12411157#	GENRL	Injection site pain/ Injection site pain	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	C4591001 1241 12411171#	MUSC	Myalgia/ Myalgia	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	C4591001 1241 12411178#	GENRL	Injection site pain/ Injection site pain	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		GENRL	Fatigue/ Fatigue	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
			Injection site pain/ Injection site pain	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1241 12411205#	GENRL	Injection site pain/ Injection site pain	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	C4591001 1241 12411220#	GENRL	Injection site pain/ Injection site pain	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site swelling/ Injection site swelling	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
		MUSC	Myalgia/ Myalgia	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	C4591001 1246 12461026	INFEC	Sinusitis/ Sinusitis	2	27OCT2020	9/15	2	No	O	NA/TC	R (10NOV2020)	N/N
	C4591001 1246 12461028#	MUSC	Pain in extremity/ Painful Left arm	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N
	C4591001 1246 12461070	INFEC	Urinary tract infection/ Urine tract Infection- pathogen unknown	2	15NOV2020	23/4	2	No	O	NA/TC	R (18NOV2020)	N/N
		PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
	C4591001 1246 12461082#	GENRL	Injection site pain/ Painful Left Arm injection area	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	C4591001 1246 12461084#	GENRL	Injection site pain/ Painful left arm injection site.	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1246 12461092#	GENRL	Injection site pain/ Painful left arm injection site	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	C4591001 1246 12461094#	GENRL	Injection site pain/ Painful left arm at injection side	3	12FEB2021	1/4	2	Yes		NA/TC	R (15FEB2021)	N/N
	C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N



## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Road traffic accident/ Motorcycle accident	2	30OCT2020	10/1	2	No	O	NA	R (30OCT2020)	N/N
	C4591001 1247 12471185	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	1	Yes		NA	R (14OCT2020)	N/N
		MUSC	Myalgia/ Muscle pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		NERV	Headache/ Headache	1	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
		GENRL	Chills/ Chills	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
			Injection site pain/ Injection site pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		GENRL	Injection site pain/ Injection pain	1	08OCT2020	3/2	1	Yes		NA	R (09OCT2020)	N/N
		GENRL	Pyrexia/ Fever	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
	C4591001 1247 12471197	GENRL	Fatigue/ Fatigue	1	07OCT2020	2/7	2	Yes		NA	R (13OCT2020)	N/N
		NERV	Headache/ Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	C4591001 1247 12471199	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/1	2	Yes		NA	R (06OCT2020)	N/N
			Injection site erythema/ Injection site redness	1	06OCT2020	1/2	3	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Injection site pain/ Injection site pain	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
			Injection site swelling/ Injection site swelling	1	06OCT2020	1/1	3	Yes		NA	R (06OCT2020)	N/N
	C4591001 1248 12481001	GENRL	Chills/ Chills	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
			Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
	C4591001 1248 12481004#	GENRL	Fatigue/ fatigue	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
			Pain/ body aches	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
			Pyrexia/ mild fever	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	C4591001 1270 12701152#	GENRL	Chills/ Chills	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
			Fatigue/ Fatigue	3	03FEB2021	1/7	1	Yes		NA	R (09FEB2021)	N/N
			Injection site pain/ Injection Site Pain	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		GASTR	Nausea/ Nausea	3	06FEB2021	4/1	1	Yes		NA	R (06FEB2021)	N/N
		GENRL	Injection site pain/ Injection Site Pain	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	C4591001 1270 12701154	PSYCH	Generalised anxiety disorder/	2	14JAN2021	39/C	1	No	O	NA/TCN	N	N/N

## 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
			Generalized Anxiety Disorder									
	C4591001 1270 12701155#	MUSC	Back pain/ Chronic Low back pain	2	19JAN2021	44/C	1	No	O	NA/TCN	N	N/N
		GENRL	Chills/ Chills	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
			Injection site pain/ Injection Site Pain	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		MUSC	Myalgia/ Muscle pain, generalized	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	C4591001 1270 12701164#	MUSC	Pain in extremity/ Right antecubital pain	2	02FEB2021	51/1	1	No	O	NA/TCN	R (02FEB2021)	N/N
		NERV	Headache/ Headache	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	C4591001 1270 12701175	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	01DEC2020	1/7	2	Yes		NA	R (07DEC2020)	N/N
	C4591001 1270 12701178	SKIN	Seborrheic dermatitis/ Seborrheic Dermatitis of Scalp	2	10JAN2021	20/C	1	No	O	NA/TC	N	N/N
	C4591001 1270 12701178#	GENRL	Injection site pain/ Injection Site Pain	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	C4591001 1270 12701186	SKIN	Rash/ Rash to trunk	2	21JAN2021	31/C	1	No	O	NA	RG	N/N

### 16.2.7.4.1.1 Listing of Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1270 12701190#	GENRL	Injection site pain/ Injection site pain	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		GENRL	Fatigue/ Fatigue	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = Prevacination AE, # = AE occurring on or after subject unblinding date, † = human immunodeficiency virus (HIV)-positive subject.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_ped

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1001 10011083	INFEC	Urinary tract infection/ urinary tract infection	2	14SEP2020	27/7	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1001 10011089	INJ&P	Fall/ Fall from mountainbike	2	04SEP2020	18/C	2	No	O	NA/TCN	N	N/N
		Ligament sprain/ Sprained shoulder	2	04SEP2020	18/C	2	No	O	NA	N	N/N
16-55/ C4591001 1001 10011092	GENRL	Chest discomfort/ intermittent chest discomfort	2	14SEP2020	27/15	1	No	O	NA	R (28SEP2020)	N/N
	INJ&P	Ligament rupture/ right ACL rupture#	2	15JAN2021	150/33	2	No	O	NA/TC	R (16FEB2021)	N/N
	GENRL	Feeling hot/ Feeling Warm#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1001 10011106	MUSC	Back pain/ Lower Back Pain	1	02AUG2020	3/2	2	Yes		NA	R (03AUG2020)	N/N
16-55/ C4591001 1001 10011113	NERV	Migraine/ worsening migraine	1	07AUG2020	5/9	2	No	O	NA	R (15AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1001 10011125	NERV	Dizziness/ dizziness*		04AUG2020	1/1	1	Yes		NA	R (04AUG2020)	N/N
	NERV	Migraine/ migraine headache	1	05AUG2020	2/5	3	Yes		NA	R (09AUG2020)	N/N
	MUSC	Myalgia/ diffuse myalgias	1	06AUG2020	3/2	3	Yes		NA	R (07AUG2020)	N/N
	PSYCH	Disorientation/ disorientation	1	08AUG2020	5/2	1	No	O	NA	R (09AUG2020)	N/N
16-55/ C4591001 1001 10011130	INJ&P	Arthropod bite/ Insect bites, left ankle	1	07AUG2020	3/3	1	No	O	NA/TC	R (09AUG2020)	N/N
16-55/ C4591001 1001 10011132	RESP	Allergic respiratory disease/ Allergy upper respiratory	2	01SEP2020	7/3	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C4591001 1001 10011135	BLOOD	Lymphadenopathy/ Left axilla lymphadenopathy#	3	15JAN2021	2/12	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Left arm pain at injection site#	3	15JAN2021	2/33	2	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1001 10011138	MUSC	Arthralgia/ exacerbation of history of left shoulder pain	2	15SEP2020	20/C	1	No	O	NA	N	N/N
16-55/ C4591001	MUSC	Pain in extremity/ right arm pain	2	11SEP2020	16/3	1	No	O	NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1001 10011143 16-55/ C4591001 1001 10011145	GASTR	Gastroesophageal reflux disease/ exacerbation of gastroesophageal reflux disease	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	03SEP2020	7/1	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1001 10011149	GENRL	Malaise/ Malaise	1	14AUG2020	8/5	1	No	O	NA	R (18AUG2020)	N/N
	NERV	Sciatica/ Back pain, subjectively described as sciatica	1	18AUG2020	12/C	1	No	O	NA/TC	N	N/N
	INJ&P	Muscle strain/ muscle strain	2	23SEP2020	27/3	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1003 10031101	SKIN	Dermatitis contact/ Poison Ivy on both legs, both arms, and both wrists.	2	09SEP2020	23/15	2	No	O	NA/TC	R (23SEP2020)	N/N
	VASC	Hypertension/ Hypertension	2	16SEP2020	30/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N
16-55/ C4591001	METAB	Obesity/ obesity	2	03SEP2020	14/C	3	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1003 10031125 16-55/ C4591001 1003 10031147	VASC	Hypertension/ worsening hypertension	2	SEP2020	7/C	1	No	O	NA/TC	N	N/N
1003 10031147	REPRO	Endometriosis/ endometriosis#	3	29JAN2021	19/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1003 10031155	GENRL	Fatigue/ Mild Fatigue	1	11AUG2020	6/2	1	No	O	NA	R (12AUG2020)	N/N
16-55/ C4591001 1003 10031156	GENRL	Pyrexia/ fever 102#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
1003 10031156	SKIN	Rash/ rash on torso#	3	31JAN2021	3/3	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1003 10031160	INJ&P	Contusion/ traumatic bruise left knee	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N
		Fall/ fall from bicycle	1	10AUG2020	5/6	2	No	O	NA/TC	R (15AUG2020)	N/N
	PSYCH	Anxiety/ Anxiety	2	NOV2020	67/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1003 10031166	GASTR	Diverticulum/ R/O worsening of diverticular disease#	2	04FEB2021	161/21	2	No	O	NA	R (24FEB2021)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1003 10031186	INJ&P	Exposure during pregnancy/ Exposure During partner Pregnancy	2	17SEP2020	15/C		No	O	NA	UNK	N/N
16-55/ C4591001 1003 10031197	CONG	Congenital ureteropelvic junction obstruction/ Congenital right ureteropelvic junction obstruction	2	01DEC2020	90/58	3	No	O	NA/TC/TCN	R (27JAN2021)	Y/N
16-55/ C4591001 1003 10031201	IMMUN	Hypersensitivity/ Allergy Attack	2	20SEP2020	18/1	1	No	O	NA/TC	R (20SEP2020)	N/N
	INFEC	Sinusitis/ Sinus Infection	2	22SEP2020	20/4	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1003 10031205	EYE	Uveitis/ bilateral Uveitis	2	DEC2020	89/C	2	No	O	NA/TC	N	N/N
	INV	Biopsy breast normal/ Left breast lesion biopsy benign	2	11JAN2021	130/1	1	No	O	NA	R (11JAN2021)	N/N
16-55/ C4591001 1003 10031206	GASTR	Colitis ulcerative/ ulcerative colitis	2	24OCT2020	51/16	3	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 1003 10031207	VASC	Deep vein thrombosis/ bilateral lower extremity DVT	2	27DEC2020	115/48	3	No	O	NA/TC	R (12FEB2021)	Y/N
	CONG	Protein S deficiency/ S protein deficiency	2	28DEC2020	116/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051003	RESP	Pulmonary embolism/ pulmonary embolism	2	28DEC2020	116/15	3	No	O	NA/TC	R (11JAN2021)	Y/N	
16-55/ C4591001 1005 10051003	MUSC	Back pain/ BACK PAIN	2	30SEP2020	32/9	2	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1005 10051024	METAB	Decreased appetite/ DECREASED APPETITE	2	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N	
16-55/ C4591001 1005 10051026	EAR	Vertigo positional/ INTERMITTENT POSITIONAL VERTIGO	1	13AUG2020	3/5	1	Yes		NA	R (17AUG2020)	N/N	
16-55/ C4591001 1005 10051028	MUSC	Myalgia/ generalized myalgia#	3	23FEB2021	1/C	2	Yes		NA/TC	N	N/N	
16-55/ C4591001 1005 10051054	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N	
16-55/ C4591001 1005 10051055	GENRL	Fatigue/ FATIGUE	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N	
16-55/ C4591001	MUSC	Myalgia/ MUSCLE PAIN	1	19AUG2020	7/2	1	Yes		NA	R (20AUG2020)	N/N	
16-55/ C4591001	GENRL	Chills/ CHILLS	2	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051066	GENRL	Chills/ CHILLS#	4	11FEB2021	2/2	2	Yes	NA	R (12FEB2021)	N/N	
16-55/ C4591001	MUSC	Fatigue/ FATIGUE#	4	11FEB2021	2/2	2	Yes	NA	R (12FEB2021)	N/N	
1005 10051071	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	11FEB2021	2/2	2	Yes	NA	R (12FEB2021)	N/N	
1005 10051071	NERV	Headache/ HEADACHE#	4	11FEB2021	2/2	2	Yes	NA	R (12FEB2021)	N/N	
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	06SEP2020	3/9	1	Yes	NA	R (14SEP2020)	N/N	
1005 10051075	GENRL	Chills/ CHILLS	2	09SEP2020	1/3	1	Yes	NA	R (11SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/3	1	Yes	NA	R (11SEP2020)	N/N	
1005 10051076	GENRL	Malaise/ MALAISE	2	09SEP2020	1/3	1	Yes	NA	R (11SEP2020)	N/N	
1005 10051076	MUSC	Myalgia/ MYALGIA	2	09SEP2020	1/2	2	Yes	NA/TC	R (10SEP2020)	N/N	
1005 10051076	GENRL	Pyrexia/ FEVER 100.9	2	10SEP2020	2/1	1	Yes	NA	R (10SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	17AUG2020	1/2	1	Yes	NA	R (18AUG2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051077	MUSC	Myalgia/ MYALGIA	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C4591001 1005 10051081	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/Y
		Injection site warmth/ CALOR AT INJECTION SITE	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y
	GASTR	Diarrhoea/ DIARRHEA	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1005 10051082	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Depressed level of consciousness/ CLOUDING OF CONCIOUSNESS	1	05SEP2020	18/8	1	No	O	NA	R (12SEP2020)	N/N
16-55/ C4591001 1005 10051084	EYE	Conjunctival oedema/ RIGHT EYE CONJUNCTIVA SWELLING	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Eye irritation/ RIGHT EYE IRRITATION	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
		Ocular hyperaemia/ RIGHT EYE ERYTHEMA	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ FEVER (101.9F)#	4	13JAN2021	2/1	2	Yes		NA/TC	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051093	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Dizziness/ DIZZINESS	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001 1005 10051094	GENRL	Dizziness/ LIGHT HEADED	2	21SEP2020	12/4	1	No	O	NA	R (24SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	18DEC2020	2/1	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1005 10051100	GENRL	Injection site pain/ SORE INJECTION SITE ARM RADIATING TO NECK	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ FEVER	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1005 10051105	MUSC	Myalgia/ MYALGIA	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1005 10051107	GENRL	Malaise/ MALAISE	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051119	MUSC	Myalgia/ GENERALIZED MYALGIA	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE*		24AUG2020	1/4	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1005 10051123	MUSC	Myalgia/ Muscle Aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1005 10051125	INFEC	Urinary tract infection/ URINATRY TRACT INFECTION	2	14OCT2020	31/15	2	No	O	NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1005 10051129	GENRL	Chills/ CHILLS	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ FATIGUE	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1005 10051129	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001	GENRL	Asthenia/ ASTHENIA	1	26AUG2020	3/1	1	Yes		NA/TC	R (26AUG2020)	N/N
	MUSC	Arthralgia/ LEFT SHOULDER PAIN	1	05SEP2020	13/18	2	No	O	NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051134	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1005 10051135	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
1005 10051145	GASTR	Diarrhoea/ DIARRHEA	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	1	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Diarrhoea/ INTERMITTENT DIARRHEA	1	02SEP2020	9/13	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Pain in extremity/ RIGHT LEG PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	2	19SEP2020	6/1	1	No	O	NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1005 10051146	GENRL	Injection site pain/ INJECTION SITE PAIN	1	25AUG2020	1/2	1	Yes		NA/TC	R (26AUG2020)	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GASTR	Nausea/ NAUSEA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Asthenia/ WEAKNESS	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ FEVER	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		Myalgia/ GENERALIZED MYALGIA	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	16SEP2020	3/1	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1005 10051150	NERV	Nerve compression/ PINCHED NERVE IN NECK	2	15SEP2020	2/72	2	Yes		NA/TC	R (25NOV2020)	N/N
16-55/ C4591001 1005 10051151	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1005 10051161	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051165	MUSC	Myalgia/ GENERALIZED MYALGIA	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	14SEP2020	20/2	1	No	O	NA	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1005 10051166	GENRL	Pyrexia/ FEVER 100.5	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	INFEC	Helicobacter gastritis/ H Pylori gastroenteritis#	3	09JAN2021	19/11	1	No	O	NA/TC	R (19JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	GENRL	Pyrexia/ FEVER#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1005 10051166	NERV	Headache/ HEADACHE#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051168	MUSC	Pyrexia/ FEVER 101.0#	4	13JAN2021	2/2	2	Yes		NA	R (14JAN2021)	N/N
		Myalgia/ GENERALIZED MYALIGAS#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Costochondritis/ LEFT CHOSTOCHONDRITIS	1	16SEP2020	21/4	1	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1005 10051169	METAB	Decreased appetite/ LACK OF APPETITE	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1005 10051170	MUSC	Musculoskeletal stiffness/ LEFT SHOULDER STIFFNESS	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Musculoskeletal stiffness/ STIFFNESS ON LEFT SIDE OF NECK	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	NERV	Dizziness/ LIGHT HEADED	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
		Headache/ HEADACHE	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	NERV	Lethargy/ LETHARGY	1	29AUG2020	3/3	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	05FEB2021	1/C	2	Yes		NA	N	N/N
	16-55/ C4591001	GASTR	Dyspepsia/ HEARTBURN	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051171		Nausea/ NAUSEA	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Migraine/ WORSENING OF MIGRINES	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1005 10051175	GENRL	Chills/ CHILLS#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ FEVER (102.6)#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1005 10051178	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	IMMUN	Allergy to arthropod sting/ BEE STING REACTION	1	11SEP2020	15/5	1	No	O	NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ FATIGUE	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER 100.4	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1005 10051179	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	
		Myalgia/ GENERALIZED MYALGIA	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	
	GASTR	Vomiting/ EMESIS	2	01OCT2020	14/1	2	No	O	NA	R (01OCT2020)	N/N	
	EYE	Eye pain/ STINGING IN EYES	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N	
	RESP	Cough/ COUGH	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y	
		Throat irritation/ TICKLE IN THROAT	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y	
		Upper-airway cough syndrome/ POST NASAL DRIP	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N	
	16-55/ C4591001 1005 10051181	GENRL	Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	16-55/ C4591001 1005 10051182	GENRL	Fatigue/ EXTREME FATIGUE	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1005 10051183	GENRL	Injection site pain/ INJECTION SITE PAIN	1	31AUG2020	1/7	1	Yes		NA	R (06SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ BODY ACHES	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
	RESP	Cough/ COUGH	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
		Nasal congestion/ NASAL CONGESTION	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1005 10051187	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	24/6	1	Yes		NA	R (28SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1005 10051188	GENRL	Fatigue/ FATIGUE	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	01SEP2020	1/8	1	Yes		NA	R (08SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	24SEP2020	1/8	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051189	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1005 10051192	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
		Pain/ BODY ACHES	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1005 10051198	GENRL	Chills/ chills#	4	12MAR2021	1/2	2	Yes		NA	R (13MAR2021)	N/N
		Pyrexia/ fever 102F#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	12MAR2021	1/2	2	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1005 10051199	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	2	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ BODY CHILLS	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051200	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1005 10051203	GASTR	Diarrhoea/ LOOSE STOOL	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
		Pyrexia/ FEVER	1	04SEP2020	2/3	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	04SEP2020	2/3	1	Yes		NA/TC	R (06SEP2020)	N/N
	INFEC	Gastroenteritis/ GASTROENTERITIS	1	19SEP2020	17/1	2	No	O	NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ BODY ACHES	2	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1005 10051210	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051216	GASTR	Diarrhoea/ DIARRHEA	2	27SEP2020	4/3	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1005 10051217	GENRL	Feeling hot/ overall body CALOR - no fever	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1005 10051219	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	RENAL	Pollakiuria/ INCREASED FREQUENCY OF URINATION	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1005 10051220	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1005 10051221	GENRL	Chills/ chills#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051223	MUSC	Pyrexia/ fever#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
		Myalgia/ generalized myalgia#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
		Headache/ headache#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1005 10051224	GENRL	Injection site pain/ injection site pain	1	13OCT2020	2/4	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1005 10051224	MUSC	Myalgia/ GENERALIZED MYALGIAS#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1005 10051232	INFEC	Ear infection/ LEFT EAR INFECTION	1	23OCT2020	12/6	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1005 10051236	GENRL	Chills/ CHILLS	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1005 10051241	GENRL	Fatigue/ FATIGUE	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	14OCT2020	2/5	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ MYALGIA	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	GENRL	Pyrexia/ FEVER	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	05NOV2020	3/8	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1005 10051244	NERV	Migraine/ WORSENING OF MIGRAINES	2	07NOV2020	6/1	2	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1005 10051246	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1005 10051259	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
		Malaise/ MALAISE	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051264	MUSC	Arthralgia/ SHOULDER ACHING NOT INJECTION ARM	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Myalgia/ MYALGIA	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Chills/ CHILLS#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
		MUSC	Myalgia/ GENERALIZED MYALGIA#	3	16DEC2020	1/4	2	Yes		NA/TC	R (19DEC2020)
	GENRL	Fatigue/ FATIGUE	1	15OCT2020	1/1	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE ARM PAIN	1	17OCT2020	2/4	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/5	2	Yes		NA	R (20OCT2020)	N/Y
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y
	MUSC	Myalgia/ GENERALIZED MYALGIA	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001	INFEC	Tooth abscess/ RIGHT TOOTH ABSCESS	1	20OCT2020	5/17	2	No	O	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1005 10051288	GENRL	Injection site pain/ INJECTION SITE PAIN	2	05NOV2020	2/31	1	Yes		NA	R (05DEC2020)	N/N
1005 10051290	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
1005 10051301	GENRL	Injection site pain/ MILD ARM PAIN AT INJECTION SITE	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
1005 10051302	GENRL	Pain/ BODY ACHES	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
1005 10051318	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ FEVER (101.5)	2	11NOV2020	2/1	2	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051335	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1005 10051340	GASTR	Nausea/ NAUSEA	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ TENDERNESS AT INJECTION SITE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1005 10051341	INFEC	Groin abscess/ LEFT GROIN ABSCESS	1	12DEC2020	53/20	2	No	O	NA/TC	R (31DEC2020)	N/N
16-55/ C4591001 1005 10051346	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1005 10051349	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y
	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051350	MUSC	Pyrexia/ FEVER (102.0)#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
		Myalgia/ GENERALIZED MYALGIA#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
		Headache/ HEADACHE#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1005 10051358	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1005 10051358	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	08FEB2021	1/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1005 10051361	GENRL	Chills/ CHILLS	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	NERV	Fatigue/ FATIGUE	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Headache/ HEADACHE	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1005 10051363	GASTR	Nausea/ NAUSEA	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051365	VASC	Hot flush/ HOT FLASHES	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT ACHES	2	01DEC2020	19/9	1	No	O	NA	R (09DEC2020)	N/N
	GENRL	Injection site pain/ BURNING SENSATION AT INJECTION SITE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Malaise/ MALAISE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ HEADACHES	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	MUSC	Back pain/ WORSENING OF LOWER BACK PAIN	1	04NOV2020	13/22	2	No	O	NA/TC	R (25NOV2020)	N/N
16-55/ C4591001 1005 10051368	NERV	Dizziness/ LIGHTHEADED	1	09NOV2020	18/2	2	No	O	NA	R (10NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051378	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Dizziness/ LIGHT HEADED	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1005 10051380	NERV	Headache/ HEADACHE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	06JAN2021	1/5	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1005 10051385	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Pyrexia/ FEVER 101.4	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1005 10051386	NERV	Headache/ WORSENING OF HEADACHE	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1005 10051390	GENRL	Malaise/ MALIASE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ MYALGIA	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ HEADACHE	1	31OCT2020	2/7	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23NOV2020	1/34	1	Yes		NA	R (26DEC2020)	N/N
	MUSC	Myalgia/ MYALGIA	2	24NOV2020	2/1	2	Yes		NA/TC	R (24NOV2020)	N/N
	GENRL	Pyrexia/ fever post injection#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ injection site reaction - arm pain#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
GENRL	Pyrexia/ fever 101F#	4	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
16-55/ C4591001 1005 10051400	GENRL	Injection site swelling/ INJECTION SITE SWELLING	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
16-55/ C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
16-55/ C4591001 1005 10051442	GENRL	Fatigue/ FATIGUE	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
		Injection site swelling/ INJECTION SITE SWELLING (1 INCH)	2	14JAN2021	2/4	1	Yes		NA	R (17JAN2021)	N/N
	MUSC	Arthralgia/ GENERALIZED ARTHRALGIA	2	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Myalgia/ GENERALIZED MYALGIA	2	14JAN2021	2/3	2	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ WORSENING OF HEADACHE	2	14JAN2021	2/3	2	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1006 10061023	INJ&P	Bone contusion/ RIGHT HIP BONE CONTUSION	1	28AUG2020	17/8	2	No	O	NA/TC	R (04SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1006 10061031	INFEC	Oral fungal infection/ ORAL YEAST INFECTION	1	16AUG2020	4/11	2	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C4591001 1006 10061032	GENRL	Chills/ generalized chills	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1006 10061040	INFEC	Pharyngitis streptococcal/ Strep throat	2	08SEP2020	5/11	2	No	O	NA/TC	R (18SEP2020)	N/N
	INFEC	Clostridium difficile infection/ Clostridium Difficile Infection	2	30SEP2020	27/152	2	No	O	NA/TC	R (28FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	INJ&P	Procedural pain/ Post Surgical Pain#	3	28DEC2020	11/16	3	No	O	NA/TC	R (12JAN2021)	N/N
	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy#	4	08FEB2021	32/C		No	O	NA	UNK	N/N
16-55/ C4591001 1006 10061052	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	01JAN2021	116/C		No	O	NA	UNK	N/N
16-55/ C4591001	NERV	Dizziness/ Lightheadedness	1	18AUG2020	1/9	2	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1006 10061053	GASTR	Nausea/ Intermittent Nausea#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
1006 10061056	MUSC	Myalgia/ Generalized Muscle Aches#	4	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1006 10061067	GENRL	Injection site pain/ Injection site tenderness#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1006 10061070	IMMUN	Seasonal allergy/ Worsening of seasonal allergies#	3	01MAR2021	7/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1006 10061074	NERV	Migraine/ Migraines - Intermittent	1	31AUG2020	13/C	3	No	O	NA	N	N/N
16-55/ C4591001 1006 10061074	INJ&P	Skin laceration/ Left Index Finger Laceration#	2	02MAR2021	174/C	3	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1006 10061079	GENRL	Chills/ CHILLS	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ BODY ACHES-GENERALIZED	2	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1006 10061088	MUSC	Myalgia/ Generalized Muscle Aches#	3	05FEB2021	1/2	3	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	3	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1006 10061089	CARD	Tachycardia/ Tachycardia	2	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1006 10061090	MUSC	Back pain/ BACK ACHE	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1006 10061093	NERV	Paraesthesia/ FACIAL TINGLING	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
	SKIN	Rash/ CHEST RASH (8 cm)	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1006 10061094	GENRL	Injection site pain/ INJECTION SITE PAIN	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1006 10061095	INJ&P	Pain/ GENERALIZED ACHES	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ FEVER	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Exposure during pregnancy/ Exposure During Pregnancy	2	15NOV2020	59/C		No	O	NA	UNK	N/N
	GASTR	Vomiting/ Vomiting#	3	21JAN2021	2/1	2	Yes		NA/TC	R (21JAN2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	3	23FEB2021	8/8	1	No	O	NA/TC	R (02MAR2021)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ mUSCLE aCHES	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	SKIN	Dermatitis/ DERMATITIS-FACIAL	2	01OCT2020	10/62	2	No	O	NA/TC	R (01DEC2020)	N/N
	16-55/ C4591001 1006 10061134	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)
16-55/ C4591001 1006 10061137	GENRL	Pain/ Body aches	1	02SEP2020	2/1	3	Yes		NA/TC	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1006 10061144	NERV	Headache/ Headache	1	22SEP2020	20/2	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1006 10061151	NERV	Headache/ Headache	2	05NOV2020	23/1	2	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1006 10061153	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactive Disorder	2	02NOV2020	22/C	2	No	O	NA	N	N/N
16-55/ C4591001 1006 10061160	GASTR	Diarrhoea/ DIARRHEA	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N
		Vomiting/ VOMITING	1	27SEP2020	3/3	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	27SEP2020	3/3	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1006 10061161	INJ&P	Maternal exposure before pregnancy/ Maternal Exposure before Pregnancy	2	28DEC2020	73/C		No	O	NA	UNK	N/N
16-55/ C4591001 1006 10061163	SKIN	Urticaria/ hives left forearm	2	15NOV2020	32/6	1	No	O	NA	R (20NOV2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	26JAN2021	104/4	2	No	O	NA/TC	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1006 10061165	GENRL	Pain/ Generalized Body Aches	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1006 10061166	GENRL	Chills/ CHILLS	1	27SEP2020	3/2	2	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1006 10061170	MUSC	Arthralgia/ Bilateral Ankle Joint Pain	2	28OCT2020	1/5	2	Yes		NA/TC	R (01NOV2020)	N/N
		Neck pain/ Pain at base of neck	2	28OCT2020	1/5	2	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1006 10061176	RESP	Asthma/ Acute Asthma Exacerbation#	2	03FEB2021	77/8	3	No	O	NA/TC	R (10FEB2021)	Y/N
16-55/ C4591001 1006 10061194	INFEC	Otitis externa/ Otitis Externa Left	2	15JAN2021	24/13	3	No	O	NA/TC/TCN	R (27JAN2021)	N/N
	INJ&P	Mouth injury/ Oral laceration#	2	15FEB2021	55/10	1	No	O	NA/TC/TCN	R (24FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1006 10061202 16-55/ C4591001 1006 10061204	GENRL	Injection site bruising/ 1 MM BRUISING AT INJECTION SITE LEFT DELTOID	2	22DEC2020	1/25	1	Yes		NA	R (15JAN2021)	N/Y
16-55/ C4591001 1006 10061205	INJ&P	Foot fracture/ Left Great Toe Fracture	2	29JAN2021	37/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1006 10061208	GENRL	Pain/ Body Aches	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	NERV	Headache/ Headache	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
16-55/ C4591001 1006 10061215	INJ&P	Ligament sprain/ Knee sprain Right	1	10DEC2020	7/3	1	No	O	NA/TC	R (12DEC2020)	N/N
	MUSC	Arthralgia/ right shoulder pain	2	23JAN2021	2/C	3	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1006 10061216	GENRL	Chills/ Chills#	3	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1006 10061240		Pyrexia/ Fever	2	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N	
16-55/ C4591001 1006 10061246	GENRL	Chills/ Chills#	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
	NERV	Headache/ Headache#	3	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001 1007 10071083	RESP	Oropharyngeal pain/ sore throat	1	05AUG2020	9/2	1	No	O	NA	R (06AUG2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
	MUSC	Myalgia/ myalgias#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
	NERV	Headache/ headache#	4	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N	
16-55/ C4591001 1007 10071087	REPRO	Menorrhagia/ exacerbation of menorrhagia	2	06SEP2020	19/14	2	No	O	NA	R (19SEP2020)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
16-55/ C4591001 1007 10071089	GENRL	Chills/ Chills#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071097		Pyrexia/ fever#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Arthralgia/ pain in elbow#	3	06JAN2021	2/C	1	Yes		NA/TC	N	N/N
	INJ&P	Hand fracture/ Fractured left 4th finger#	4	13FEB2021	19/C	2	No	O	NA	RG	N/N
	MUSC	Myalgia/ Right Scapular Muscle Pain	2	21AUG2020	2/12	3	No	O	NA/TC/TCN	R (01SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Bilateral Swollen Cervical Lymph Nodes	2	23AUG2020	4/12	1	No	O	NA/TC	R (03SEP2020)	N/N
	MUSC	Tendonitis/ Exacerbation of tendonitis	2	23SEP2020	28/C	2	No	O	NA/TCN	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	PSYCH	Anxiety/ exacerbation of anxiety	2	07SEP2020	15/120	2	No	O	NA/TC	R (04JAN2021)	N/N
16-55/ C4591001 1007 10071117	BLOOD	Lymphadenopathy/ right supraclavicular swollen lymph node#	4	09MAR2021	2/C	1	Yes		NA	RG	N/N
	GENRL	Chills/ chills#	4	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071119	MUSC	Myalgia/ myalgias#	4	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ fever#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
	NERV	Syncope/ fainting episode	1	11AUG2020	7/1	2	No	O	NA	R (11AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Muscle Soreness#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site nodule/ nodule at injection site	2	27AUG2020	1/8	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071151	METAB	Type 2 diabetes mellitus/ Type 2 Diabetes	2	11JAN2021	134/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1007 10071154	GENRL	Injection site pain/ Injection Site Arm Soreness#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ chills#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ fever#	4	02FEB2021	1/2	2	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1007 10071157	GENRL	Injection site pain/ burning sensation at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C4591001 1007 10071158	GENRL	Injection site pain/ tenderness at injection site	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
	INFEC	Folliculitis/ Folliculitis#	3	02MAR2021	13/5	1	No	O	NA/TCN	R (06MAR2021)	N/N
16-55/ C4591001 1007 10071159	BLOOD	Lymphadenopathy/ Left axilla enlarged lymph node	1	11AUG2020	2/2	1	Yes		NA/TC	R (12AUG2020)	N/N
16-55/ C4591001 1007 10071162	GENRL	Injection site pain/ Muscle soreness at injection site#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071171	GENRL	Injection site pain/ injection site pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1007 10071172	EAR	Ear discomfort/ Right ear pressure	2	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1007 10071175	GENRL	Injection site pain/ Injection site soreness#	3	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ chills#	3	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1007 10071181	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	17AUG2020	6/8	1	No	O	NA	R (24AUG2020)	N/N
	SKIN	Rash/ generalized Rash	2	05SEP2020	4/7	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1007 10071185	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/3	2	Yes		NA/TCN	R (07JAN2021)	N/N
16-55/ C4591001 1007 10071186	INFEC	Dermatitis infected/ Infected Atopic Dermatitis of the cheek	2	28SEP2020	26/11	2	No	O	NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071194	SKIN	Ecchymosis/ right foot ecchymosis	1	25AUG2020	13/64	2	No	O	NA/TC/TCN	R (27OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	3	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
	NERV	Headache/ Headache#	3	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1007 10071203	GENRL	Fatigue/ fatigue	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ injection site soreness	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N
16-55/ C4591001 1007 10071207	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	RENAL	Dysuria/ intermittent dysuria	2	09SEP2020	2/26	2	No	O	NA/TC	R (04OCT2020)	N/N
		Pollakiuria/ intermittent urinary frequency	2	09SEP2020	2/26	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001	INFEC	Viral infection/ viral illness	2	08SEP2020	1/84	1	No	O	NA	R (30NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071208	CARD	Palpitations/ heart palpitations	2	23SEP2020	16/69	1	No	O	NA/TC	R (30NOV2020)	N/N
	GENRL	Chest pain/ Chest Pain	2	23SEP2020	16/69	1	No	O	NA/TC	R (30NOV2020)	N/N
16-55/ C4591001 1007 10071217	NERV	Headache/ Headache	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/Y
16-55/ C4591001 1007 10071218	MUSC	Myalgia/ myalgia to neck and shoulder	1	21AUG2020	3/3	1	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1007 10071219	INJ&P	Joint injury/ Left Knee Injury	1	09SEP2020	22/104	2	No	O	NA/TCN	R (21DEC2020)	N/N
16-55/ C4591001 1007 10071228	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1007 10071229	GENRL	Injection site pain/ Injection site pain#	3	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071233		Injection site pain/ injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1007 10071235	GENRL	Injection site pain/ Injection site arm pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1007 10071236	MUSC	Myalgia/ left arm muscle pain*		20AUG2020	1/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1007 10071238	SKIN	Rash/ rash	2	12SEP2020	3/17	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1007 10071246	GENRL	Injection site pain/ Injection site pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1007 10071253	GENRL	Injection site erythema/ redness at injection site	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/Y
		Injection site induration/ induration at injection site	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/Y
	GENRL	Injection site erythema/ redness at injection site	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1007 10071256	GENRL	Injection site pain/ Injection site pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1007 10071276	BLOOD	Leukocytosis/ leukocytosis	2	24SEP2020	8/26	3	No	O	NA	R (19OCT2020)	N/N
		Thrombocytosis/ thromboeytosis	2	24SEP2020	8/33	3	No	O	NA	R (26OCT2020)	N/N
	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1007 10071280	GENRL	Injection site pain/ Muscle Soreness in arm of injection#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	BLOOD	Lymphadenopathy/ bilateral deep cervical swollen lymph nodes#	4	18FEB2021	2/8	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1007 10071284	GENRL	Injection site pain/ Right Arm Injection Site Pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
	SKIN	Rash/ rash on chest	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071289	RESP	Reflux laryngitis/ laryngopharyngeal reflux	2	02OCT2020	16/1	1	No	O	NA	R (02OCT2020)	N/N
	GENRL	Injection site erythema/ redness at injection	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pain/ Bodyaches	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ fever	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	2	17SEP2020	1/7	1	Yes		NA	R (23SEP2020)	N/Y
16-55/ C4591001 1007 10071295	NERV	Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	INJ&P	Fall/ Fall	2	03OCT2020	18/1	1	No	O	NA	R (03OCT2020)	N/N
		Skin laceration/ Laceration to left leg	2	03OCT2020	18/60	2	No	O	NA/TCN	R (01DEC2020)	N/N
16-55/ C4591001 1007 10071296	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1007 10071307	GENRL	Injection site pain/ pain at injection site	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071334	GENRL	Chills/ chills	2	04NOV2020	1/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		Pyrexia/ fever	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Pain in extremity/ pain right arm	2	04NOV2020	1/3	2	Yes		NA	R (06NOV2020)	N/N
	RESP	Dry throat/ dry throat	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1007 10071337	GENRL	Injection site pain/ burning at injection site#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/Y
16-55/ C4591001 1007 10071339	EAR	Vertigo/ Vertigo	2	05NOV2020	3/9	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071341	GENRL	Injection site pain/ Injection site pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1007 10071342	GENRL	Injection site pain/ Muscle Soreness in Arm of Injection site#	3	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1007 10071350	MUSC	Pain in extremity/ Sore Arm	1	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071352	GENRL	Pyrexia/ fever	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	2	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	METAB	Decreased appetite/ loss of appetite	2	06NOV2020	2/13	1	Yes		NA	R (18NOV2020)	N/N
	MUSC	Myalgia/ bilateral quadriceps myalgia	2	13NOV2020	4/4	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
		Malaise/ Malaise	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/4	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071365	NERV	Headache/ Headache	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	03MAR2021	1/4	1	Yes		NA	R (06MAR2021)	N/N
	NERV	Headache/ Headache#	3	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1007 10071367	GASTR	Gingival discomfort/ Gum irritation	1	03NOV2020	16/8	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1007 10071368	GENRL	Injection site pain/ Tenderness at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1007 10071373	GENRL	Injection site pain/ Injection Site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
16-55/ C4591001 1007 10071374	CARD	Palpitations/ heart palpitations	1	09NOV2020	21/3	1	Yes		NA/TC	R (11NOV2020)	N/N
	INFEC	Vaginal infection/ Vaginitis	1	09NOV2020	21/10	2	No	O	NA/TC	R (18NOV2020)	N/N
	GASTR	Nausea/ nausea	2	12NOV2020	3/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	3/2	2	Yes		NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071376	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches	2	11NOV2020	2/1	1	Yes		NA	R (11NOV2020)	N/N
	SKIN	Alopecia/ Increased Hair Loss	2	23NOV2020	14/C	1	No	O	NA	RG	N/N
	NERV	Headache/ Headache#	3	12JAN2021	1/2	3	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Pain in extremity/ Generalized soreness left upper arm#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Pyrexia/ fever	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	11NOV2020	2/1	1	Yes		NA/TCN	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/5	2	Yes		NA	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071388	NERV	Headache/ Headache	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1007 10071390	MUSC	Pain in extremity/ sore arm	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071392	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1007 10071397	GENRL	Injection site pain/ pain in injection arm	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	PSYCH	Anxiety/ Anxiety#	3	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/Y
16-55/ C4591001	GENRL	Chills/ Chills#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071398		Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1007 10071399	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1007 10071400	GENRL	Pyrexia/ fever	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1007 10071401	GENRL	Injection site pain/ injection site pain	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Malaise/ Malaise	1	22OCT2020	2/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1007 10071404	GASTR	Nausea/ nausea	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071406	GENRL	Vomiting/ vomiting	1	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/Y
16-55/ C4591001 1007 10071407	RESP	Epistaxis/ epistaxis	1	16NOV2020	26/1	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1007 10071408	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	04DEC2020	2/4	1	Yes		NA	R (07DEC2020)	N/N
GENRL		Vomiting/ Vomiting	2	04DEC2020	2/3	1	Yes		NA	R (06DEC2020)	N/N
		Chills/ Chills	2	04DEC2020	2/3	1	Yes		NA/TC	R (06DEC2020)	N/N
MUSC		Pyrexia/ fever	2	04DEC2020	2/3	2	Yes		NA/TC	R (06DEC2020)	N/N
GENRL		Myalgia/ Myalgia	2	04DEC2020	2/3	2	Yes		NA/TC	R (06DEC2020)	N/N
		Injection site pain/ Injection site arm pain#	3	12JAN2021	1/2	2	Yes		NA/TC	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1007 10071410	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ chills#	4	11MAR2021	1/3	1	Yes		NA	R (13MAR2021)	N/N
	MUSC	Myalgia/ myalgias#	4	11MAR2021	1/3	2	Yes		NA/TC	R (13MAR2021)	N/N
	NERV	Headache/ headache#	4	11MAR2021	1/3	2	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1007 10071416	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1007 10071421	GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/4	2	Yes		NA/TC	R (16NOV2020)	N/N
		Injection site pain/ injection site tenderness	2	13NOV2020	2/5	2	Yes		NA/TC	R (17NOV2020)	N/N
	NERV	Headache/ headache	2	13NOV2020	2/4	2	Yes		NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1007 10071422	GENRL	Vessel puncture site pain/ Pain at blood draw site*		22OCT2020	1/1	1	No	O	NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071423	GENRL	Fatigue/ fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Vessel puncture site pain/ pain at blood draw site*		22OCT2020	1/2	1	No	O	NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
		Fatigue/ fatigue	1	27OCT2020	6/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N
	Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N	
NERV	Headache/ Headache	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N	
16-55/ C4591001 1007 10071424	GENRL	Injection site pain/ sorness at injection site	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1007 10071426	GENRL	Injection site pain/ Injection Site Pain*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ Myalgia (Generalized)	1	24OCT2020	3/2	2	Yes		NA	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071427	GENRL	Injection site pain/ injection site tenderness	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Arthralgia/ generalized arthralgia	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pain/ Body Aches#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1007 10071433	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ headache	1	30OCT2020	4/7	2	Yes		NA/TC	R (05NOV2020)	N/N
	GASTR	Nausea/ Nausea	1	31OCT2020	5/3	2	Yes		NA	R (02NOV2020)	N/N
	GENRL	Pyrexia/ fever	1	31OCT2020	5/2	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1007 10071439	GASTR	Vomiting/ Vomiting	1	01NOV2020	6/1	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	20NOV2020	4/C	1	Yes		NA	RG	N/N
	GENRL	Chills/ Chills	2	20NOV2020	2/2	1	Yes		NA/TC	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	20NOV2020	2/2	2	Yes		NA/TC	R (21NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071440	NERV	Headache/ Headache	2	20NOV2020	2/2	1	Yes		NA/TC	R (21NOV2020)	N/N
	GENRL	Chills/ chills	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
		Pyrexia/ fever	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1007 10071441	NERV	Headache/ headache	2	20NOV2020	2/1	2	Yes		NA/TC	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1007 10071442	NERV	Facial paralysis/ Bell's Palsy#	4	13MAR2021	3/C	3	Yes		NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1007 10071443	NERV	Generalised tonic-clonic seizure/ Grand Mal Seizure	2	29NOV2020	5/1	3	No	O	NA	R (29NOV2020)	N/N
16-55/ C4591001 1007 10071449	GENRL	Injection site pain/ muscle pain at injection site#	3	23FEB2021	1/4	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1007 10071455 16-55/ C4591001	EYE	Lacrimation increased/ Watery Eyes#	3	03MAR2021	3/3	1	No	O	NA	R (05MAR2021)	N/N
1007 10071463 16-55/ C4591001	GASTR	Nausea/ nausea	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
1007 10071464 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
1007 10071470	NERV	Headache/ Headache#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	2	22FEB2021	63/3	1	Yes		NA	R (24FEB2021)	N/N
1007 10071493	GENRL	Fatigue/ Fatigue#	3	23FEB2021	2/8	1	No	O	NA	R (02MAR2021)	N/N
	NERV	Headache/ Headache#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site discomfort/ Weighted feeling in injection site arm	1	03DEC2020	1/3	1	Yes		NA	R (05DEC2020)	N/N
1007 10071502	INFEC	Cellulitis/ Right axillary cellulitis	2	01JAN2021	11/8	2	No	O	NA/TC	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1007 10071510	GENRL	Folliculitis/ Right axillary folliculitis	2	01JAN2021	11/8	2	No	O	NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	22FEB2021	1/2	1	Yes		NA/TC/TCN	R (23FEB2021)	N/N
16-55/ C4591001 1007 10071538	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1007 10071548	NERV	Presyncope/ Vasovagal response with venipuncture#	2	11MAR2021	72/1	2	No	O	NA	R (11MAR2021)	N/N
16-55/ C4591001 1007 10071553	GENRL	Injection site pain/ injection site pain	1	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/Y
	NERV	Dizziness/ Lightheaded*		10DEC2020	1/1	1	No	O	NA	R (10DEC2020)	N/N
	GENRL	Chills/ Chills#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ Body aches#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	3	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GASTR	Nausea/ nausea#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081029	GENRL	Chills/ chills#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ fatigue#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Pain/ bodyaches#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ headache#	4	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1008 10081030	INFEC	Otitis media/ Right otitis media	2	24OCT2020	51/15	1	No	O	NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1008 10081032	MUSC	Synovitis/ Synovitis, right wrist(etiology unknown)	2	06OCT2020	23/57	1	No	O	NA/TC	R (01DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1008 10081046	NERV	Headache/ headache#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1008 10081064	GENRL	Chills/ chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ fatigue	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081089	GENRL	Pyrexia/ fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Chills/ Chills	2	17SEP2020	3/1	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1008 10081095	GENRL	Pain/ Body aches	2	17SEP2020	3/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1008 10081099	INFEC	Fatigue/ fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		Gastroenteritis/ gastroenteritis	2	03OCT2020	19/5	2	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1008 10081101	NERV	Nerve compression/ pinched nerve right shoulder#	4	02MAR2021	21/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chills/ chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Fatigue/ fatigue#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ injection site pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ headache#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081103	GENRL	Chills/ chills#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ injection site pain#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N
	GASTR	Vomiting/ vomiting#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pain/ body aches#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1008 10081138	INJ&P	Skin laceration/ Finger laceration	1	06SEP2020	10/32	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1008 10081142	GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1008 10081143	GENRL	Pain/ body aches#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081149		Injection site pain/ Injection site pain left arm	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body aches	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1008 10081150	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1008 10081151	GENRL	Pain/ body aches#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ low grade fever#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
16-55/ C4591001 1008 10081152	NERV	Optic neuritis/ Optic neuritis left eye	2	09DEC2020	80/14	3	No	O	NA/TC	R (22DEC2020)	Y/N
16-55/ C4591001 1008 10081155	MUSC	Myalgia/ Generalized muscle aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain Left deltoid	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081159	GENRL	Pain/ Body aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection site pain left arm	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1008 10081160	GENRL	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1008 10081166		Nausea/ Nausea	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	11/4	1	Yes		NA	R (15SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	8/4	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1008 10081183	GENRL	Chills/ Chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1008 10081193	GENRL	Pain/ body aches	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081194	GENRL	Chills/ chills#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ bodyaches#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1008 10081197	GASTR	Vomiting/ VOMITING#	4	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1008 10081198	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1008 10081215	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1008 10081217	CARD	Tachycardia/ Tachycardia	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/Y
16-55/ C4591001 1008 10081225	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081232	GENRL	Pain/ Body aches	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	4/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1008 10081235	VASC	Hypertension/ Hypertension#	2	17DEC2020	81/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1008 10081240	GENRL	Pain/ Body aches#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1008 10081244	GENRL	Injection site pain/ intermittent injection site pain#	3	18JAN2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1008 10081256	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site pain#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081257	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1008 10081258		Pain/ Body aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	01OCT2020	1/4	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1008 10081260	SKIN	Alopecia areata/ Alopecia areata	1	23SEP2020	15/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1008 10081261	GENRL	Pain/ Body aches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headaches	1	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	1/2	2	Yes		NA	R (02OCT2020)	N/N
		Pain/ Body aches	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	2	Yes		NA/TC	R (02OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081271	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pain/ bodyaches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1008 10081281	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		Pain/ Body aches#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1008 10081289	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ Body aches	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1008 10081293	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GASTR	Eosinophilic oesophagitis/ Eosinophilic esophagitis#	2	08JAN2021	99/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081300 16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
1008 10081313 16-55/ C4591001	INFEC	Urinary tract infection/ Urinary tract infection	1	30SEP2020	17/11	1	No	O	NA/TC	R (10OCT2020)	N/N
1008 10081314	GENRL	Pyrexia/ fever(102.5)#	4	10FEB2021	1/2	3	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1008 10081316	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pain/ Body aches	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1008 10081321	GENRL	Pain/ Body aches	2	06OCT2020	2/5	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081327	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		Pain/ Body aches	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081333	NERV	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		Headache/ Headache	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
		Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1008 10081337	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1008 10081338	GENRL	Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	23DEC2020	79/C		No	O	NA	UNK	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1008 10081341	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081343	NERV	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Headache/ Headache	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	VASC	Hypertension/ Hypertension	2	NOV2020	27/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1008 10081344	GENRL	Injection site bruising/ Injection site bruising#	3	01JAN2021	2/15	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1008 10081346	GENRL	Injection site pain/ Injection site pain#	3	01JAN2021	2/2	2	Yes		NA	R (02JAN2021)	N/N
		Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1008 10081347	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection site soreness	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081348	GENRL	Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N
		Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Pain/ Body aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
Headache/ Headache		2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N	
16-55/ C4591001 1008 10081350	INFEC	Gastroenteritis viral/ viral gastroenteritis	2	22OCT2020	15/3	2	No	O	NA	R (24OCT2020)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1008 10081361	GASTR	Diarrhoea/ diarrhea	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1008 10081364	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Pain/ Bodyaches#	4	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1008 10081365	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1008 10081366	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Migraine/ Migraine	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1008 10081367	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1008 10081382	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1008 10081384	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081388	METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1008 10081391	GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
		Nausea/ Nausea	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
		Vomiting/ Vomiting	1	30SEP2020	14/1	1	No	O	NA	R (30SEP2020)	N/N
	INFEC	Ear infection/ Left ear infection	2	31OCT2020	24/10	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081393 16-55/ C4591001 1008 10081402	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	10OCT2020	2/2	3	Yes		NA	R (11OCT2020)	N/N
		Fatigue/ Fatigue	2	10OCT2020	2/1	3	Yes		NA	R (10OCT2020)	N/N
		Injection site erythema/ Injection site redness	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
		Injection site pain/ Injection site pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N
		Injection site swelling/ Injection site swelling	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1008 10081404	PSYCH	Anxiety/ Anxiety episode	1	18SEP2020	1/1	2	Yes		NA/TCN	R (18SEP2020)	N/Y
16-55/ C4591001 1008 10081408	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1008 10081410	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081425	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1008 10081427	NERV	Pyrexia/ Fever#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1008 10081430	NERV	Headache/ Headache	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
		Pain/ bodyaches#	4	19JAN2021	2/2	2	Yes		NA/TC	R (20JAN2021)	N/N
		Pyrexia/ fever#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1008 10081435	INFEC	Tooth infection/ Tooth infection	2	07NOV2020	27/6	1	No	O	NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1008 10081453	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1008 10081462	GENRL	Pain/ body aches#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1008 10081463	INFEC	Sinusitis/ Sinus infection	2	01NOV2020	20/13	2	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1008 10081468	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081471	GENRL	Injection site pain/ injection site pain#	4	09JAN2021	2/3	2	Yes		NA	R (11JAN2021)	N/N
		Pain/ Body aches#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
		Pyrexia/ Fever#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1008 10081474	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1008 10081477	GENRL	Pyrexia/ Fever(101.3 degrees fahrenheit)	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1008 10081485	GASTR	Nausea/ Nausea	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081492	GASTR	Toothache/ Toothache	1	03OCT2020	11/5	1	No	O	NA/TC	R (07OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N	
		Injection site erythema/ Injection site redness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N	
		Injection site pain/ Injection site arm soreness	2	10NOV2020	2/4	1	Yes		NA	R (13NOV2020)	N/N	
16-55/ C4591001 1008 10081496	GASTR	Tooth impacted/ Impacted wisdom tooth	1	08OCT2020	16/1	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N	
16-55/ C4591001 1008 10081497	GASTR	Abdominal pain upper/ Upper abdominal pain	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Pain/ Body aches	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Pain/ Body aches	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N	
16-55/ C4591001 1008 10081500	GENRL	Pain/ Body aches	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081513	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Pain/ Body aches	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1008 10081518	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1008 10081524	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1008 10081525	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1008 10081532	NERV	Headache/ headache#	3	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pyrexia/ Low grade temperature#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081533	GENRL	Injection site pain/ Injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1008 10081541	GENRL	Pain/ Body aches	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1008 10081548	GENRL	Injection site pain/ Injection site pain	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	GASTR	Nausea/ nausea	1	03OCT2020	6/1	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Dizziness/ Dizziness	1	03OCT2020	6/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GASTR	Nausea/ nausea	2	24OCT2020	6/1	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	24OCT2020	6/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1008 10081549	GENRL	Fatigue/ Fatigue	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081551	GENRL	Chills/ Chills	2	20OCT2020	2/3	2	Yes		NA	R (22OCT2020)	N/N
		Pain/ Body aches	2	20OCT2020	2/3	2	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	20OCT2020	2/3	2	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ injection site pain#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
		NERV	Headache/ headache#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)
16-55/ C4591001 1008 10081554	GENRL	Injection site pain/ injection site pain	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Pain/ body aches	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ fever	2	22OCT2020	2/1	2	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1008 10081555	MUSC	Myalgia/ generalized muscle pain#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1008 10081557	GENRL	Injection site pain/ injection site pain	2	23OCT2020	2/8	2	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
		Pain/ bodyaches	2	24OCT2020	3/7	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1008 10081567	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ Chills	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1008 10081568	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1008 10081572	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Fatigue/ Fatigue	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Pain/ Body aches	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1008 10081574	GENRL	Injection site pain/ Injection site pain	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081576	GENRL	Pain/ Body aches	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1008 10081576	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1008 10081577	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081578	GENRL	Chills/ Chills	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1008 10081579	GENRL	Fatigue/ Fatigue	1	13OCT2020	5/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1008 10081579	GENRL	Injection site pain/ Injection site pain	1	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1008 10081580	GENRL	Fatigue/ Fatigue	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1008 10081581	MUSC	Myalgia/ Muscle aches	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1008 10081581	GENRL	Injection site pain/ Injection site pain	1	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081595	GENRL	Injection site pruritus/ Injection site itching	1	10OCT2020	2/8	1	Yes		NA	R (17OCT2020)	N/N
		Fatigue/ Fatigue	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
		Chills/ Chills	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	03NOV2020	2/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site pain/ Injection site pain	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
		Pain/ Body aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
NERV	Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N	
16-55/ C4591001 1008 10081598	GENRL	Fatigue/ fatigue#	3	10FEB2021	3/1	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	3	10FEB2021	3/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1008 10081600	GENRL	Chills/ Chills	2	04NOV2020	1/4	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	1/4	3	Yes		NA/TC	R (07NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081605	GENRL	Pain/ Body aches	2	05NOV2020	2/5	1	Yes		NA	R (09NOV2020)	N/N	
	GENRL	Chills/ Chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
		Fatigue/ Fatigue	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N	
		Pain/ Body aches	1	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N	
	GENRL	Chills/ chills	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N	
	GASTR	Vomiting/ vomiting	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	GENRL	Pain/ body aches	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	NERV	Headache/ headache	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N	
	16-55/ C4591001 1008 10081620	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N	
16-55/ C4591001 1008 10081628	BLOOD	Lymphadenopathy/ swollen lymph nodes left armpit#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081629	NERV	Injection site erythema/ injection site redness#	4	13FEB2021	2/6	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ injection site pain#	4	13FEB2021	2/4	2	Yes		NA/TC	R (16FEB2021)	N/N
		Pain/ body aches#	4	13FEB2021	2/2	2	Yes		NA	R (14FEB2021)	N/N
		Headache/ headache#	4	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1008 10081629	INJ&P	Ligament rupture/ Torn ligament left knee(no further information)	1	31OCT2020	16/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1008 10081643	GENRL	Fatigue/ fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1008 10081647	GENRL	Pyrexia/ fever#	3	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N
		Chills/ Chills	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
		Pain/ Body aches	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		Fatigue/ Fatigue#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081648	NERV	Headache/ Headache#	3	20JAN2021	1/2	1	Yes	NA		R (21JAN2021)	N/N
16-55/ C4591001 1008 10081653	GENRL	Chills/ Chills	2	11NOV2020	1/3	1	Yes	NA		R (13NOV2020)	N/N
		Pain/ Body aches	2	11NOV2020	1/3	1	Yes	NA		R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes	NA/TC		R (12NOV2020)	N/N
16-55/ C4591001 1008 10081654	GENRL	Chills/ Chills	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	11NOV2020	1/2	1	Yes	NA		R (12NOV2020)	N/N
16-55/ C4591001 1008 10081655	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes	NA		R (23FEB2021)	N/N
16-55/ C4591001 1008 10081659	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes	NA		R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081663	INFEC	Urinary tract infection/ Urinary tract infection	1	05NOV2020	16/6	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1008 10081669	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	28DEC2020	47/C	1	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ hypertension	2	28DEC2020	47/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1008 10081673	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1008 10081680	GENRL	Chills/ Chills	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
		Fatigue/ Fatigue	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1008 10081695	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N
	RENAL	Nephrolithiasis/ Kidney stone	1	02NOV2020	8/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1008 10081696	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/8	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ Headache	1	31OCT2020	6/1	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1008 10081703	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1008 10081710	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Fatigue/ Fatigue	2	18NOV2020	1/4	2	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Left arm pain(injection site pain)	2	18NOV2020	1/7	2	Yes		NA	R (24NOV2020)	N/N
16-55/ C4591001 1008 10081712	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	1	Yes		NA	RS (03FEB2021)	N/N
	NERV	Headache/ headache#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1008 10081715	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1008 10081719		Injection site pain/ Injection site pain	1	29OCT2020	2/4	1	Yes	NA	R	(01NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	27JAN2021	2/2	1	Yes	NA	R	(28JAN2021)	N/N
1008 10081720		Injection site pain/ Injection site pain	1	29OCT2020	1/3	1	Yes	NA	R	(31OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever (101.0 F)	1	31OCT2020	2/12	2	Yes	NA	R	(11NOV2020)	N/N
1008 10081727		Injection site pain/ injection site pain#	3	02FEB2021	1/2	1	Yes	NA	R	(03FEB2021)	N/N
16-55/ C4591001	GENRL	Pain/ body aches#	3	27FEB2021	2/3	2	Yes	NA/TC	R	(01MAR2021)	N/N
1008 10081738		Pyrexia/ Fever#	3	27FEB2021	2/3	2	Yes	NA/TC	R	(01MAR2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	27FEB2021	2/C	2	Yes	NA/TC	RG		N/N
1008 10081776		Fatigue/ fatigue#	3	16JAN2021	2/2	1	Yes	NA	R	(17JAN2021)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1009 10091012		Pain/ body aches#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1009 10091045	MUSC	Muscle spasms/ back muscle spasm#	3	17JAN2021	18/C	2	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ worsening hypertension#	3	21JAN2021	22/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091061	PSYCH	Anxiety/ anxiety	2	20DEC2020	104/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091079	SKIN	Dermal cyst/ CYST ON FOREHEAD	1	28AUG2020	9/15	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1009 10091080	INFEC	Nasopharyngitis/ HEAD COLD	2	03OCT2020	24/8	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1009 10091081	MUSC	Pain in extremity/ Worsening Pain in left foot arch#	2	18FEB2021	162/C	3	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1009 10091084	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Disorder	2	16DEC2020	97/C	2	No	O	NA/TC	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1009 10091088	GENRL	Chills/ CHILLS	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1009 10091108	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	16SEP2020	2/C	1	Yes		NA	RG	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	16SEP2020	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1009 10091109	NERV	Dysgeusia/ Metallic Taste In Mouth Following Vaccination	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
16-55/ C4591001 1009 10091110	GASTR	Aphthous ulcer/ CANKER SORES	2	07OCT2020	24/17	2	No	O	NA/TC	R (23OCT2020)	N/N
	INFEC	Gingivitis/ RIGHT UPPER MOUTH GUM INFECTION	2	07OCT2020	24/17	2	No	O	NA	R (23OCT2020)	N/N
16-55/ C4591001 1009 10091112	MUSC	Myalgia/ generalized muscle aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1009 10091113	INFEC	Herpes zoster/ Shingles#	4	05FEB2021	8/14	2	No	O	NA/TC	R (18FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1009 10091116	MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
	INJ&P	Concussion/ CONCUSSION	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N
		Fall/ FALL	2	23OCT2020	37/1	2	No	O	NA	R (23OCT2020)	N/N
		Muscle strain/ NECK MUSCLE STRAIN	2	23OCT2020	37/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1009 10091117	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1009 10091129	GENRL	Axillary pain/ LEFT AXILLA TENDERNESS	2	17SEP2020	2/19	1	Yes		NA/TC	R (05OCT2020)	N/N
		Chills/ CHILLS	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Fatigue/ FATIGUE	2	17SEP2020	2/6	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/8	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN, GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1009 10091138	GENRL	Chills/ CHILLS	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INFEC	Bacterial rhinitis/ BILATERAL NOSTRIL STAPHYLOCOCCUS INFECTION	2	01DEC2020	72/C	2	No	O	NA/TC	RG	N/N
	GASTR	Gastroesophageal reflux disease/ WORSENING GERD#	2	01FEB2021	134/C	2	No	O	NA/TC	RG	N/N
	GASTR	Constipation/ constipation#	3	03FEB2021	1/2	1	No	O	NA	R (04FEB2021)	N/N
16-55/ C4591001 1009 10091142	INJ&P	Limb traumatic amputation/ ACCIDENTAL LEFT THUMB FINGER TIP AMPUTATION	1	07SEP2020	7/C	2	No	O	NA/TC/TCN	RG	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	1	11SEP2020	11/2	1	No	O	NA	R (12SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ fatigue	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1009 10091158	INJ&P	Ear injury/ RIGHT EAR TRAUMA	2	05DEC2020	67/15	2	No	O	NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1009 10091159											
16-55/ C4591001 1009 10091166	REPRO	Breast cyst/ Left Breast Cysts	1	17SEP2020	8/C	1	No	O	NA	N	N/N
16-55/ C4591001 1009 10091171	MUSC	Back pain/ WORSENING LOWER BACK PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091175	GENRL	Pain in extremity/ BILATERAL LEG PAIN	1	15SEP2020	5/C	1	No	O	NA/TC	N	N/N
	GENRL	Chills/ chills	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	15SEP2020	2/6	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1009 10091188	METAB	Hyperlipidaemia/ hyperlipidemia	2	31DEC2020	80/C	1	No	O	NA	N	N/N	
	GENRL	Chills/ chills#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1009 10091194	INFEC	Bacterial vulvovaginitis/ Vaginal Bacterial Infection	1	30SEP2020	7/19	2	No	O	NA/TC	R (18OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
		Injection site pain/ muscle pain at injection site	2	16OCT2020	2/3	2	Yes		NA/TC	R (18OCT2020)	N/N	
	NERV	Headache/ headache	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N	
16-55/ C4591001 1009 10091201	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01DEC2020	30/C	2	No	O	NA/TC	RG	N/N	
	NEOPL	Haemangioma of skin/ NEOPLASM OF UNCERTAIN BEHAVIOR OF SKIN, LEFT EAR 2mm dark freckle or hemangioma	2	04DEC2020	33/15	1	No	O	NA	R (18DEC2020)	N/N	
	SKIN	Dermatitis allergic/ ALLERGIC DERMATITIS, FACIAL	2	04DEC2020	33/3	1	No	O	NA/TC	R (06DEC2020)	N/N	
16-55/ C4591001	GASTR	Abdominal pain upper/ LEFT UPPER QUADRANT PAIN	2	08NOV2020	3/C	2	No	O	NA/TC	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1009 10091206	SKIN	Acne/ acne	2	07DEC2020	32/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1009 10091210	MUSC	Musculoskeletal chest pain/ left side rib pain	2	01DEC2020	16/3	1	No	O	NA/TC	R (03DEC2020)	N/N
16-55/ C4591001 1009 10091242	VASC	Hypertension/ hypertension	1	22OCT2020	1/C	1	No	O	NA	N	N/N
16-55/ C4591001 1009 10091244	MUSC	Myalgia/ generalized muscle soreness	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ chills	2	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N
		Pain/ body aches	2	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ fever	2	19NOV2020	2/1	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1009 10091253	GASTR	Dyspepsia/ heartburn	2	08FEB2021	85/2	1	No	O	NA	R (09FEB2021)	N/N
16-55/ C4591001 1009 10091254	GENRL	Chills/ chills	1	29OCT2020	4/1	1	Yes		NA	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1009 10091256	GENRL	Pain/ body aches	1	29OCT2020	4/1	1	Yes		NA	R (29OCT2020)	N/N
		Chills/ chills	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1009 10091261	INJ&P	Skin laceration/ left index finger laceration	2	10FEB2021	71/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1009 10091278	EAR	Ear pain/ ear ache	2	21JAN2021	31/8	1	No	O	NA	R (28JAN2021)	N/N
16-55/ C4591001 1009 10091285	GENRL	Injection site pain/ pain at injection site	2	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	INFEC	Impetigo/ impetigo on face	2	12JAN2021	22/9	1	No	O	NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1009 10091286	GENRL	Chills/ chills#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Pain/ body aches#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
		Headache/ Headache#	3	06JAN2021	2/4	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1011 10111006	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
1011 10111021		Pyrexia/ Fever 100.6#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
	MUSC	Myalgia/ Generalized Muscles Aches#	4	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	19AUG2020	6/4	1	Yes		NA	R (22AUG2020)	N/N
1011 10111035											
16-55/ C4591001	GENRL	Injection site erythema/ Injection site redness	1	14AUG2020	1/9	1	Yes		NA	R (22AUG2020)	N/N
1011 10111039											
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	04FEB2021	24/2	1	Yes		NA	R (05FEB2021)	N/N
1011 10111042											
		Injection site pain/ Injection Site Pain#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	3	04FEB2021	24/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1011 10111043	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1011 10111046	GENRL	Injection site bruising/ Bruise on left arm around the injection site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Pyrexia/ Fever 101.4	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1011 10111052	GENRL	Pyrexia/ Fever - 101.0#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1011 10111070	EYE	Eye pruritus/ Itchy Eyes	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	1	15SEP2020	28/10	1	No	O	NA	R (24SEP2020)	N/N
	RESP	Respiratory tract congestion/ Chest Congestion	1	25SEP2020	38/4	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1011 10111071	GENRL	Chills/ Chills	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever 100.6	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1011 10111079	GENRL	Chills/ Chills	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
		Fatigue/ Fatigue	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever 101.9	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/6	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1011 10111088	INFEC	Oral candidiasis/ Oral Thrush	1	03SEP2020	11/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1011 10111107	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever 101.5	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1011 10111116	INFEC	Labyrinthitis/ Inner Ear Infection	1	17SEP2020	22/9	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1011 10111117	GENRL	Chills/ Chills	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever 101.0	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1011 10111118	MUSC	Myalgia/ Left shoulder muscle pain	2	28SEP2020	11/12	1	Yes		NA/TC	R (09OCT2020)	N/N
		Myalgia/ Muscle pain left side of neck	2	28SEP2020	11/12	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1011 10111123	GENRL	Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever 100.7	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1011 10111124	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/1	1	Yes	NA	R	(09JAN2021)	N/N
		Pyrexia/ Fever - 101.5#	4	09JAN2021	2/1	2	Yes	NA/TC	R	(09JAN2021)	N/N
16-55/ C4591001 1011 10111125	GENRL	Chills/ Chills	2	17SEP2020	1/2	1	Yes	NA	R	(18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	1/2	1	Yes	NA	R	(18SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	18SEP2020	2/2	1	Yes	NA	R	(19SEP2020)	N/N
16-55/ C4591001 1011 10111129	NERV	Headache/ Headache	2	21SEP2020	1/1	2	Yes	NA	R	(21SEP2020)	N/N
16-55/ C4591001 1011 10111141	GENRL	Injection site pain/ Injection Site Pain#	4	12JAN2021	2/2	1	Yes	NA	R	(13JAN2021)	N/N
16-55/ C4591001 1011 10111154	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes	NA	R	(25SEP2020)	N/N
		Pyrexia/ Fever 100.4	2	24SEP2020	1/2	1	Yes	NA	R	(25SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	24SEP2020	1/3	1	Yes	NA	R	(26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111168	GENRL	Fatigue/ Fatigue#	3	13JAN2021	21/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1011 10111169	GENRL	Pyrexia/ Fever	1	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Axillary pain/ Soreness in left auxiliary area	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1011 10111170	GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
		Pyrexia/ Fever 100.00	2	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1011 10111186	GENRL	Chills/ Chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever - 100.4#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	4	14JAN2021	3/3	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111190	GENRL	Fatigue/ Fatigue#	4	06FEB2021	9/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	06FEB2021	9/3	1	Yes		NA	RS (08FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	9/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1011 10111199	GASTR	Nausea/ Nausea#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever - 100.6#	4	14JAN2021	1/2	2	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	3	14JAN2021	24/1	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	3	14JAN2021	24/1	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1011 10111203	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
Injection site pain/ Injection Site Pain#		4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1011 10111212	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	2/5	1	Yes		NA	R (23JAN2021)	N/N
	INV	Body temperature increased/ Elevated Body Temp - 99.9#	4	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	VASC	Hot flush/ Hot Flashes	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/1	2	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	INV	Body temperature increased/ Increased Body temperature (99.7)	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Hip/Pelvic Joint Pain	1	31OCT2020	2/7	2	Yes		NA	R (06NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1011 10111235	NERV	Headache/ Headache	1	31OCT2020	2/1	1	Yes		NA	R (31OCT2020)	N/N
	SKIN	Rash/ Rash on left arm	1	04NOV2020	6/6	2	No	O	NA	R (09NOV2020)	N/N
	GENRL	Chills/ Chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
	INV	Body temperature increased/ Increased Body Temperature 99.0	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1011 10111236	GENRL	Chills/ Chills	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	21NOV2020	2/1	1	Yes		NA/TC	R (21NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	21NOV2020	2/1	1	Yes		NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1012 10121006	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Back pain/ Back pain#	3	11FEB2021	1/2	1	No	CND	NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1012 10121024	GENRL	Pyrexia/ Fever#	4	10MAR2021	2/1	1	Yes		NA	R (10MAR2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121055	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1012 10121058	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1012 10121065	INJ&P	Ligament sprain/ Left Ankle Sprain	1	30SEP2020	38/C	1	No	CND	NA/TC	RG	N/N
16-55/ C4591001 1012 10121073	GENRL	Chills/ CHILLS	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ RIGHT ARM INJECTION SITE PAIN	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	PSYCH	Insomnia/ INSOMNIA	2	14SEP2020	1/1	2	Yes		NA	R (14SEP2020)	N/N
	HEPAT	Cholelithiasis/ Cholelithiasis	2	28SEP2020	15/C	2	No	CND	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121074	GENRL	Chills/ BODY CHILLS#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE SORENESS#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ LOW GRADE FEVER#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
	GENRL	Chills/ Body Chills#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1012 10121076	GENRL	Injection site erythema/ Redness at injection site#	4	20FEB2021	2/6	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1012 10121079	NERV	Headache/ Intermittent Headaches	2	23SEP2020	9/C	1	No	CND	NA	RG	N/N
	NERV	Amnesia/ Short-Term Memory Loss#	3	13FEB2021	6/C	2	No	O	NA	RG	N/N
16-55/ C4591001	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121085	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes	NA	R	(06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/4	1	Yes	NA	R	(28SEP2020)	N/N
		Injection site pain/ Left Arm Injection Site Pain	2	25SEP2020	1/4	2	Yes	NA	R	(28SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/34	2	Yes	NA	R	(28OCT2020)	N/N
16-55/ C4591001 1012 10121087	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	16SEP2020	1/4	1	Yes	NA	R	(19SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	17SEP2020	2/2	1	Yes	NA	R	(18SEP2020)	N/N
		Pain/ BODY ACHES	2	17SEP2020	2/2	2	Yes	NA	R	(18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	2/2	2	Yes	NA/TC	R	(18SEP2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	17SEP2020	2/2	2	Yes	NA	R	(18SEP2020)	N/N
16-55/ C4591001 1012 10121095	GENRL	Fatigue/ Fatigue	1	07SEP2020	8/8	1	Yes	NA	R	(14SEP2020)	N/N
	NERV	Dizziness/ Lightheadedness	1	07SEP2020	8/3	1	Yes	NA	R	(09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121096	INFEC	Ear infection/ Bilateral Ear Infection	1	01SEP2020	2/10	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1012 10121101	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE PAIN	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Right Arm Injection Site Pain	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1012 10121103	PSYCH	Anxiety/ ANXIETY	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
		Post-traumatic stress disorder/ POST TRAUMATIC STRESS DISORDER	2	22SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C4591001 1012 10121105	GENRL	Injection site swelling/ Right arm localized swelling at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site discolouration/ Right arm hyperpigmentation at injection site	1	05SEP2020	5/C	1	Yes		NA	RG	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site discolouration/ Hyperpigmentation at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121108	GASTR	Injection site pain/ PAIN AT INJECTION SITE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Diarrhoea/ Diarrheal Episode	1	15SEP2020	15/1	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1012 10121111	GASTR	Nausea/ NAUSEA	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Pyrexia/ FEVER	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ FEVER	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	SURG	Dental implantation/ Dental Implant Right Upper Molar	2	15OCT2020	25/1	1	No	CND	NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121118 16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
1012 10121121 16-55/ C4591001	BLOOD	Anaemia/ ANEMIA	2	01OCT2020	7/C	1	No	CND	NA/TC	N	N/N
1012 10121124 16-55/ C4591001	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
1012 10121130 16-55/ C4591001	GASTR	Nausea/ NAUSEA	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
1012 10121131	GENRL	Chills/ CHILLS	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1012 10121132	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121137	GENRL	Chills/ Body Chills	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/C	2	Yes		NA/TC	RG	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	EYE	Diplopia/ Double Vision	2	26SEP2020	2/2	1	No	CND	NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1012 10121144		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE#	3	23JAN2021	1/4	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1012 10121145		Injection site pain/ LEFT INJECTION SITE ARM PAIN#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GASTR	Nausea/ Nausea	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		Vomiting/ Vomiting	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121146	NERV	Pyrexia/ Fever	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Headache/ Headache	2	25SEP2020	1/C	2	Yes		NA	RG	N/N
16-55/ C4591001 1012 10121146	MUSC	Myalgia/ MUSCLE ACHES	1	05SEP2020	1/4	2	Yes		NA/TC	R (08SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1012 10121154	GENRL	Injection site pain/ Arm Pain at Injection Site	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1012 10121162	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1012 10121163	GASTR	Nausea/ NAUSEA	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	02OCT2020	2/32	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/32	2	Yes		NA/TC	R (02NOV2020)	N/N
	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
	PSYCH	Insomnia/ INSOMNIA	1	12SEP2020	4/C	2	Yes		NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121172	INV	Weight decreased/ WEIGHT LOSS	1	14SEP2020	6/21	3	Yes		NA	R (04OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	21OCT2020	20/4	1	No	O	NA	R (24OCT2020)	N/N
	NERV	Dizziness/ LIGHTHEADEDNESS#	3	23JAN2021	1/1	1	No	O	NA	R (23JAN2021)	N/N
	INJ&P	Skin laceration/ Forehead laceration#	3	12FEB2021	21/7	1	No	O	NA/TCN	R (18FEB2021)	N/N
	NERV	Syncope/ Syncope#	3	12FEB2021	21/1	1	No	O	NA	R (12FEB2021)	N/N
	GENRL	Chills/ Body chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
		Pain/ Body aches#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1012 10121173	EAR	Vertigo/ Vertigo#	4	14FEB2021	3/1	1	No	O	NA	R (14FEB2021)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1012 10121174	GENRL	Injection site pain/ LOCALIZED LEFT ARM PAIN AT INJECTION SITE	1	11SEP2020	2/4	2	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121178	GENRL	Chills/ CHILLS	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ FATIGUE	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
		Pain/ BODY ACHES	2	01OCT2020	2/1	2	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
		Fatigue/ FATIGUE	2	08OCT2020	1/C	1	Yes		NA	RG	N/N
		Pain/ BODY ACHES	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1012 10121181	GENRL	Fatigue/ FATIGUE#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/Y
16-55/ C4591001	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1012 10121182	GENRL	Chills/ CHILLS	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ FATIGUE	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ BODY ACHES	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1012 10121183	GENRL	Chills/ CHILLS	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1012 10121187	NERV	Paraesthesia/ Left Shoulder Tingling	2	23OCT2020	22/3	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C4591001 1012 10121188	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	2	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131003	GENRL	Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	28JUL2020	1/11	1	Yes		NA	R (07AUG2020)	N/N
	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	09AUG2020	13/4	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C4591001 1013 10131005	MUSC	Arthropathy/ CYST, WRIST, LEFT	2	SEP2020	14/	1	No	O	NA/TCN	R	N/N
16-55/ C4591001 1013 10131006	MUSC	Myalgia/ MUSCLE PAIN	1	04AUG2020	8/1	2	Yes		NA	R (04AUG2020)	N/N
16-55/ C4591001 1013 10131014	GENRL	Fatigue/ FATIGUE	1	31JUL2020	3/6	1	Yes		NA	R (05AUG2020)	N/N
	INFEC	Tonsillitis/ TONSILLITIS	2	17NOV2020	89/13	1	No	O	NA/TC	R (29NOV2020)	N/N
	GENRL	Chills/ CHILLS#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1013 10131015	MUSC	Pain in extremity/ SORE ARM#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	29JUL2020	1/8	1	Yes		NA	R (05AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ FATIGUE	1	29JUL2020	1/8	2	Yes		NA	R (05AUG2020)	N/N
16-55/ C4591001 1013 10131021	GASTR	Diarrhoea/ DIARRHEA	1	13AUG2020	15/9	2	No	O	NA	R (21AUG2020)	N/N
16-55/ C4591001 1013 10131030	MUSC	Pain in extremity/ PAIN IN ARMS AND HANDS	2	22AUG2020	5/C	3	Yes		NA/TC	RG	N/N
		Pain in extremity/ PAIN IN LEGS AND FEET	2	22AUG2020	5/C	3	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131032	NERV	Headache/ HEADACHE	1	05AUG2020	7/2	1	Yes		NA	R (06AUG2020)	N/N
16-55/ C4591001 1013 10131044	REPRO	Benign prostatic hyperplasia/ BENIGN PROSTATIC HYPERPLASIA	2	25NOV2020	99/C	1	No	O	NA/TC	RG	N/N
	INFEC	Gonorrhoea/ GONORRHEA#	2	25FEB2021	191/C	1	No	O	NA/TC	RG	N/N
	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA#	2	01MAR2021	195/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131051	INJ&P	Skin laceration/ LACERATION TO LEFT EYEBROW	2	01OCT2020	38/7	1	No	O	NA/TCN	R (07OCT2020)	N/N
16-55/ C4591001	MUSC	Arthralgia/ PAIN RIGHT SHOULDER	2	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131055	INFEC	Tooth abscess/ TOOTH ABSCESS	2	20OCT2020	58/16	1	No	O	NA/TC	R (04NOV2020)	N/N
	MUSC	Back pain/ BACK PAIN	2	15DEC2020	114/22	2	No	O	NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1013 10131059	GENRL	Fatigue/ FATIGUE	2	26AUG2020	2/1	3	Yes		NA	R (26AUG2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	26AUG2020	2/1	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1013 10131066	INJ&P	Arthropod bite/ ERYTHEMA FROM BUG BITES#	4	29JAN2021	25/6	1	No	O	NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1013 10131067	NERV	Headache/ HEADACHE	1	08AUG2020	5/4	1	Yes		NA	R (11AUG2020)	N/N
	SKIN	Rash/ UNDERARM SKIN RASH	2	08NOV2020	75/16	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001 1013 10131068	INFEC	Otitis media/ left middle ear infection	1	15AUG2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131072	MUSC	Myalgia/ muscle pain left hip	1	05AUG2020	2/C	1	Yes		NA	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131084	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N	
16-55/ C4591001 1013 10131089	VASC	Deep vein thrombosis/ LEFT ARM DEEP VEIN THROMBOSIS	2	20DEC2020	116/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131112	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
		Pain/ BODY ACHES	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N	
16-55/ C4591001 1013 10131113	PSYCH	Depression/ Recurrence of depression.	2	15SEP2020	15/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131124	VASC	Hypertension/ HYPERTENSION	1	20AUG2020	10/C	1	No	O	NA/TC	RG	N/N	
	MUSC	Bursitis/ BURSITIS LEFT SHOULDER	1	28AUG2020	18/1	1	No	O	NA/TC	R (28AUG2020)	N/N	
16-55/ C4591001 1013 10131125	EAR	Ear discomfort/ ear discomfort	1	26AUG2020	16/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001	RESP	Pulmonary embolism/ Pulmonary Embolism Bilateral	2	14DEC2020	104/C	3	No	O	NA/TC	RG	Y/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131165 16-55/ C4591001	ENDO	Hypothyroidism/ HYPOTHYROIDISM	2	12OCT2020	41/C	1	No	O	NA/TC	N	N/N
1013 10131169 16-55/ C4591001	RENAL	Nephrolithiasis/ kidney stones	2	04JAN2021	119/2	3	No	O	NA/TCN	R (05JAN2021)	Y/N
1013 10131190 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
1013 10131204 16-55/ C4591001	GENRL	Chills/ CHILLS	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
1013 10131207		Fatigue/ FATIGUE	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
		Pain/ BODY ACHES	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ FEVER	2	10SEP2020	2/8	2	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Pain/ body aches	2	14SEP2020	6/2	3	Yes		NA	R (15SEP2020)	N/N
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS RIGHT POPTIAL VEIN	2	23SEP2020	15/6	3	No	O	NA/TC	R (28SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131209	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131215	GENRL	Injection site bruising/ 1/2 CM BY 1/2 CM BRUISE AT INJECTION SITE	1	18AUG2020	1/13	1	Yes		NA	R (30AUG2020)	N/Y
16-55/ C4591001 1013 10131218	GENRL	Injection site pain/ INJECTION SITE PAIN	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1013 10131219	NERV	Headache/ HEADACHE	1	19AUG2020	2/3	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1013 10131221	NERV	Headache/ FRONTAL HEADACHES	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1013 10131225	GENRL	Chills/ CHILLIS	2	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain/ BODY ACHES	2	11SEP2020	3/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	11SEP2020	3/2	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131229	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	10DEC2020	92/C		No	O	NA	RG	N/N
16-55/ C4591001 1013 10131231	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1013 10131239	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09OCT2020	30/2	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1013 10131245	NERV	Headache/ HEADACHE	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	5/3	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ FEVER	2	14SEP2020	5/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1013 10131251	GENRL	Chills/ CHILLS	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ JOINT PAIN	2	09SEP2020	2/4	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1013 10131255	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	SEP2020	1/		No	O	NA	R	N/N
	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N
16-55/ C4591001 1013 10131258	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	2/5	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ FATIGUE	2	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1013 10131259	GENRL	Injection site pain/ INJECTION SITE PAIN	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1013 10131264	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE	2	11SEP2020	2/4	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22AUG2020	3/3	2	Yes		NA	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131268 16-55/ C4591001	NERV	Headache/ HEADACHE	2	17SEP2020	1/8	2	Yes		NA	R (24SEP2020)	N/N
1013 10131271	GENRL	Injection site swelling/ SWELLING AT INJECTION SITE	2	24SEP2020	8/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
1013 10131276		Pain/ BODY ACHES	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
1013 10131280	GENRL	Chills/ INTERMITTENT CHILLS	2	16SEP2020	1/4	2	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ INTERMITTENT LOW GRADE FEVER	2	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001	GENRL	Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
1013 10131283	GASTR	Gastroesophageal reflux disease/ ACID REFLUX	2	01DEC2020	79/10	1	No	O	NA/TC	R (10DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131285	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26AUG2020	3/2	3	No	O	NA/TC	R (27AUG2020)	N/N
	GENRL	Chills/ CHILLS	1	26AUG2020	3/2	1	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C4591001 1013 10131287	GENRL	Pyrexia/ FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1013 10131293	GENRL	Chills/ CHILLS	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pain/ BODY ACHES	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1013 10131299	GENRL	Chills/ CHILLS	2	18SEP2020	4/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1013 10131303	GENRL	Injection site haematoma/ INJECTION SITE HEMATOMA	2	18SEP2020	2/19	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	19OCT2020	33/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131304		Pain/ BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1013 10131305	GENRL	Injection site pain/ INJECTION SITE PAIN	2	20SEP2020	4/4	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1013 10131318	SKIN	Pyrexia/ LOW GRADE FEVER Ingrowing nail/ RIGHT BIG TOE INGROWN TOE TAIL	2	20SEP2020	4/2	2	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1013 10131338	GENRL	Chills/ CHILLS	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GASTR	Vomiting/ VOMITING	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	18SEP2020	2/3	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1013 10131348	GENRL	Chills/ CHILLS	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131349	INJ&P	Procedural pain/ RIGHT ARM SORENESS SECONDARY TO INJECTION	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1013 10131351	GENRL	Chills/ CHILLS#	4	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ LEFT ARM INJECTION SITE PAIN#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	INFEC	Diverticulitis/ DIVERTICULITIS#	4	19FEB2021	2/14	2	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1013 10131352	SURG	Tonsillectomy/ TONSILLECTOMY	2	10NOV2020	55/1	2	No	O	NA/TCN	R (10NOV2020)	N/N
16-55/ C4591001 1013 10131355	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pain/ BODY ACHES	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131357	GENRL	Chills/ CHILLS	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ FATIGUE	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1013 10131361	MUSC	Injection site pain/ INJECTION SITE PAIN	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N	
		Pyrexia/ LOW GRADE FEVER	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N	
		Arthralgia/ JOINT PAIN	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Chills/ CHILLS	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	
	16-55/ C4591001 1013 10131365	INFEC	Sinusitis/ SINUS INFECTION	1	16SEP2020	17/14	1	No	O	NA/TC	R (29SEP2020)	N/N
		MUSC	Myalgia/ MILD MUSCLE ACHES	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N
		NERV	Headache/ HEADACHE	2	25SEP2020	5/3	1	Yes		NA	R (27SEP2020)	N/N
		INFEC	Sinusitis/ SINUS INFECTION	2	03NOV2020	44/11	2	No	O	NA/TC	R (13NOV2020)	N/N
INFEC		Staphylococcal infection/ BILATERAL STAPH INFECTION TO THE ELBOWS AND HANDS	2	20NOV2020	61/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1013 10131371	GASTR	Nausea/ NAUSEA	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Pain/ BODY ACHES	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131377	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ FATIGUE	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
		Pain/ LEFT UPPER BODY PAIN	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1013 10131385	SKIN	Rash/ RASH TO UPPER EXTREMITIES	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
		Rash/ RASH TO UPPER TORSO	2	26SEP2020	4/2	2	Yes		NA/TC	R (27SEP2020)	N/N
	SKIN	Rash/ RASH TO LOWER EXTREMITIES	2	27SEP2020	5/1	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1013 10131388	NERV	Tension headache/ TENSION HEADACHE	1	10SEP2020	10/2	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131391	MUSC	Muscle tightness/ MUSCLE TIGHTNESS	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	9/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131395	GENRL	Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	2/3	2	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131405	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131406	MUSC	Intervertebral disc degeneration/ MILD L5-S1 DISC DEGENERATION	1	13SEP2020	12/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131409	NERV	Dizziness/ LIGHTHEADEDNESS	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
		Headache/ HEADACHE	1	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N
		Lethargy/ LETHARGIC	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Dizziness/ LIGHTHEADEDNESS	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		Headache/ HEADACHE	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/Y
		Lethargy/ LETHARGIC	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131416	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
		Pain/ BODY ACHES	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain/ BODY ACHES	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131419	GENRL	Injection site pain/ INJECTION SITE PAIN	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Malaise/ MALAISE	1	07SEP2020	6/10	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ CHILLS	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131423	GENRL	Injection site pain/ INJECTION SITE PAIN	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131424	GENRL	Injection site pain/ INJECTION SITE PAIN	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N
		Pain/ BODY ACHES	1	04SEP2020	2/3	2	Yes		NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1013 10131427	SKIN	Pruritus/ ITCHING ON ARMS AND LEGS	1	08SEP2020	6/26	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1013 10131438	GENRL	Chills/ CHILLS	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131445	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131448	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02OCT2020	2/3	2	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1013 10131451		Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131463	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1013 10131469	GENRL	Injection site pain/ INJECTION SITE PAIN	1	28SEP2020	21/1	1	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131470	GASTR	Nausea/ NAUSEA	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	09SEP2020	2/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1013 10131472	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pain/ BODY ACHES	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ BODY ACHES	1	30SEP2020	22/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1013 10131476	GENRL	Injection site pain/ INJECTION SITE PAIN	2	28SEP2020	1/4	2	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		Pain/ BODY ACHES	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1013 10131486	GENRL	Injection site pain/ INJECTION PAIN	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131492	GENRL	Injection site pain/ INJECTION PAIN	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
	GENRL	Injection site pain/ INJECTION PAIN	1	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1013 10131493	GENRL	Injection site pain/ INJECTION SITE PAIN	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1013 10131499	MUSC	Arthralgia/ LEFT SHOULDER PAIN	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131507 16-55/ C4591001	NERV	Headache/ HEADACHE	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
1013 10131513 16-55/ C4591001	MUSC	Arthralgia/ RIGHT SHOULDER PAIN#	4	24FEB2021	15/C	1	No	O	NA	N	N/N
1013 10131514 16-55/ C4591001	GENRL	Chills/ CHILLS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
1013 10131515 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)	N/N
1013 10131518 16-55/ C4591001	GENRL	Pyrexia/ LOW GRADE FEVER	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N
1013 10131518 16-55/ C4591001	GENRL	Injection site pain/ INJECTION PAIN	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
1013 10131518 16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	02OCT2020	3/2	1	Yes		NA	R (03OCT2020)	N/N
1013 10131518 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
1013 10131518 16-55/ C4591001	SKIN	Rash erythematous/ 2 RASH ON CHEST (PRURITIS AND REDDENED)	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
1013 10131518 16-55/ C4591001	NERV	Headache/ HEADACHE	1	15SEP2020	2/15	1	No	O	NA/TC	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131529 16-55/ C4591001 1013 10131533	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	1	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1013 10131534	GENRL	Chills/ Chills	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ BODY ACHES	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1013 10131546	GENRL	Chills/ CHILLS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	07OCT2020	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1013 10131553	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131556	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/4	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1013 10131557	INJ&P	Ligament sprain/ ANKLE SPRAIN RIGHT	1	26SEP2020	11/17	2	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1013 10131563	GENRL	Injection site pain/ INJECTION SITE PAIN	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1013 10131567	GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1013 10131568	GENRL	Fatigue/ FATIGUE	1	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL ARMS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131569		Myalgia/ ACHING UPPER BODY MUSCLES BILATERAL SHOULDERS	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ MUSCLE SORENESS AT INJECTION SITE	1	18SEP2020	2/4	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	28OCT2020	21/C	2	No	O	NA/TC	RG	N/N
	METAB	Diabetes mellitus/ NEW ONSET DIABETES	2	31DEC2020	85/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131571†	GENRL	Injection site pain/ PAIN INJECTION SITE	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1013 10131580	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		Pain/ BODY ACHES	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131581	NERV	Headache/ HEADACHE	2	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ FEVER	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1013 10131595	SURG	Nasal polypectomy/ NASAL POLYPECTOMY	2	17DEC2020	67/1	1	No	O	NA/TCN	R (17DEC2020)	N/N
16-55/ C4591001 1013 10131597	INJ&P	Meniscus injury/ MENISCAL TEAR#	4	08MAR2021	19/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1013 10131599	GENRL	Injection site pain/ INJECTION SITE PAIN	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1013 10131600	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131601	RESP	Nasal congestion/ NASAL CONGESTION	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1013 10131603	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1013 10131607	RESP	Oropharyngeal pain/ SORE THROAT	1	25SEP2020	4/2	1	Yes		NA	R (26SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	28SEP2020	7/2	1	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1013 10131612	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1013 10131614†	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131630	GENRL	Fatigue/ FATIGUE	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	26OCT2020	22/2	2	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1013 10131633		Pain/ GENERALIZED BODY ACHES	1	26OCT2020	22/2	2	Yes		NA	R (27OCT2020)	N/N
	GENRL	Pain/ BODY ACHES	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1013 10131634		Pyrexia/ LOW GRADE FEVER	1	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Tendonitis/ LEFT WRIST TENDONITIS	2	25JAN2021	91/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131637	GENRL	Injection site pain/ INJECTION SITE PAIN	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	27OCT2020	2/3	3	Yes		NA/TC	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131639		Injection site nodule/ HARD NODULE INJECTION SITE LEFT	2	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N
		Injection site swelling/ INJECTION SITE SWELLING	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ GENERALIZED BODY ACHES	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN FINGERS LEFT ARM	2	27OCT2020	2/4	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ FRONTAL HEADACHES	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
		Headache/ HEADACHE	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Pyrexia/ LOW GRADE TEMP	2	28OCT2020	3/3	1	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	30OCT2020	2/2	1	Yes		NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1013 10131643	NERV	Headache/ FRONTAL HEADACHE	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
	PSYCH	Insomnia/ INSOMNIA	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131644	GENRL	Fatigue/ FATIGUE	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
		Myalgia/ MUSCLE PAIN	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1013 10131644	SURG	Toe operation/ 5 TOES RIGHT FOOT HAMMER TOE RELEASE	2	03NOV2020	9/1	2	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1013 10131645	GENRL	Chills/ CHILLS	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1013 10131653		Pain/ BODY ACHES	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	VASC	Deep vein thrombosis/ RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	2	15NOV2020	20/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1013 10131656	METAB	Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2	18JAN2021	84/4	3	No	O	NA/TC	R (21JAN2021)	Y/N
16-55/ C4591001 1013 10131657	GENRL	Injection site pain/ INJECTION SITE PAIN	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131658	BLOOD	Lymphadenopathy/ LYMPH NODE SWELLING LEFT AUXILLARY	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1013 10131664	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1013 10131666	INJ&P	Ligament rupture/ TORN LIGAMENTS TO LEFT FOOT	1	09OCT2020	2/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1013 10131676	GENRL	Pain/ BODY ACHES	2	03NOV2020	2/3	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1013 10131678	GENRL	Fatigue/ FATIGUE	1	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/Y
		Injection site pain/ INJECTION SITE PAIN	1	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/4	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
		Fatigue/ FATIGUE	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Pain/ BODY ACHES	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131681	GENRL	Pyrexia/ LOW GRADE FEVER	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ FATIGUE	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
		Headache/ HEADACHE	1	13OCT2020	2/5	2	Yes		NA/TC	R (17OCT2020)	N/N
		Diarrhoea/ DIARRHEA	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1013 10131685	GENRL	Pain/ BODY ACHES	1	14OCT2020	3/4	2	Yes		NA/TC	R (17OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	2/6	2	Yes		NA	R (18OCT2020)	N/N
		Fatigue/ FATIGUE	2	02NOV2020	1/3	1	Yes		NA/TC	R (04NOV2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)
16-55/ C4591001 1013 10131689	MUSC	Myalgia/ MUSCLE PAIN	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Pain/ BODY ACHES	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1013 10131693	GENRL										
16-55/ C4591001	GENRL	Pain/ BODY ACHES	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131696 16-55/ C4591001	INFEC	Tinea infection/ RINGWORM#	4	04MAR2021	57/C	1	No	O	NA/TC	RG	N/N
1013 10131697 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
1013 10131708	NERV	Headache/ HEADACHE	1	14OCT2020	2/4	1	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	03NOV2020	1/4	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ CHILLS	2	04NOV2020	2/1	3	Yes		NA/TC	R (04NOV2020)	N/N
		Pain/ BODY ACHES	2	04NOV2020	2/4	2	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
1013 10131709	GENRL	Injection site pruritus/ PRURITUS AT INJECTION SITE	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001	GENRL	Pain/ BODY ACHES	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
1013 10131713	NERV	Dizziness/ LIGHTHEADEDNESS	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131718	GENRL	Chills/ CHILLS	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N
		Fatigue/ FATIGUE	2	04NOV2020	3/2	1	Yes		NA	R (05NOV2020)	N/N
	HEPAT	Cholecystitis/ CHOLECYSTITIS#	3	07MAR2021	12/4	2	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001 1013 10131721	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	06NOV2020	2/6	2	Yes		NA	R (11NOV2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	2	06NOV2020	2/6	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1013 10131729	GENRL	Chills/ CHILLS	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1013 10131737	GENRL	Injection site pain/ injection site pain	1	15OCT2020	1/4	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ HEADACHE (FRONTAL)	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ CHILLS	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131744		Fatigue/ FATIGUE	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
		Pain/ BODY ACHES	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1013 10131749	GENRL	Fatigue/ FATIGUE	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1013 10131752	GENRL	Fatigue/ FATIGUE	1	19OCT2020	1/8	1	Yes		NA	R (26OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	19OCT2020	1/8	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Pain/ BODY ACHES	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
	RESP	Cough/ COUGH	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
		Nasal congestion/ NASAL CONGESTION	1	20OCT2020	2/7	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1013 10131759	GENRL	Injection site pain/ INJECTION SITE PAIN	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1013 10131771	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131772	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	2	12NOV2020	3/3	2	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	12NOV2020	3/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1013 10131783	GENRL	Chills/ CHILLS	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
		Injection site pruritus/ PRURITUS AT INJECTION SITE	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1013 10131783	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Chills/ CHILLS	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1013 10131790	GENRL	Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1013 10131793	GENRL	Fatigue/ FATIGUE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131794	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ BODY ACHES	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
	NERV	Headache/ FRONTAL HEADACHE	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1013 10131796	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1013 10131800	GENRL	Fatigue/ FATIGUE	1	22OCT2020	1/2	2	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
		Pain/ BODY ACHES	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	2/4	2	Yes		NA	R (15NOV2020)	N/N
		Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1013 10131802	GENRL	Injection site pain/ INJECTION SITE PAIN	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1013 10131808	NERV	Injection site swelling/ INJECTION SITE SWELLING	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Headache/ TEMPORAL HEADACHE	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1013 10131809	NERV	Headache/ TEMPORAL HEADACHE	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
		INJ&P	Limb injury/ SHOULDER INJURY LEFT	1	11NOV2020	21/14	2	No	O	NA/TC	R (24NOV2020)
16-55/ C4591001 1013 10131815	GENRL	Fatigue/ FATIGUE	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1013 10131817	GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1015 10151006	GENRL	Injection site pain/ INJECTION SITE PAIN	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
		INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	23JAN2021	73/C	1	No	O	NA/TC	RG
	GENRL	Chills/ Chills#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151009	INV	Fatigue/ Fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Body temperature increased/ Increased body temperature 99F#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Injection site pain/ Injection site pain#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
		Myalgia/ Myalgias#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Arthralgia/ General joint pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
NERV	Headache/ Head ache#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1015 10151011	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	25NOV2020	84/C		No	O	NA	UNK	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151015	MUSC	Pain in extremity/ Leg pain	2	05SEP2020	2/2	1	No	O	NA	R (06SEP2020)	N/N	
16-55/ C4591001 1015 10151017	NERV	Syncope/ syncope*		14AUG2020	1/1	1	No	O	NA/TCN	R (14AUG2020)	N/N	
16-55/ C4591001 1015 10151018	GENRL	Chills/ Chills#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N	
	INV	Body temperature increased/ Increased body temperature#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N	
	MUSC	Myalgia/ Muscle aches#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N	
	NERV	Headache/ Headache#	4	08JAN2021	3/2	1	Yes		NA	R (09JAN2021)	N/N	
16-55/ C4591001 1015 10151021	GENRL	Injection site bruising/ Bruising at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
		Injection site pain/ Injection site pain#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Headache/ Headache#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151023	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	8/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1015 10151026	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1015 10151029	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y
16-55/ C4591001 1015 10151031	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1015 10151035	BLOOD	Lymphadenopathy/ Swollen lymph node - left armpit axillary	2	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1015 10151041	GASTR	Abdominal pain upper/ Stomach cramps	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N
		Nausea/ Nausea	1	08SEP2020	23/2	1	No	CD	NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151045	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1015 10151046	GENRL	Chills/ Chills	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	12SEP2020	5/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1015 10151047	EYE	Corneal irritation/ Right corneal irritation	1	17AUG2020	1/4	2	No	O	NA	R (20AUG2020)	N/N
	GENRL	Shoulder injury related to vaccine administration/ SIRVA - shoulder injury related to vaccine administration	2	09SEP2020	1/153	3	Yes		NA	R (08FEB2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151049	RESP	Oropharyngeal pain/ Sore throat	2	21SEP2020	13/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N
	INV	Body temperature increased/ Increased body temperature#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GASTR	Vomiting/ Single episode of vomiting#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Injection site urticaria/ Hives around injection site#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Fever 100.1 F#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151051	GENRL	Injection site pain/ Soreness of injection site arm	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever 101.2	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151053	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1015 10151054	GENRL	Malaise/ general malaise	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ low grade fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1015 10151055	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	INV	Body temperature increased/ Increased temperature of 99 degrees Fahrenheit	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1015 10151056	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/5	1	Yes		NA/TC	R (22DEC2020)	N/N
	GENRL	Malaise/ Malaise#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ injection site pain#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
		Malaise/ general malaise#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151058	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1015 10151061	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1015 10151063	GENRL	Injection site pain/ Soreness at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/Y
16-55/ C4591001 1015 10151068	GENRL	Vaccination site pain/ Pain in arm at site of tetanus shot	2	28OCT2020	49/2	1	No	CD	NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151069		Injection site pain/ Injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1015 10151071	INJ&P	Exposure during pregnancy/ Exposure during pregnancy#	3	07JAN2021	18/C		No	O	NA	UNK	N/N
16-55/ C4591001 1015 10151073	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ Body aches#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1015 10151077	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151080	MUSC	Injection site pain/ Soreness over the injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Arthralgia/ Shoulder pain located lateral to deltoid muscle, near acromion.	2	09SEP2020	1/84	1	Yes		NA/TC	R (01DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1015 10151081	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/4	2	Yes		NA/TC	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1015 10151082	GENRL	Injection site pain/ Soreness at injection site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1015 10151083	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Arm soreness at injection site	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151084	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1015 10151085	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1015 10151088	GENRL	Fatigue/ Fatigue#	3	18DEC2020	1/4	1	Yes		NA/TC	R (21DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	18DEC2020	1/4	1	Yes		NA/TC	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
		Pyrexia/ Fever 101.6#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Swollen left axillary lymph node	2	11SEP2020	1/8	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151089	GENRL	Pyrexia/ Fever	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	INJ&P	Procedural pain/ Whole arm pain - received injection	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1015 10151092	GENRL	Pyrexia/ Fever T 100.3F	2	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1015 10151100	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1015 10151101	METAB	Gout/ Gout	2	01OCT2020	17/12	1	Yes		NA/TC	R (12OCT2020)	N/N
	PREG	Exposure during pregnancy/ Exposure during pregnancy (partner)#	2	22JAN2021	130/C		No	O	NA	UNK	N/N
16-55/ C4591001 1015 10151102	GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151104	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GASTR	Abdominal discomfort/ GI distress#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151105	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151107	GENRL	Injection site pain/ Pain at injection site#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1015 10151108	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	2/1	1	Yes		NA/TC	R (22DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Aches#	3	22DEC2020	2/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ Fatigue#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ Body aches#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
		Pyrexia/ Fever 102 F#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1015 10151112	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1015 10151115	GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Malaise/ General malaise	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1015 10151116	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1015 10151119	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/Y
	GENRL	Chills/ Chills#	4	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151120	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
		Pyrexia/ Fever 103#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151122	MUSC	Pain in extremity/ Soreness in left arm	1	26AUG2020	1/4	2	Yes		NA	R (29AUG2020)	N/Y
	GENRL	Chest discomfort/ Tightness in chest	1	07SEP2020	13/3	1	No	O	NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Soreness in injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
	GASTR	Diarrhoea/ Diarrhea	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N
		Vomiting/ Vomiting	2	19OCT2020	34/2	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1015 10151126	MUSC	Arthralgia/ Bilateral joint pain in elbow and knees#	2	21JAN2021	127/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1015 10151130	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1015 10151131	GENRL	Vessel puncture site induration/ 3mm induration in left antecubital area at the phlebotomy site	1	28AUG2020	2/98	1	No	O	NA	R (03DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151132	GENRL	Injection site pain/ Soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pain/ Body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever 101.2	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1015 10151134	EAR	Vertigo/ Worsening and continuing episode of Veritgo	1	28AUG2020	2/116	2	Yes		P	R (21DEC2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		Nausea/ Nausea	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	2/5	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151135	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Chills/ Chills#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
		Pyrexia/ Fever 100.4#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151137	NERV	Headache/ Headache#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ Fever 100.7F#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1015 10151139	RESP	Nasal congestion/ Nasal congestion	2	29SEP2020	12/2	1	No	O	NA	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151143 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
1015 10151146	GENRL	Chills/ chills#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ fatigue#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Single episode of diarrhea	1	02SEP2020	3/1	1	Yes		NA	R (02SEP2020)	N/N
1015 10151148	GENRL	Injection site pain/ Injection site soreness	2	23SEP2020	2/9	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Implant site pain/ Pain at left breast implant#	3	21DEC2020	6/5	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Implant site pain/ Pain in left breast implant#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
1015 10151153											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151154	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1015 10151157		Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pain/ Body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1015 10151159		Pyrexia/ Fever - 99.2	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1015 10151161	GENRL	Injection site pain/ Soreness of injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ Low grade temperature	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	1/3	3	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151162	GENRL	Pyrexia/ Fever - 100.7	2	21SEP2020	1/1	1	Yes		NA/TC	R (21SEP2020)	N/Y
	INJ&P	Procedural pain/ Whole arm pain - received IP	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/Y
	MUSC	Myalgia/ Myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	24DEC2020	2/1	1	Yes		NA	R (24DEC2020)	N/N
	MUSC	Myalgia/ Upper left arm pain - pain in the deltoid, bicep and tripep muscles with movement	1	02SEP2020	1/7	1	Yes		NA	R (08SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1015 10151166	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/Y
	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151167	GENRL	Injection site pain/ Arm injection site soreness (Pain)	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Pyrexia/ Fever	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site pain/ Injection site soreness	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever - 102.0	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1015 10151170	GENRL	Injection site pain/ Injection site soreness	1	02SEP2020	1/3	3	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1015 10151171	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever - 99.6	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/4	2	Yes		NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151172	GENRL	Chills/ Chills#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1015 10151174	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
		Injection site pain/ Pain at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
		Pyrexia/ Fever 99.5	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
	GENRL	Chills/ Chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever 102.6	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever 100.2	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1015 10151175	GENRL	Injection site pain/ Injection site soreness in left arm	1	03SEP2020	1/20	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1015 10151176		Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes	NA	NA	R (25SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	24SEP2020	1/2	1	Yes	NA	NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes	NA	NA	R (25SEP2020)	N/N
16-55/ C4591001 1015 10151177	GENRL	Injection site pain/ Soreness at injection site	1	03SEP2020	1/3	1	Yes	NA	NA	R (05SEP2020)	N/Y
		Pyrexia/ Mild fever	1	03SEP2020	1/2	1	Yes	NA	NA	R (04SEP2020)	N/Y
	GENRL	Chills/ Chills	2	25SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
		Injection site pain/ Muscle pain at injection site	2	25SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
		Pain/ Body aches	2	25SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever - 100.0	2	25SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1015 10151179	GENRL	Fatigue/ fatigue#	4	08JAN2021	2/1	1	Yes	NA	NA	R (08JAN2021)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151180	GENRL	Injection site pain/ injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N	
		Chills/ Chills#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
		Fatigue/ Fatigue#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
		Injection site pain/ Injection site pain#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
		Pain/ Body aches#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N	
16-55/ C4591001 1015 10151183	GENRL	Chills/ chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N	
		INV	Body temperature increased/ increased body temperature#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
		MUSC	Myalgia/ myalgia#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151184	GENRL	Pain/ Body aches	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
		Pyrexia/ Fever - 99.4	1	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/Y	
		GENRL	Pyrexia/ Fever - 99.0	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151185	MUSC	Myalgia/ Muscle pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15JAN2021	1/3	2	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
	REPRO	Vaginal lesion/ Vaginal lesion#	4	18JAN2021	4/11	1	No	O	NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1015 10151187	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
		Injection site paraesthesia/ Tingling at injection site, down arm	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/Y
		Pyrexia/ Fever 99.9	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151188	MUSC	Myalgia/ Generalized muscle aches	2	28SEP2020	1/4	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever 100.3	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscel aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N
		Myalgia/ Myalgias#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1015 10151192	GENRL	Injection site pain/ Soreness at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/Y
	GENRL	Pyrexia/ Fever - 101.0	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151193	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ General muscle aches#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151199	GENRL	Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1015 10151202	GENRL	Pain/ Body aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1015 10151203	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Soreness of injection site	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	SKIN	Rash/ Rash - both shins	2	15OCT2020	16/6	2	No	O	NA	R (20OCT2020)	N/N
	SKIN	Rash/ Rash - left knee	2	25OCT2020	26/102	2	Yes		NA/TC	RS (03FEB2021)	N/N
	GENRL	Peripheral swelling/ Right lower leg swollen	2	26OCT2020	27/101	2	Yes		NA/TC	RS (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151205	RESP	Rhinorrhoea/ Nasal discharge	1	10SEP2020	2/8	3	No	O	NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1015 10151207	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ Worsening headache	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/4	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1015 10151209	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/5	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/5	1	Yes		NA	R (11JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151210	GENRL	Chills/ Chills	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1015 10151211	GENRL	Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Migraine/ Migraine	1	17SEP2020	8/3	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1015 10151212	INV	Body temperature increased/ body temperature increased#	3	16DEC2020	1/2	1	Yes		NA/TC	R (17DEC2020)	N/N
	MUSC	Myalgia/ Muscle aches#	3	16DEC2020	1/2	1	Yes		NA/TC	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001 1015 10151214	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle ache near chest area	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151217	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Migraine/ Worsening Migraine	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1015 10151220	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1015 10151221		Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ Body aches#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1015 10151222		Pyrexia/ Fever - 100.7	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151223	MUSC	Pain in extremity/ Sore arm - whole arm received investigational product	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pyrexia/ Fever - 100.5F#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/1	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1015 10151224	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injectin site	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1015 10151225	NERV	Dizziness/ Dizziness	2	08OCT2020	1/5	1	Yes		NA	R (12OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen neck lymph nodes - both sides#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
		Pyrexia/ Fever 100.7#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N
	MUSC	Myalgia/ General muscle aches#	3	23DEC2020	2/2	1	Yes		NA/TC	R (24DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	1/3	2	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ Fever 101.0#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1015 10151226	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1015 10151229	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	7/1	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C4591001 1015 10151231	GENRL	Swelling face/ Swollen face	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N
	SKIN	Pruritus/ Itching all over body	2	01NOV2020	19/1	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1015 10151233	GENRL	Injection site pain/ Injection site pain	1	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ Increased temperature - 99.0	1	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Increased fever from 99.0 to 100.4	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	INJ&P	Administration related reaction/ Sore arm - whole arm that received IP	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1015 10151234	GENRL	Asthenia/ Low energygy	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1015 10151235	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1015 10151236	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151240	MUSC	Pyrexia/ Fever 100.2#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Myalgia/ Myalgia#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1015 10151241	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1015 10151246	NERV	Headache/ Headache	1	12OCT2020	6/1	1	No	O	NA	R (12OCT2020)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Injection site pain/ Soreness at IP injection site	1	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1015 10151248	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1015 10151248	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	1	Yes		NA/TC	R (24DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151249	GENRL	Injection site pain/ Injection site pain#	4	14JAN2021	1/3	2	Yes		NA/TC	R (16JAN2021)	N/Y
	GENRL	Chills/ Chills#	4	15JAN2021	2/2	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	15JAN2021	2/2	2	Yes		NA/TC	R (16JAN2021)	N/N
	NERV	Headache/ Worsening headache#	4	17JAN2021	4/2	2	Yes		NA/TC	R (18JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	MUSC	Myalgia/ Mild general muscle aches#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1015 10151255	GENRL	Injection site pain/ Injection site pain#	3	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1015 10151259	GENRL	Fatigue/ Fatigue	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		Injection site pain/ Soreness at injection site	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N
		Fatigue/ Exhaustion	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1015 10151260	GENRL	Injection site pain/ Injection site arm pain	2	17NOV2020	1/4	1	Yes		NA	R (20NOV2020)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/Y
16-55/ C4591001 1015 10151260	MUSC	Myalgia/ myalgia#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/Y
	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1015 10151261	GENRL	Chills/ Chills	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1015 10151262	GENRL	Malaise/ General malaise	1	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1015 10151263	MUSC	Arthralgia/ Generalized joint aches	1	29OCT2020	2/7	1	Yes		NA/TC	R (04NOV2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	MUSC	Myalgia/ Muscle aches	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N	
	16-55/ C4591001 1016 10161003	GASTR	Nausea/ nausea#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Chills/ chills#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N	
16-55/ C4591001 1016 10161009	MUSC	Pain/ generalized body aches#	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N	
		Pyrexia/ subjective fever#	3	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N	
		Muscle spasms/ Back Muscle Cramp	2	04SEP2020	18/3	3	No	O	NA/TC/TCN	R (06SEP2020)	N/N	
16-55/ C4591001 1016 10161020	INFEC	Urinary tract infection/ Urinary Tract Infection	2	08SEP2020	21/7	1	No	O	NA/TC	R (14SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161021	GENRL	Chills/ chills#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
		Pain/ body aches#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	1/1	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1016 10161028	SKIN	Dermatitis contact/ Contact dermatitis	1	08AUG2020	6/8	2	No	O	NA/TC	R (15AUG2020)	N/N
16-55/ C4591001 1016 10161031	GASTR	Salivary gland calculus/ Left Parotid Sialolithiasis	2	21SEP2020	29/2	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1016 10161051	GENRL	Pyrexia/ fever#	4	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1016 10161054	INFEC	Herpes zoster/ zoster without complications(shingles)	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N
	SKIN	Dermatitis contact/ contact dermatitis, right thigh and right side of neck	2	06SEP2020	13/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1016 10161057	VASC	Lymphoedema/ lymphedema	2	19SEP2020	24/5	2	No	O	NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	CONG	BRCA2 gene mutation/ BRCA 2 Gene positive#	3	DEC2020	1/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1016 10161069	NERV	Dysgeusia/ odd taste in mouth	1	07AUG2020	2/3	1	Yes		NA	R (09AUG2020)	N/N
16-55/ C4591001 1016 10161073	RENAL	Haematuria/ hematuria	1	12AUG2020	7/2	1	No	O	NA	R (13AUG2020)	N/N
16-55/ C4591001 1016 10161080	MUSC	Neck pain/ cervicalgia	2	21SEP2020	26/3	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1016 10161082	GENRL	Fatigue/ fatigue#	4	05JAN2021	1/C	2	Yes		NA	N	N/N
		Pain/ generalized body aches#	4	05JAN2021	1/C	2	Yes		NA/TC	N	N/N
	MUSC	Arthralgia/ joint pain#	4	05JAN2021	1/C	2	Yes		NA/TC	N	N/N
	GENRL	Pyrexia/ fever#	4	06JAN2021	2/C	2	Yes		NA/TC	N	N/N
	NERV	Headache/ headache#	4	06JAN2021	2/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1016 10161085	GENRL	Fatigue/ fatigue#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161087	MUSC	Pyrexia/ fever#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
		Myalgia/ muscle pain#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1016 10161087	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N
16-55/ C4591001 1016 10161093	EYE	Vision blurred/ Blurry vision in Left Eye	2	08SEP2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1016 10161103	INFEC	Cellulitis/ cellulitis of face#	4	31JAN2021	19/11	1	No	O	NA/TC	R (10FEB2021)	N/N
	INJ&P	Exposure during pregnancy/ exposure during pregnancy#	4	03FEB2021	22/C		No	O	NA	UNK	N/N
16-55/ C4591001 1016 10161105	NERV	Headache/ headache#	3	02FEB2021	13/3	1	No	O	NA/TC	R (04FEB2021)	N/N
	RESP	Nasal congestion/ nasal congestion#	3	02FEB2021	13/3	1	No	O	NA	R (04FEB2021)	N/N
16-55/ C4591001 1016 10161107	GASTR	Nausea/ Nausea	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161120	NERV	Brachial plexopathy/ left brachial nerve plexopathy#	3	11JAN2021	20/18	3	No	O	NA	R (28JAN2021)	Y/N
16-55/ C4591001 1016 10161126	MUSC	Back pain/ Low Back Pain	1	17AUG2020	4/4	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1016 10161128	NEOPL	Intraductal proliferative breast lesion/ ductal carcinoma in situ, right breast	2	26OCT2020	48/45	2	No	O	NA/TCN	R (09DEC2020)	Y/N
16-55/ C4591001 1016 10161154	GENRL	Pyrexia/ fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1016 10161181	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Arthralgia/ Joint Pain, Generalized	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1016 10161183	GENRL	Injection site pain/ injection site pain, left deltoid#	3	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	3	24FEB2021	2/2	2	Yes		NA	R (25FEB2021)	N/N
		Pain/ generalized body aches#	3	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1016 10161186	GENRL	Injection site pain/ injection site pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1016 10161192	INFEC	Sinusitis/ sinusitis	2	08OCT2020	23/4	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1016 10161193	GENRL	Chills/ chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1016 10161210	GASTR	Vomiting/ vomiting	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1016 10161216	INJ&P	Radius fracture/ Left Radial Head Fracture	1	04SEP2020	4/C	2	No	O	NA/TCN	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161218	GASTR	Nausea/ nausea#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
		Oral pruritus/ itching in mouth#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Chills/ chills#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	SKIN	Pruritus/ facial itching#	3	18DEC2020	1/2	2	Yes		NA/TCN	R (19DEC2020)	N/N
	VASC	Flushing/ facial flushing#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1016 10161226		Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ muscle pain, unknown	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Nausea/ nausea	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1016 10161230	GENRL	Chills/ chills	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	1/3	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161231		Pyrexia/ fever	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Vessel puncture site haematoma/ hematoma at blood draw site	2	21OCT2020	29/C	1	No	O	NA	N	N/N
	RESP	Nasal congestion/ nasal congestion	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N
	SKIN	Rash/ diffuse rash(everywhere but more on neck,chest,back)	1	11SEP2020	10/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1016 10161242	MUSC	Myalgia/ muscle pain#	4	09FEB2021	2/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1016 10161245	PSYCH	Depression/ worsening depression	1	10SEP2020	7/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1016 10161248	GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Chills/ chills#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1016 10161258 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	63/		No	O	NA	UNK	N/N
1016 10161265 16-55/ C4591001	INJ&P	Skin laceration/ laceration to nose	2	25OCT2020	27/8	1	No	O	NA	R (01NOV2020)	N/N
1016 10161268 16-55/ C4591001	GENRL	Chills/ chills#	4	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
1016 10161272		Pyrexia/ fever, 102.1#	4	06FEB2021	2/2	3	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ headache#	4	06FEB2021	2/3	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001	SKIN	Dermatitis contact/ contact dermatitis on bilateral lower legs	2	26OCT2020	28/8	1	No	O	NA/TC	R (02NOV2020)	N/N
1016 10161276 16-55/ C4591001	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N
1016 10161277 16-55/ C4591001	GENRL	Chills/ chills	1	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
1016 10161289											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1016 10161300	INJ&P	Pyrexia/ fever	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		Concussion/ concussion	2	31OCT2020	25/C	2	No	O	NA	RG	N/N
		Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N
		Road traffic accident/ motor vehicle accident	2	31OCT2020	25/1	3	No	O	NA	R (31OCT2020)	N/N
16-55/ C4591001 1016 10161300	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1016 10161317	MUSC	Pain in extremity/ right hand pain	2	17NOV2020	12/19	1	No	O	NA	R (05DEC2020)	N/N
16-55/ C4591001 1016 10161333	GENRL	Chills/ chills	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1016 10161342	GASTR	Pyrexia/ fever	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Diarrhoea/ worsening of diarrhea	1	22OCT2020	1/7	2	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1016 10161347	GASTR	Nausea/ nausea	2	24NOV2020	2/2	2	Yes		NA	R (25NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ muscle aches	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	NERV	Headache/ headache	2	24NOV2020	2/2	2	Yes		NA	R (25NOV2020)	N/N
16-55/ C4591001 1016 10161348	METAB	Glucose tolerance impaired/ prediabetes	1	23NOV2020	19/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1016 10161349	SKIN	Rash erythematous/ rash, top ten toes(red rash)	1	09NOV2020	4/C	1	No	O	NA	N	N/N
16-55/ C4591001 1018 10181028	NERV	Cervical radiculopathy/ cervical radiculopathy C5-C6	1	12AUG2020	10/14	2	No	O	NA/TC/TCN	R (25AUG2020)	N/N
16-55/ C4591001 1018 10181031	INFEC	Appendicitis/ Appendicitis	2	06JAN2021	136/3	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N
16-55/ C4591001 1018 10181048	GENRL	Fatigue/ Fatigue#	4	13JAN2021	3/4	3	Yes		NA/TC	R (16JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	3/4	2	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1018 10181049	INJ&P	Ligament sprain/ Right Ankle Sprain	1	15AUG2020	12/2	1	No	O	NA/TC	R (16AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181050	GASTR	Food poisoning/ Food Poisoning	1	01SEP2020	29/3	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1018 10181062	EYE	Dry eye/ Right Eye Dryness	1	08AUG2020	4/15	1	No	O	NA	R (22AUG2020)	N/N	
	INJ&P	Contusion/ Right third finger contusion	1	21AUG2020	17/8	2	No	O	NA/TCN	R (28AUG2020)	N/N	
	MUSC	Arthralgia/ right ankle pain	1	23AUG2020	19/8	2	No	O	NA	R (30AUG2020)	N/N	
	NERV	Presyncope/ Vasovagal Reaction (to Blood draw)	2	25SEP2020	31/1	1	No	O	NA	R (25SEP2020)	N/N	
16-55/ C4591001 1018 10181064	INFEC	Hordeolum/ Hordeolum	2	12SEP2020	15/7	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N	
16-55/ C4591001 1018 10181081	INFEC	Paronychia/ Left Hallux Ingrown Toenail (Infected)	1	14AUG2020	10/C	2	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1018 10181084	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/9	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Chest pain/ Sharp Pain, Mid-Sternal	2	27AUG2020	2/1	1	No	O	NA	R (27AUG2020)	N/N	
16-55/ C4591001	GENRL	Pain/ Body aches/pains, Full body	2	28AUG2020	2/1	3	Yes		NA/TC	R (28AUG2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181089	NERV	Headache/ headache	2	28AUG2020	2/1	3	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1018 10181090	VASC	Deep vein thrombosis/ Deep Vein Thrombosis, left leg	2	27NOV2020	93/C	3	No	O	NA/TC	RG	Y/N
	RESP	Pulmonary embolism/ Pulmonary Embolism, bilateral, segmental and sub segmental	2	14DEC2020	110/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1018 10181111	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	24NOV2020	85/C		No	O	NA	UNK	N/N
16-55/ C4591001 1018 10181118	GENRL	Medical device pain/ Pain in mouth due to dental implant	1	31AUG2020	22/3	1	No	O	NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1018 10181120	GASTR	Abdominal pain/ Abdominal Pain	1	24AUG2020	15/7	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1018 10181133	SURG	Wisdom teeth removal/ Wisdom tooth extraction	1	20AUG2020	9/1	1	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	11SEP2020	2/14	2	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181144 16-55/ C4591001 1018 10181145	NERV	Headache/ Headache	2	14SEP2020	12/1	1	No	O	NA	R (14SEP2020)	N/N
1018 10181145	SKIN	Dermatitis allergic/ Allergic reaction (entire body), rash	2	14SEP2020	12/2	2	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1018 10181159	NERV	Paraesthesia/ Right Leg Paresthesia	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N
16-55/ C4591001 1018 10181174	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1018 10181182	GENRL	Injection site pain/ Injection Site Pain, Left deltoid	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1018 10181184	INJ&P	Ligament sprain/ Back Sprain/Strain	2	01OCT2020	22/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1018 10181185	GENRL	Injection site pain/ Pain at the injection side - Left Shoulder	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181186	INV	Body temperature increased/ Elevation of Body temperature 98.7 F	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joints Pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	GASTR	Faeces soft/ Soft Stools	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
		Nausea/ Nausea	2	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02SEP2020	1/8	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	2	02SEP2020	1/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	28SEP2020	27/18	2	No	O	NA/TC	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site tenderness	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001		Injection site swelling/ Swelling at injection site	1	21AUG2020	1/1	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Injection site swelling/ Injection Site swelling	1	11SEP2020	22/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181199	GENRL	Injection site erythema/ Injection Site Redness	1	21AUG2020	1/2	2	Yes	NA	NA	R (22AUG2020)	N/N
16-55/ C4591001 1018 10181200	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	2	Yes	NA	NA	R (22AUG2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	21AUG2020	1/2	2	Yes	NA	NA	R (22AUG2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (12SEP2020)	N/N
		Pain/ Body Aches	2	11SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever - 102.1	2	11SEP2020	2/2	3	Yes	NA/TC	NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1018 10181201	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes	NA	NA	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	1/2	1	Yes	NA	NA	R (22AUG2020)	N/N
	GENRL	Chills/ Chills	1	22AUG2020	2/2	1	Yes	NA	NA	R (23AUG2020)	N/N
		Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes	NA	NA	R (23AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181206	GASTR	Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
		Pyrexia/ Fever	2	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ Headache	2	13SEP2020	2/2	1	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1018 10181207	GENRL	Injection site pain/ Injection site soreness	1	23AUG2020	2/7	1	Yes		NA/TC	R (29AUG2020)	N/N
	INJ&P	Post procedural discomfort/ Nasal swab site discomfort right nostril	1	23AUG2020	2/12	1	No	O	NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Soreness at the injection site	2	11SEP2020	1/5	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever - 100.5 F	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1018 10181208	GENRL	Pyrexia/ Fever 101.0	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13SEP2020	3/C	1	Yes		NA	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	13SEP2020	3/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1018 10181215	GENRL	Injection site pain/ Soreness at the injection side	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pain/ Body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever 100.9	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1018 10181221	SKIN	Pruritus allergic/ Pruritus, extremities (Food or Cosmetics)	2	26SEP2020	2/4	1	No	O	NA	R (29SEP2020)	N/N
	SKIN	Urticaria/ Urticaria, extremities	2	27SEP2020	3/2	2	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1018 10181222	NERV	Headache/ Headache	1	29AUG2020	1/1	1	Yes		NA/TC	R (29AUG2020)	N/Y
	GENRL	Injection site pain/ Mild injection site pain	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1018 10181224	GENRL	Injection site pain/ Injection site pain	1	30AUG2020	2/4	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/5	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Low-Grade Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181226	MUSC	Myalgia/ Muscle Pain	2	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	30AUG2020	2/4	2	Yes		NA	R (02SEP2020)	N/N
		Pyrexia/ Fever	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
	MUSC	Pain in extremity/ Arm pain, left side	1	30AUG2020	2/6	2	Yes		NA/TC	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1018 10181228	NERV	Headache/ Headache	1	20SEP2020	21/3	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Soreness at the injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1018 10181230	NERV	Headache/ Headache	1	06SEP2020	7/2	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181234	MUSC	Arthralgia/ Joint Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	VASC	Hypertension/ Worsening Hypertension	2	07OCT2020	14/C	1	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Pain, injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	SKIN	Urticaria/ Urticaria, Bilateral Arms progressing to lower extremities	2	25SEP2020	2/C	2	Yes		NA/TC	RG	N/N
	16-55/ C4591001 1018 10181244	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181246	INV	Blood pressure increased/ Elevated Blood Pressure	2	27OCT2020	33/C	1	No	O	NA	N	N/N
16-55/ C4591001 1018 10181247	METAB	Hyperlipidaemia/ Hyperlipidemia	2	20OCT2020	26/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1018 10181256	INV	Blood pressure increased/ Elevated Blood Pressure without Dx of Hypertension	2	27OCT2020	33/C	1	No	O	NA	N	N/N
16-55/ C4591001 1018 10181256	NERV	Headache/ Headache	1	02SEP2020	1/6	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chill	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Injection Pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1018 10181261	GENRL	Pyrexia/ Fever, low grade	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181267	NERV	Migraine/ migraine	2	08OCT2020	16/2	1	No	CD	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1018 10181267	VASC	Hypertension/ Worsening of hypertension	2	12OCT2020	18/8	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1018 10181279	GENRL	Pain/ Body aches	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1018 10181283	GENRL	Pyrexia/ Fever, low grade Injection site pain/ Soreness at the Left Shoulder - Injection site	2 1	02OCT2020 12SEP2020	1/2 1/3	1 1	Yes Yes		NA/TC NA	R (03OCT2020) R (14SEP2020)	N/N N/N
16-55/ C4591001 1018 10181284	GENRL	Fatigue/ fatigue	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1018 10181287	GENRL	Injection site pain/ injection site pain Injection site pain/ Soreness at injection site	2 1	03OCT2020 15SEP2020	2/2 2/1	1 1	Yes Yes		NA NA/TC	R (04OCT2020) R (15SEP2020)	N/N N/N
16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	15SEP2020	2/1	1	No	O	NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1018 10181288 16-55/ C4591001 1018 10181294	GASTR	Palatal disorder/ Palate irritation	1	17SEP2020	3/5	1	No	O	NA	R (21SEP2020)	N/N
	RESP	Paranasal sinus discomfort/ Sinus pressure	1	17SEP2020	3/1	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C4591001 1018 10181295	REPRO	Erectile dysfunction/ erectile dysfunction	1	18SEP2020	3/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1018 10181305	GASTR	Diarrhoea/ Loose Stool	1	27SEP2020	7/1	1	No	O	NA	R (27SEP2020)	N/N
16-55/ C4591001 1018 10181314	INJ&P	Bone contusion/ Right Rib Contusion	1	24OCT2020	12/11	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C4591001 1018 10181323	GASTR	Nausea/ Nausea	1	16OCT2020	3/3	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	3/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Limb discomfort/ Left arm heaviness	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/Y
	NERV	Headache/ Headache	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181324	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Back pain/ Worsening of back pain	1	28OCT2020	15/7	2	No	O	NA	R (03NOV2020)	N/N
	EAR	Vertigo/ Vertigo	2	04NOV2020	1/3	3	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	1/3	2	Yes		NA	R (06NOV2020)	N/N
		Pain/ Generalized Body aches	2	04NOV2020	1/2	2	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	1/3	3	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1018 10181326	MUSC	Back pain/ Worsening of chronic back pain	2	04NOV2020	1/C	2	No	O	NA	RG	N/N
	GENRL	Injection site pain/ Pain, Injection Site	1	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	1/2	2	Yes		NA/TC/TCN	R (15OCT2020)	N/N
	GASTR	Noninfective gingivitis/ Pain/Inflammation, Gums, lower, frontal	1	15OCT2020	2/C	2	Yes		NA/TC/TCN	RG	N/N
16-55/ C4591001 1018 10181329	GENRL	Fatigue/ Fatigue	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1018 10181345	GENRL	Injection site pain/ Soreness at the injection site	1	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/N
		Chills/ Chills#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
		Myalgia/ Muscle pain#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1019 10191002	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	26SEP2020	27/C		No	CD	NA	UNK	N/N
16-55/ C4591001 1019 10191047	GENRL	Injection site pain/ Injection Pain Moderate	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain Mild	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1019 10191063	NERV	Head discomfort/ Head Pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1019 10191110	GENRL	Injection site pain/ Pain at injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	INJ&P	Contusion/ Bruise on left upper arm#	3	22JAN2021	15/12	1	No	O	NA	R (02FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1019 10191140	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	22/6	1	No	O	NA	R (17OCT2020)	N/N	
16-55/ C4591001 1019 10191145	NEOPL	Breast cancer/ Ductal carcinoma right Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Invasive ductal breast carcinoma/ Ductal Carcinoma Left Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Metastases to lymph nodes/ Right Axillary Metastases	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
	INJ&P	Intentional overdose/ Overdose Intentional#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
	PSYCH	Suicide attempt/ Attempted Suicide#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
16-55/ C4591001 1019 10191157	GENRL	Injection site pain/ injection site soreness	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
		Pain/ general body aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N	
16-55/ C4591001 1019 10191159	GENRL	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
		Fatigue/ Fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
16-55/ C4591001	GENRL	Pain/ Moderate Body Aches	1	10SEP2020	2/6	2	Yes		NA	R (15SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1019 10191175 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Soreness#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
1019 10191181 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
1019 10191184 16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
1019 10191195 16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site Mild#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
1019 10191197 16-55/ C4591001	NERV	Headache/ Mild Headache#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
1019 10191198 16-55/ C4591001	GENRL	Pain/ Body Aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
1019 10191206 16-55/ C4591001	NERV	Headache/ Mild Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
1019 10191211											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1019 10191213	NERV	Hypoaesthesia/ Left Upper extremity numbness ulnar distal numbness	1	15SEP2020	1/8	2	Yes		NA	R (22SEP2020)	N/N
	NERV	Hypoaesthesia/ Ulnar Distal Numbness	2	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site erythema/ Localized erythematoses dermal reaction Left deltoid at injection site#	4	10JAN2021	3/4	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1019 10191215	BLOOD	Lymphadenopathy/ Axial Lymph Node Swelling Left	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Left arm site injection pain	1	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		Fatigue/ Fatigue	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ L Arm Pain Injection Site	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	INJ&P	Ligament sprain/ Left Ankle Sprain	2	10NOV2020	20/86	1	No	O	NA	R (03FEB2021)	N/N
16-55/ C4591001 1019 10191216	GENRL	Chills/ Chills#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Aches#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1019 10191226	GENRL	Fatigue/ Mild Fatigue	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	INFEC	COVID-19/ COVID-19 Illness	2	28DEC2020	76/27	3	No	O	NA	R (23JAN2021)	Y/N
16-55/ C4591001 1019 10191234	GENRL	Injection site pain/ Left Arm Soreness at Injection Site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1019 10191242	GENRL	Injection site pain/ Injection Site Pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1019 10191249	GASTR	Nausea/ Nausea	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1019 10191254	INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA/TC	R (24OCT2020)	Y/N
	GASTR	Diverticulum/ Diverticulosis	1	24OCT2020	20/C	1	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NEOPL	Benign pancreatic neoplasm/ Serious cystadenoma of Pancreas	1	24OCT2020	20/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1019 10191255	INFEC	Ear infection/ Worsening Left Ear Infection	2	25DEC2020	60/7	2	No	O	NA/TC	R (31DEC2020)	N/N
	MUSC	Myalgia/ Muscle Soreness#	3	20JAN2021	2/4	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1019 10191260	GENRL	Injection site pain/ Left upper arm pain injection site	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1019 10191262	NERV	Headache/ Headache	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1019 10191264	NERV	Headache/ Headache	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	GASTR	Nausea/ Nausea Mild	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Chills/ Chills Mild	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Mild Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1019 10191270		Injection site pain/ Mild Soreness at Injection Site#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1019 10191280	GENRL	Injection site pain/ Injection Site Soreness#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
16-55/ C4591001 1019 10191290	GENRL	Injection site pain/ Injection site muscle ache	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1019 10191292	GENRL	Injection site pruritus/ Pruritus at injection site#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1019 10191293	GENRL	Injection site pain/ Injection Site Soreness	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1019 10191301	GENRL	Injection site pain/ Injection Site Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1019 10191312	GENRL	Injection site pain/ Mild Soreness at Injection Site#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Aches, Mild#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1021 10211032	GENRL	Chills/ Body chills	1	20AUG2020	8/1	1	No	O	NA	R (20AUG2020)	N/N
16-55/ C4591001 1021 10211083	GASTR	Nausea/ Nausea	2	28SEP2020	15/2	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1021 10211104	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		Nausea/ Nausea	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
		Vomiting/ Vomiting	2	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site	2	18SEP2020	2/3	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1021 10211117	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
		Pyrexia/ Fever	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	RESP	Asthma/ Worsening of Asthma	2	19SEP2020	2/C	2	Yes		NA	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1021 10211127	CARD	Acute left ventricular failure/ NYHA Class IV Acute on Chronic Systolic Heart Failure	2	19OCT2020	27/3	3	No	O	NA/TC	R (21OCT2020)	Y/N	
	METAB	Hypokalaemia/ Hypokalemia	2	19OCT2020	27/3	3	No	CD	NA/TC	R (21OCT2020)	N/N	
	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N	
16-55/ C4591001 1021 10211156	INFEC	Conjunctivitis/ R Eye Conjunctivits	1	22SEP2020	19/6	2	No	O	NA/TC	R (27SEP2020)	N/N	
16-55/ C4591001 1021 10211185	RESP	Asthma/ Worsening of Asthma	2	12OCT2020	14/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1021 10211212	INJ&P	Tooth fracture/ Ruptured Tooth	1	27SEP2020	13/2	2	No	O	NA/TC/TCN	R (28SEP2020)	N/N	
16-55/ C4591001 1021 10211223	GENRL	Injection site pain/ muscle soreness at injection site	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ fever	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1021 10211235 16-55/ C4591001	METAB	Hypercholesterolaemia/ Worsening of Hypercholesterolemia	2	29JAN2021	110/C	1	No	O	NA/TC	RG	N/N
1021 10211239 16-55/ C4591001	GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
1021 10211240 16-55/ C4591001	MUSC	Fatigue/ Fatigue Osteoarthritis/ Osteoarthritis Left Leg	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
1021 10211242 16-55/ C4591001	GENRL	Chills/ Chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
1021 10211244 16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
1021 10211247 16-55/ C4591001	GENRL	Injection site pain/ Left Arm Soreness at Injection Site	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
1021 10211247 16-55/ C4591001	GASTR	Vomiting/ Vomiting#	4	26FEB2021	3/3	2	Yes		NA	R (28FEB2021)	N/N
1021 10211247 16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221010	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Moderate Fatigue#	4	04JAN2021	1/C	2	Yes		NA	N	N/N
1022 10221013	GENRL	Chills/ Chills#	4	05JAN2021	2/C	2	Yes		NA	N	N/N
		Pyrexia/ Low Grade Fever#	4	05JAN2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
1022 10221017	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
1022 10221018	GENRL	Fatigue/ Moderate Fatigue	2	09SEP2020	2/4	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221019	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	27/6	1	No	O	NA/TC	R (12OCT2020)	N/N
1022 10221020	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21JAN2021	2/7	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Mild headache#	3	21JAN2021	2/7	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
1022 10221023		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	09SEP2020	1/1	2	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Axillary pain/ Axillary Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
1022 10221024											



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221025	MUSC	Groin pain/ Groin Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	GASTR	Diarrhoea/ Loose Stools	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathy of Head (left side)	2	22SEP2020	15/43	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Mild Chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ Exacerbation of Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
GENRL	Pain/ Body Aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221027	NERV	Headache/ Headache	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ Medial Pain left knee	2	20SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C4591001 1022 10221028	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1022 10221030	GENRL	Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1022 10221031	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221033	MUSC	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
		Myalgia/ Generalized Myalgias#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Myalgia/ Generalized Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	Pyrexia/ Low Grade Fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221048	MUSC	Myalgia/ Generalized Myalgias#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
	GENRL	Chills/ Moderate Chills#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1022 10221049		Fatigue/ Mild fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1022 10221051	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1022 10221052	GASTR	Nausea/ Nausea	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Mild Chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221054	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1022 10221055	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/Y
	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
		Paranasal sinus discomfort/ Sinus Pressure	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
		Upper-airway cough syndrome/ Post Nasal Drainage	2	21SEP2020	6/4	1	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001 1022 10221062	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	16DEC2020	1/3	2	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221064	NERV	Headache/ Moderate Headache#	3	17DEC2020	2/2	2	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Mild Chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Moderate Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1022 10221066	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1022 10221069	GENRL	Fatigue/ Mild Fatigue#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	18JAN2021	1/1	1	Yes		NA	R (18JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Mild Headache#	4	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1022 10221070	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1022 10221074	GENRL	Injection site pain/ Mind Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Moderate fatigue	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Moderate pain at the injection site	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1022 10221076	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/1	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
		Pyrexia/ Fever#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221078	GENRL	Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Mild headache#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	21DEC2020	1/2	2	Yes		NA	R (22DEC2020)	N/N
	GENRL	Axillary pain/ Left Armpit soreness#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Chills/ Chills#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site bruising/ Injection Site Bruising#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Moderate Injection Site Pain#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	INFEC	Genital herpes simplex/ HSV2 outbreak Genital#	4	19JAN2021	8/11	1	No	O	NA	R (29JAN2021)	N/N
16-55/ C4591001 1022 10221080	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221081		Malaise/ Malaise	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	PSYCH	Abnormal dreams/ Unusually Vivid Dreams	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site bruising/ Bruise at the injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	SKIN	Night sweats/ Mild Night Sweats#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1022 10221084	MUSC	Myalgia/ Generalized Myalgias#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Back pain/ Musculoskeletal Pain upper back	1	14SEP2020	19/5	2	No	O	NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Mild Headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Headache*		28AUG2020	1/1	2	Yes		NA	R (28AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221093	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1022 10221094	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1022 10221098	GENRL	Fatigue/ Mild Fatigue#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Mild Injection Site Pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	NERV	Headache/ Mild headache#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	PSYCH	Insomnia/ Insomnia#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1022 10221100	GENRL	Injection site pain/ Moderate Injection site pain	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/Y
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221101	GENRL	Injection site pain/ Mild Injection Site Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Pyrexia/ Low grade fever#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
1022 10221105	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Mild injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
1022 10221106		Vomiting/ Vomiting	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Moderate Injection site pain	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221108	SKIN	Hyperhidrosis/ Sweats	1	02SEP2020	2/1	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/C	2	Yes		NA	N	N/N
		Injection site pain/ Moderate Injection site pain	2	22SEP2020	2/C	2	Yes		NA	N	N/N
		Pyrexia/ Fever	2	22SEP2020	2/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ Moderate Generalized Myalgias	2	22SEP2020	2/C	2	Yes		NA	N	N/N
	GENRL	Injection site pain/ Mild Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
	MUSC	Myalgia/ Moderate Myalgias	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Moderate Headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Moderate Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Left Axillary Adenopathy	2	24SEP2020	3/5	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1022 10221110	GENRL	Injection site pain/ Achy pain around injection site	1	11SEP2020	10/18	1	Yes		NA	R (28SEP2020)	N/N
	GASTR	Nausea/ Mild Nausea	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221111	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Mild Chills#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
		Fatigue/ Mild Fatigue#	3	21JAN2021	2/4	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1022 10221112		Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
	NERV	Headache/ Headache	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1022 10221115	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221120	GENRL	Injection site pain/ Mild Injection Site Pain#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low Grade Fever#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1022 10221122	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/7	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
	GASTR	Nausea/ Moderate Nausea	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Mild Chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Fatigue/ Mild Fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
	Injection site pain/ Mild Injection Site Pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N	
MUSC	Myalgia/ Generalized Myalgias#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221123	GENRL	Injection site pain/ Mild Injection Site Pain#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1022 10221125	MUSC	Myalgia/ Moderate Myalgias	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Moderate Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1022 10221126		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ Mild Chills#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1022 10221127	GENRL	Fatigue/ Moderate Fatigue#	4	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1022 10221128	RESP	Paranasal sinus discomfort/ Sinus Pressure#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Oedema peripheral/ Bilateral Hand Edema	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Rhinorrhoea/ Rhinorrhea	1	05SEP2020	2/1	1	No	O	NA	R (05SEP2020)	N/N
	REPRO	Breast cyst/ Right Breast Cyst	2	20OCT2020	27/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	17DEC2020	1/3	2	Yes		NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Mild Generalized Myalgias#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Mild fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1022 10221131	MUSC	Myalgia/ Mild Myalgias#	4	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1022 10221133	MUSC	Myalgia/ Generalized Moderate Myalgias*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221134	NERV	Headache/ Moderate Headache*		04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Mild Chills	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Injection Site Pain#	3	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	GASTR	Diarrhoea/ Mild Diarrhea#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Mild Headache#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
NERV	Headache/ Headache#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221136	GENRL	Injection site pain/ Moderate Injection site pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1022 10221137	NERV	Cervical radiculopathy/ C7 left sided radiculopathy	2	30SEP2020	2/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1022 10221138	NERV	Headache/ Mild Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Mild Headache	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Mild Headache#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Mild Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1022 10221139	GASTR	Diarrhoea/ Episodes of loose stools	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1022 10221142	INJ&P	Arthropod bite/ Mosquito Bite inner thigh	2	10OCT2020	13/7	1	No	O	NA/TC	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	19JAN2021	1/4	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgias#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Swollen Gland in left arm#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221143	MUSC	Myalgia/ Generalized Myalgias#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Pain in extremity/ Pain in whole left arm#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ Mild Fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Mild Injection Site Pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1022 10221144	GENRL	Injection site pain/ Injection Site pain	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1022 10221147	GENRL	Chills/ Mild Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Mild injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Mild generalized myalgias	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	SKIN	Mechanical urticaria/ Worsening of Dermographism of TRUNK	1	13SEP2020	5/43	1	No	O	NA	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Mild Headache#	3	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221156	NERV	Injection site pain/ Mild Injection Site Pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills	2	05OCT2020	1/1	2	Yes		NA	R (05OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1022 10221164	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Flank pain/ Moderate left flank pain	1	02OCT2020	16/C	2	No	O	NA/TC/TCN	N	N/N
	GENRL	Injection site pain/ Mild Injection Site Pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	EAR	Injection site papule/ Erythematous Papules around injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Vertigo positional/ Benign Paroxysmal Positional Vertigo	2	16OCT2020	9/C	2	No	O	NA	N	N/N
NEOPL	Plasma cell myeloma/ IGA Kappa Multiple Myeloma	2	27NOV2020	51/C	2	No	O	NA	N	Y/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1022 10221179	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
		Vomiting/ Vomitting#	4	16JAN2021	2/1	2	Yes		NA	R (16JAN2021)	N/N
	GENRL	Pyrexia/ Fever 102.0#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16JAN2021	2/1	2	Yes		NA/TC	R (16JAN2021)	N/N
	GENRL	Fatigue/ Worsening Fatigue#	4	17JAN2021	3/2	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1024 10241004	GASTR	Diarrhoea/ Diarrhea	1	14AUG2020	3/1	1	No	O	NA	R (14AUG2020)	N/N
16-55/ C4591001 1024 10241061	GENRL	Pain/ Body Aches	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1024 10241064	GENRL	Injection site pain/ Injection Site Pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1024 10241080	GENRL	Fatigue/ Fatigue#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1024 10241104	MUSC	Arthralgia/ Joint Pain - Elbows	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Arthralgia/ Joint pain - Knees	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Arthralgia/ Joint pain - Neck	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1024 10241114	GENRL	Chills/ chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Pain/ generalized body aches	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1024 10241121†	GENRL	Injection site pain/ Injection Site Pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1024 10241129	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1027 10271049	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1027 10271061	GENRL	Fatigue/ FATIGUE	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
		Pain/ BODY ACHES	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1027 10271105	IMMUN	Drug hypersensitivity/ Allergic Reaction to investigational product	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
	RESP	Pharyngeal swelling/ Throat Swelling	1	29AUG2020	2/11	2	Yes		NA/TC	R (08SEP2020)	N/N
	GASTR	Gastroesophageal reflux disease/ GERD	1	08SEP2020	12/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chest pain/ Left-sided chest pain	1	08SEP2020	12/1	1	No	O	NA/TC	R (08SEP2020)	N/N
	MUSC	Back pain/ Lower back pain	1	08SEP2020	12/4	1	No	O	NA	R (11SEP2020)	N/N
	MUSC	Muscular weakness/ Right leg weakness	1	10SEP2020	14/1	2	No	O	NA/TCN	R (10SEP2020)	N/N
	MUSC	Back pain/ Mid back pain	1	11SEP2020	15/4	1	No	O	NA	R (14SEP2020)	N/N
	NERV	Hypoaesthesia/ Right arm numbness	1	11SEP2020	15/1	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1027 10271129	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	19OCT2020	27/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue post Covid Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1027 10271173		Pain/ Body Aches post Covid Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature post Vaccination 4#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1028 10281002	GENRL	Pain/ generalized body ache#	4	13MAR2021	2/C	1	Yes		NA	N	N/N
	INV	Body temperature increased/ elevated body temperature#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1028 10281003	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	87/C		Yes		NA/W	N	N/N
16-55/ C4591001 1028 10281022	GENRL	Injection site pain/ Left Arm Pain at injection site	1	19AUG2020	1/2	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ body aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Pain in extremity/ left arm soreness	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	BLOOD	Leukocytosis/ leukocytosis	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281023	GASTR	Abdominal pain/ abdominal pain	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
		Nausea/ nausea	2	05OCT2020	19/2	2	No	O	NA/TC	R (06OCT2020)	N/N
	METAB	Dehydration/ dehydration	2	05OCT2020	19/1	2	No	O	NA/TC	R (05OCT2020)	N/N
	RENAL	Acute kidney injury/ acute kidney injury	2	05OCT2020	19/1	2	No	O	NA	R (05OCT2020)	N/N
16-55/ C4591001 1028 10281026	MUSC	Pain in extremity/ bilateral hand pain	2	14SEP2020	4/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1028 10281027	GENRL	Chills/ CHILLS	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
		Pain/ BODY ACHES	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1028 10281028	BLOOD	Lymphadenopathy/ enlarged lymph glands left armpit#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ headache#	3	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	NERV	Dystonia/ Dystonia	1	23AUG2020	4/1	2	No	CD	NA/TC	R (23AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281030	GASTR	Cheilitis/ RASH RIGHT UPPER LIP	1	01SEP2020	13/64	2	No	O	NA/TC	R (03NOV2020)	N/N
1028 10281031	INV	Body temperature increased/ elevated body temperature	1	21AUG2020	2/2	2	Yes		NA	R (22AUG2020)	N/N
1028 10281033	SOCCI	Miscarriage of partner/ miscarriage for pregnant partner	2	22DEC2020	103/1	2	No	O	NA	R (22DEC2020)	Y/N
1028 10281035	GENRL	Injection site erythema/ left arm redness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
		Injection site pain/ left arm soreness at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
		Injection site swelling/ left arm swelling at injection site	1	21AUG2020	1/3	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
		Injection site swelling/ left arm swelling at injection site	2	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
1028 10281043	GASTR	Haemorrhoids/ internal hemorrhoids	2	28SEP2020	15/C	2	No	O	NA	N	N/N
1028 10281043	GENRL	Injection site pain/ left arm soreness at injection site#	4	18JAN2021	1/3	2	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281044	INV	Body temperature increased/ increased body temperature	1	27AUG2020	4/1	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1028 10281050	INFEC	Viral upper respiratory tract infection/ Non-COVID viral Upper respiratory infection	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N
	RESP	Asthma/ mild asthma exacerbation	2	05OCT2020	20/6	2	No	O	NA/TC	R (10OCT2020)	N/N
		Rhinitis allergic/ allergic rhinitis	2	05OCT2020	20/6	2	No	O	NA	R (10OCT2020)	N/N
	GENRL	Pain/ generalized body aches#	4	25FEB2021	2/4	2	Yes		NA	R (28FEB2021)	N/N
	GASTR	Abdominal discomfort/ upset stomach#	4	26FEB2021	3/3	2	Yes		NA	R (28FEB2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	27FEB2021	4/2	2	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1028 10281059	GENRL	Injection site pain/ left arm soreness at injection site.	1	27AUG2020	2/3	2	Yes		NA	R (29AUG2020)	N/N
	REPRO	Breast mass/ left breast lump	1	27AUG2020	2/34	2	No	O	NA	R (29SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	01SEP2020	7/1	2	Yes		NA	R (01SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1028 10281060	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/8	2	Yes		NA	R (03SEP2020)	N/N
	INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1028 10281062	NERV	Migraine/ worsening of migraines	1	15SEP2020	21/23	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1028 10281065	MUSC	Pain in extremity/ SORE ARM, LEFT	1	27AUG2020	1/2	2	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Injection site erythema/ left arm redness at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain at injection site	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1028 10281070	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001	GENRL	Injection site erythema/ LEFT ARM INJECTION SITE REDNESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281075		Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
		Injection site pruritus/ LEFT ARM INJECTION SITE ITCHINESS	1	28AUG2020	1/7	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ injection site soreness left	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
	GASTR	Vomiting/ vomiting	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
		Chills/ rigors	2	19SEP2020	2/1	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1028 10281077	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1028 10281078	GASTR	Nausea/ NAUSEA	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pain/ body aches	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281079	INV	Body temperature increased/ increased body temperature	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ redness at injection site left deltoid#	3	21DEC2020	1/8	2	Yes		NA	R (28DEC2020)	N/N
		Injection site swelling/ swelling at injection site left deltoid#	3	21DEC2020	1/8	2	Yes		NA	R (28DEC2020)	N/N
	GASTR	Abdominal pain upper/ stomach ache#	4	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	12JAN2021	2/3	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1028 10281085	NERV	Headache/ increase in headaches	1	02SEP2020	3/48	2	Yes		NA	R (19OCT2020)	N/N
	INFEC	Ear infection/ bilateral ear infection	1	05SEP2020	6/12	2	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1028 10281087	GENRL	Injection site erythema/ redness at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ pain at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281088	GASTR	Injection site swelling/ swelling at injection site left arm	2	22SEP2020	2/7	2	Yes		NA	R (28SEP2020)	N/N
		Nausea/ nausea	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)
RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1028 10281089	GENRL	Pain/ body aches	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1028 10281090	GENRL	Chills/ body chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		NERV	Headache/ headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)
16-55/ C4591001 1028 10281096	GENRL	Injection site pain/ injection site pain, left	1	01SEP2020	1/3	2	Yes		NA	R (03SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ body chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1028 10281098	GENRL	Chills/ chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1028 10281100	GENRL	Injection site pain/ pain at injection site left side#	3	15FEB2021	1/C	2	Yes		NA	N	N/N
	GENRL	Injection site swelling/ swelling at injection site left side#	3	16FEB2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1028 10281103	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N
		Injection site pruritus/ ITCHINESS AT INJECTION SITE	1	03SEP2020	2/7	2	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1028 10281104	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
	INV	Body temperature increased/ increased body temperature	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1028 10281105	MUSC	Myalgia/ right deltoid muscle pain	1	04SEP2020	3/3	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281112	MUSC	Pain in extremity/ Left Arm Soreness	1	04SEP2020	2/1	2	Yes		NA	R (04SEP2020)	N/N
	GASTR	Haemorrhoids/ internal hemorrhoids	2	18NOV2020	56/C	2	No	O	NA	N	N/N
		Large intestine polyp/ colon polyp, benign	2	18NOV2020	56/1	2	No	O	NA/TCN	R (18NOV2020)	N/N
		Rectal polyp/ rectal polyp, benign	2	18NOV2020	56/1	2	No	O	NA/TCN	R (18NOV2020)	N/N
16-55/ C4591001 1028 10281121	MUSC	Myalgia/ muscle aches	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	2/2	2	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1028 10281122	GENRL	Injection site pain/ left arm soreness at injection site#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/Y
		Injection site reaction/ left arm stiffness at injection site#	3	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/Y
	GENRL	Injection site bruising/ bruising at injection site left arm#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ left arm soreness at injection site#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281124	GENRL	Injection site reaction/ left arm stiffness at injection site#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/Y
		Injection site pain/ left arm soreness at injection site	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1028 10281131	NERV	Headache/ headache	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1028 10281141	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	1/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1028 10281141	GENRL	Fatigue/ fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1028 10281143	GENRL	Pain/ body aches	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		INV	Body temperature increased/ increased body temperature	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281150	GENRL	Pyrexia/ fever	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ left deltoid injection site soreness#	3	08JAN2021	1/4	2	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site warmth/ left deltoid injection site warm#	3	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness right deltoid#	4	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site warmth/ injection site warmth right deltoid#	4	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1028 10281153		Pain/ general body aches#	4	29JAN2021	2/1	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Pain/ generalized body ache#	4	12MAR2021	2/2	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1028 10281155	NERV	Headache/ headache#	4	12MAR2021	2/2	1	Yes		NA	R (13MAR2021)	N/N
	GENRL	Chills/ chills	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ left arm injection site soreness	2	30SEP2020	2/15	2	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	2/18	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	30SEP2020	2/18	2	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Bone pain/ bone aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N
		Myalgia/ muscle aches	2	01OCT2020	3/17	2	Yes		NA	R (17OCT2020)	N/N
	NERV	Migraine/ worsening of migraine	2	01OCT2020	3/17	2	No	O	NA	R (17OCT2020)	N/N
	EYE	Lacrimation increased/ watery eyes	2	05OCT2020	7/C	2	Yes		NA	N	N/N
	EYE	Vitreous detachment/ posterior vitreous detachment right eye	2	09NOV2020	42/C	2	No	O	NA	N	N/N
16-55/ C4591001 1028 10281158	METAB	Impaired fasting glucose/ impaired fasting glucose	1	15SEP2020	6/C	2	No	O	NA/TC	N	N/N
	GASTR	Nausea/ nausea	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pain/ body aches	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ worsening headache	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1028 10281167	GENRL	Injection site pain/ left arm soreness at injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001	INV	Heart rate increased/ increased heart rate	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281170	GENRL	Chills/ body chills	2	30SEP2020	1/2	2	Yes	NA	R	(01OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	1/2	2	Yes	NA	R	(01OCT2020)	N/N
	MUSC	Arthralgia/ joint aches	2	30SEP2020	1/2	2	Yes	NA	R	(01OCT2020)	N/N
		Myalgia/ muscle aches	2	30SEP2020	1/2	2	Yes	NA	R	(01OCT2020)	N/N
	NERV	Headache/ headache	2	30SEP2020	1/2	2	Yes	NA	R	(01OCT2020)	N/N
16-55/ C4591001 1028 10281174	NERV	Dizziness/ lightheadedness	1	14SEP2020	1/1	2	Yes	NA	R	(14SEP2020)	N/Y
16-55/ C4591001 1028 10281177	GENRL	Chills/ chills	2	06OCT2020	2/2	2	Yes	NA	R	(07OCT2020)	N/N
		Fatigue/ fatigue	2	06OCT2020	2/2	2	Yes	NA	R	(07OCT2020)	N/N
		Pain/ body aches	2	06OCT2020	2/2	2	Yes	NA	R	(07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	2	Yes	NA/TC	R	(07OCT2020)	N/N
16-55/ C4591001 1028 10281183	GENRL	Fatigue/ fatigue	2	07OCT2020	2/3	2	Yes	NA	R	(09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281184	INV	Injection site pain/ left arm injection site pain	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Pain/ body aches	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
		Body temperature increased/ elevated body temperature	2	07OCT2020	2/3	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Presyncope/ vasovagal episode*		15SEP2020	1/1	2	No	O	NA/TCN	R (15SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site left arm#	3	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site erythema/ injection site redness#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain left deltoid#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
		Injection site swelling/ swelling of injection site left deltoid#	3	19DEC2020	2/3	2	Yes		NA	R (21DEC2020)	N/N
Pyrexia/ Fever#		4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281198	GENRL	Pain/ body aches	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	10OCT2020	3/4	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1028 10281200	GENRL	Injection site pain/ right arm soreness (injection site)#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1028 10281202	INJ&P	Upper limb fracture/ left arm fracture	1	23SEP2020	6/32	2	No	O	NA/TCN	R (24OCT2020)	N/N
16-55/ C4591001 1028 10281205	GENRL	Injection site pain/ right arm soreness at injection site#	3	26JAN2021	1/4	2	Yes		NA	R (29JAN2021)	N/N
	BLOOD	Lymphadenopathy/ enlarged lymph glands left armpit#	4	16FEB2021	1/6	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1028 10281207	GENRL	Pyrexia/ fever	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281208	INFEC	Tooth infection/ tooth infection left lower side	1	06OCT2020	16/13	2	No	O	NA/TC	R (18OCT2020)	N/N
	MUSC	Back pain/ acute back pain	2	16DEC2020	66/6	2	No	O	NA/TC	R (21DEC2020)	N/N
16-55/ C4591001 1028 10281213	NERV	Presyncope/ vasovagal episode*		30SEP2020	1/1	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1028 10281221	GENRL	Injection site pain/ left arm soreness at injection site	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	26JAN2021	1/8	2	Yes		NA	R (02FEB2021)	N/Y
	GENRL	Injection site hypoaesthesia/ left arm numbness at injection site#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/Y
16-55/ C4591001 1028 10281223	GENRL	Injection site pain/ left arm soreness at injection site	1	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1028 10281224	GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281227	GENRL	Injection site pain/ left arm soreness at injection site	1	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1028 10281228	GENRL	Injection site pain/ left deltoid soreness at injection site	1	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Arthralgia/ achiness in shoulders	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16OCT2020	3/2	2	Yes		NA	R (17OCT2020)	N/N
	INFEC	Trichomoniasis/ trichomoniasis	2	28OCT2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1028 10281229	REPRO	Erectile dysfunction/ ERECTION DYSFUNCTION	2	15JAN2021	93/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1028 10281237	GENRL	Chills/ chills	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
		Pain/ body aches	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
		Pyrexia/ fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281246	NERV	Headache/ headache	2	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site nodule/ injection site nodule left arm#	3	16FEB2021	1/11	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site left arm#	3	17FEB2021	2/7	2	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1028 10281247	GENRL	Injection site erythema/ redness injection site left deltoid	1	07OCT2020	1/15	2	Yes		NA	R (21OCT2020)	N/N
		Injection site swelling/ swelling injection site left deltoid	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	GASTR	Vomiting/ vomiting	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pain/ body aches	2	28OCT2020	1/3	2	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ chills	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	29OCT2020	2/2	2	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Headache/ headache	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1028 10281253	GENRL	Pain/ body aches	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ fever	1	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site erythema/ injection site redness right arm	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Injection site swelling/ injection site swelling right arm	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
		Pain/ body aches	2	03NOV2020	1/2	2	Yes		NA	R (04NOV2020)	N/N
	GASTR	Nausea/ nausea	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
		Vomiting/ vomiting	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1028 10281256	GENRL	Pyrexia/ fever	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1028 10281257	GENRL	Chills/ chills	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N
		Pain/ body aches	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N
	INV	Body temperature increased/ increased body temperature	2	06NOV2020	2/1	2	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1028 10281271	MUSC	Myalgia/ generalized muscle pain	1	26OCT2020	6/3	2	Yes		NA	R (28OCT2020)	N/N
	NERV	Headache/ worsening headache	1	26OCT2020	6/3	2	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1028 10281274	NERV	Headache/ worsening of headache	1	22OCT2020	1/4	2	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	23OCT2020	2/4	2	Yes		NA	R (26OCT2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ fatigue	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	INV	Body temperature increased/ elevated body temperature	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1028 10281275	GENRL	Chills/ chills#	4	05MAR2021	1/2	2	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1028 10281276	GASTR	Nausea/ nausea	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1028 10281279	IMMUN	Food allergy/ allergy reaction: avocado	2	13DEC2020	25/1	2	No	O	NA/TC	R (13DEC2020)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ urinary tract infection	2	27NOV2020	11/3	2	No	O	NA/TC	R (29NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1028 10281284 16-55/ C4591001	GENRL	Pain/ body aches#	3	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
1028 10281285 16-55/ C4591001	NERV	Headache/ headache#	3	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
1028 10281287 16-55/ C4591001	INV	Body temperature increased/ increased body temperature	1	29OCT2020	2/1	2	Yes		NA	R (29OCT2020)	N/N
1030 10301011 16-55/ C4591001	GENRL	Injection site pain/ injection site soreness left deltoid	2	17NOV2020	2/1	2	Yes		NA	R (17NOV2020)	N/N
1030 10301011 16-55/ C4591001	GENRL	Malaise/ general malaise	2	17NOV2020	2/1	2	Yes		NA	R (17NOV2020)	N/N
1030 10301011 16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
1030 10301011 16-55/ C4591001	GENRL	Injection site pain/ left arm pain from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
1030 10301022 16-55/ C4591001	GENRL	Injection site pain/ right arm pain from injection site#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
1030 10301026 16-55/ C4591001	GENRL	Injection site pain/ left arm pain from injection#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1030 10301030	INFEC	Urinary tract infection/ urinary tract infection	1	05SEP2020	5/11	1	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1030 10301041	GENRL	Injection site pain/ left arm pain from injection#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
16-55/ C4591001 1030 10301049	GENRL	Injection site pain/ left arm soreness from injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1030 10301055	MUSC	Pain in extremity/ left arm pain	1	01OCT2020	24/5	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1030 10301061	RENAL	Nephrolithiasis/ kidney stone	1	30SEP2020	22/10	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1030 10301069	GENRL	Fatigue/ Fatigue#	2	22DEC2020	82/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Right Arm injection site pain#	2	22DEC2020	82/2	1	Yes		NA	R (23DEC2020)	N/N
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	4	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ Elevated Body Temperature#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1030 10301075	GENRL	Injection site pain/ left arm pain from injection site#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1030 10301077	GENRL	Chills/ chills#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Injection site pain/ left arm pain at injection point#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
16-55/ C4591001 1030 10301099	GENRL	Injection site pain/ left arm pain from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1030 10301110	INFEC	Pharyngitis streptococcal/ pharyngitis streptococcal#	2	17JAN2021	101/14	2	No	O	NA/TC	R (30JAN2021)	Y/N
16-55/ C4591001 1030 10301113	GENRL	Injection site pain/ left arm pain from injection site#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
16-55/ C4591001 1030 10301134	GENRL	Injection site pain/ left arm soreness from injection#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1030 10301146	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Injection site pain/ left arm soreness from injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1036 10361021	GENRL	Chills/ Subject developed chills after injection	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	RESP	Cough/ Subject developed cough after injection.	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1036 10361074	GENRL	Chills/ Chills#	4	18FEB2021	1/C	1	Yes		NA	N	N/N
		Pain/ Body Soreness#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1036 10361125	GASTR	Nausea/ Nausea#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Asthenia/ Body Weakness#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1036 10361126	GENRL	Pyrexia/ Feverish#	4	19FEB2021	2/2	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/Y
	NERV	Headache/ Headache	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1036 10361141	GENRL	Lethargy/ Lethargy	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ muscle pain at injection site#	3	04FEB2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1036 10361144	GENRL	Injection site pain/ Injection Site Pain*		26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Pain/ Body Aches	1	28OCT2020	3/5	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea	1	29OCT2020	4/3	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371007		Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1037 10371008	GENRL	Fatigue/ FATIGUE	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
		Pyrexia/ LOW GRADE FEVER	2	09SEP2020	1/1	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1037 10371041	GASTR	Diarrhoea/ DIARRHEA	2	11SEP2020	1/13	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	21SEP2020	11/1	1	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1037 10371047	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	29SEP2020	20/17	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1037 10371051	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	2	09DEC2020	87/9	2	No	O	NA/TC	R (17DEC2020)	N/N
16-55/ C4591001 1037 10371052	GENRL	Pyrexia/ LOW GRADE FEVER	1	24AUG2020	1/2	1	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/30	1	No	CD	NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	EAR	Ear pain/ EAR ACHE	2	18SEP2020	5/11	1	No	O	NA/TC	R (28SEP2020)	N/N
	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	18SEP2020	5/3	1	Yes		NA	R (20SEP2020)	N/N
	RESP	Dyspnoea/ INCREASED SHORTNESS OF BREATH#	2	31JAN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1037 10371067	GENRL	Fatigue/ FATIGUE	2	14SEP2020	1/3	2	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1037 10371076	SKIN	Dermatitis allergic/ ALLERGIC RASH	1	26AUG2020	1/26	1	No	O	NA/TC	R (20SEP2020)	N/N
	IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
	RESP	Wheezing/ WORSENING OF WHEEZING	1	09SEP2020	15/12	2	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1037 10371124	GENRL	Pyrexia/ FEVER	1	03SEP2020	2/1	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1037 10371125	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371154	MUSC	Myalgia/ MUSCLE PAIN	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ Low grade fever	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1037 10371170	MUSC	Myalgia/ Generalized muscle aches	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1037 10371183		Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ RIGHT ARM SORENESS INJECTION SITE	2	02OCT2020	2/14	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1037 10371198	PSYCH	Anxiety disorder/ ANXIETY DISORDER	2	OCT2020	1/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY#	4	08FEB2021	29/C	1	No	O	NA	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371214	GENRL	Injection site induration/ INJECTION SITE REACTION LEFT ARM INDURATION	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1037 10371216	GENRL	Injection site pain/ PAIN AT LEFT UPPER ARM INJECTION SITE	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	16SEP2020	2/5	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ ERYTHEMA AT INJECTION SITE LEFT UPPER ARM	1	17SEP2020	3/4	2	Yes		NA/TCN	R (20SEP2020)	N/N
16-55/ C4591001 1037 10371223	GENRL	Chills/ CHILLS	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ FEVER	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1037 10371236	GASTR	Diarrhoea/ DIARRHEA	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	RESP	Dysphonia/ WORSENING OF HOARSENESS	2	20OCT2020	13/25	1	No	O	NA/TC/TCN	R (13NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371237	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1037 10371272	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ FEVER	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1037 10371277	MUSC	Pain in extremity/ ARM PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain in jaw/ JAW PAIN LEFT	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1037 10371290	INFEC	Tooth infection/ TOOTH INFECTION	1	06OCT2020	12/8	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1037 10371306	NERV	Headache/ HEADACHE	1	30SEP2020	1/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ RIGHT LEG PAIN	2	27NOV2020	40/6	1	No	O	NA	R (02DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371308 16-55/ C4591001	MUSC	Muscle spasms/ LEFT LEG MUSCLE SPASMS	1	06OCT2020	7/6	2	No	O	NA	R (11OCT2020)	N/N
1037 10371309 16-55/ C4591001	GASTR	Abdominal pain upper/ PAIN IN LEFT UPPER QUADRANT	2	24OCT2020	2/C	1	No	O	NA	N	N/N
1037 10371312 16-55/ C4591001	GASTR	Diarrhoea/ DIARRHEA	1	04OCT2020	3/6	1	Yes		NA	R (09OCT2020)	N/N
1037 10371317	INV	Blood glucose increased/ ELEVATED GLUCOSE	1	10OCT2020	9/9	1	No	O	NA	R (18OCT2020)	N/N
	SKIN	Rash/ RASH ON CHEST	1	17OCT2020	16/10	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001 1037 10371330	SKIN	Dermatitis contact/ CONTACT DERMATITIS LEGS AND BREASTS	2	24NOV2020	29/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1037 10371336	GENRL	Chills/ CHIILLS	1	20OCT2020	8/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	20OCT2020	8/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ DIARRHEA	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1037 10371342	GENRL	Chills/ CHILLS	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
		Pyrexia/ FEVER	2	07NOV2020	2/3	1	Yes		NA	R (09NOV2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	07NOV2020	2/3	2	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1037 10371353	RENAL	Nephrolithiasis/ RIGHT KIDNEY RENAL STONE	2	26DEC2020	46/3	2	No	O	NA/TC	R (28DEC2020)	N/N
16-55/ C4591001 1037 10371359	GENRL	Injection site pain/ LEFT SHOULDER MUSCLE ACHE AT INJECTION SITE	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1038 10381002	GENRL	Fatigue/ fatigue	1	09SEP2020	23/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1038 10381003	GENRL	Chills/ Chills	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
		Pain/ Body aches	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1038 10381014	GASTR	Pain/ body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Nausea/ nausea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1038 10381016	GENRL	Pyrexia/ low grade fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1038 10381022	GENRL	Chills/ Chills	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
		Injection site erythema/ Redness at injection site	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
		Injection site swelling/ swelling at injection site	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
		Pain/ Body aching	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
16-55/ C4591001 1038 10381023	GENRL	Fatigue/ fatigue	2	10SEP2020	2/8	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection Site#	3	14JAN2021	2/8	1	Yes		NA	R (21JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1038 10381044		Injection site pruritus/ Itching at Injection Site#	3	14JAN2021	2/8	1	Yes		NA	R (21JAN2021)	N/N
		Injection site swelling/ Swelling at Injections Site#	3	14JAN2021	2/8	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1038 10381091	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1038 10381094	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection Site Tenderness	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ injection site tenderness	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1038 10381095	GENRL	Injection site pain/ Injection site tenderness	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1038 10381096	GENRL	Chills/ chills	1	06SEP2020	3/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1038 10381121	NERV	Restless legs syndrome/ Restless Leg Syndrome	2	29OCT2020	23/C	1	No	O	NA/TC	N	N/N
	RESP	Sleep apnoea syndrome/ Obstructive Sleep Apnea	2	29OCT2020	23/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1038 10381131	GASTR	Nausea/ nausea	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Chills/ chills	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ aching	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1038 10381133	GENRL	Injection site pain/ injection site tenderness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/Y
16-55/ C4591001 1038 10381136	GENRL	Injection site pain/ injection site tenderness	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	29SEP2020	9/C	1	No	O	NA	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1038 10381138	GASTR	Diarrhoea/ diarrhea#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N
		Vomiting/ vomiting#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N
	GENRL	Chills/ chills#	3	05JAN2021	2/1	1	Yes		NA/TC	R (05JAN2021)	N/N
		Pyrexia/ fever#	3	05JAN2021	2/1	2	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1039 10391003	GENRL	Injection site pain/ Injection Arm Soreness#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1039 10391004	GENRL	Pain/ GENERALIZED ACHING	2	12SEP2020	2/7	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1039 10391009	MUSC	Myalgia/ left arm muscle soreness#	3	19JAN2021	2/3	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1039 10391011	GENRL	Injection site pain/ Injection site soreness#	4	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391016	RESP	Oropharyngeal pain/ sore throat	1	25AUG2020	2/2	1	No	O	NA	R (26AUG2020)	N/N
16-55/ C4591001 1039 10391017	GENRL	Injection site pain/ left arm injection site pain#	3	18JAN2021	1/4	2	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever (101)#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	INFEC	Taeniasis/ taeriasis#	4	12FEB2021	5/26	1	No	O	NA/TC	R (09MAR2021)	N/N
	GASTR	Abdominal pain upper/ left upper abdomen pain#	4	21FEB2021	14/3	1	No	O	NA	R (23FEB2021)	N/N
16-55/ C4591001 1039 10391025	GENRL	Injection site pain/ injection site soreness#	3	22JAN2021	1/5	1	Yes		NA	R (26JAN2021)	N/N
		Pain/ generalized body aches#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ right upper arm pain	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391026	RENAL	Dysuria/ dysuria,increased frequency	1	01SEP2020	8/53	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1039 10391036	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Asthenia/ generalized weakness	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Tension headache/ TENSION HEADACHE	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1039 10391045	RESP	Oropharyngeal pain/ sore throat	1	28AUG2020	1/2	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N
		Pain/ left side body aches#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391057	MUSC	Myalgia/ generalized muscle aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Pain/ general body ache#	3	18JAN2021	1/2	2	Yes		NA/TC	R (19JAN2021)	N/N
16-55/ C4591001 1039 10391058	GENRL	Injection site pain/ Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Chills/ chills	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1039 10391065	MUSC	Joint stiffness/ multiple joint stiffness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Injection site pain/ injection arm soreness#	4	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ fever#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1039 10391067	GENRL	Injection site pain/ injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIAS	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1039 10391076	GENRL	Injection site pain/ left arm injection site soreness	1	02SEP2020	1/5	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1039 10391085	GENRL	Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1039 10391086	INJ&P	Wrist fracture/ broken left wrist	2	12DEC2020	80/34	1	No	O	NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection arm soreness#	4	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1039 10391087	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1039 10391097	MUSC	Fatigue/ fatigue#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
		Injection site pain/ injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
		Pyrexia/ fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
		Myalgia/ muscle aches#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N	
	NERV	Headache/ headache#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N	
	GENRL	Chills/ CHILLS	2	25SEP2020	1/4	2	Yes		NA	R (28SEP2020)	N/N	
	16-55/ C4591001 1039 10391099	GENRL	Fatigue/ FATIGUE	2	25SEP2020	1/5	2	Yes		NA	R (29SEP2020)	N/N
			Injection site pain/ INJECTION SITE PAIN	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
			Pain/ GENERALIZED ACHING	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
			Pyrexia/ FEVER	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
Injection site pain/ left arm injection site soreness#			3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N	
INFEC			Urinary tract infection/ UTI#	3	11FEB2021	15/9	1	No	O	NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391104	GENRL	Injection site pain/ injection site soreness	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1039 10391108	GENRL	Injection site pain/ left arm injection site soreness#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1039 10391109	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1039 10391110	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1039 10391112	GENRL	Injection site pain/ injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391114	GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Piriformis syndrome/ left hip piriformi syndrome#	3	24JAN2021	11/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1039 10391115	GENRL	Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1039 10391119	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site soreness	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ bodyache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1039 10391120	GENRL	Fatigue/ fatigue#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ injection site soreness#	3	19JAN2021	1/3	1	Yes		NA/TC	RS (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391127	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathy Left armpit#	4	12FEB2021	4/4	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pain/ Aches-generalized	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1039 10391128		Pyrexia/ fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ FEVER	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
MUSC	Myalgia/ MYALGIAS	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
NERV	Headache/ HEADACHE	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391136	GENRL	Injection site pain/ injection arm soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1039 10391153	INV	Body temperature increased/ Increased Body temperature	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Paraesthesia/ Finger tingling in injection arm	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1039 10391157	GENRL	Injection site pain/ injection site pain	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1039 10391166	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1039 10391168	GENRL	Injection site pain/ Injection Arm Soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391172	GENRL	Injection site pain/ Injection Arm Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ injection site soreness	1	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Pain/ generalized aching	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1039 10391175	GENRL	Chills/ chills	2	25OCT2020	3/1	1	Yes		NA/TC	R (25OCT2020)	N/N
	PSYCH	Anxiety/ recurrent anxiety	1	05OCT2020	1/C	1	No	O	NA	RG	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1039 10391176	GENRL	Fatigue/ fatigue	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1039 10391178	GENRL	Injection site pain/ injection arm soreness#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391180	GENRL	Fatigue/ fatigue#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	CARD	Palpitations/ pounding heart	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
	NERV	Dizziness/ lightheaded	1	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
	MUSC	Pain in extremity/ Injection Arm Pain#	3	18JAN2021	1/4	2	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1039 10391181	GENRL	Pyrexia/ Fever(100.4)#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Paraesthesia/ left arm tingling	2	28OCT2020	1/8	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1039 10391185	INFEC	Chronic sinusitis/ exacerbation of chronic sinusitis	1	28OCT2020	21/7	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1039 10391198	GENRL	Pain/ generalized achiness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Migraine with aura/ ocular migraine#	3	27JAN2021	7/4	2	No	O	NA	R (30JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Vomiting/ Vomitting#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Pain/ general Body Aches#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1039 10391199	GENRL	Injection site pain/ injection site soreness	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1039 10391208	MUSC	Arthralgia/ Left posterior shoulder pain	2	17NOV2020	8/36	1	No	O	NA/TC	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391212	GENRL	Injection site pain/ Injection Site Soreness#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1039 10391214	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/Y
	GENRL	Injection site pain/ Injection arm soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391225	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ chills#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ fatigue#	4	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ fever#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1039 10391233	GENRL	Injection site pain/ injection site soreness#	4	28JAN2021	2/1	1	Yes		NA	RS (28JAN2021)	N/N
16-55/ C4591001 1039 10391237	GENRL	Chills/ chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Pain/ generalized aches	2	20NOV2020	1/2	1	Yes		NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1039 10391239	NERV	Fatigue/ fatigue#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
		Headache/ headache#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1039 10391239	GENRL	Injection site pain/ Injection Arm Soreness#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1039 10391240	GENRL	Injection site pain/ right arm injection soreness*		30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	NERV	Headache/ headache	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	RESP	Sinus congestion/ sinus congestion	2	24NOV2020	2/2	1	No	O	NA	R (25NOV2020)	N/N
16-55/ C4591001 1039 10391243	GENRL	Injection site pain/ Injection Arm Soreness#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1039 10391254	GENRL	Injection site pain/ injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1042 10421001	GENRL	Chills/ Chills#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body Aches#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1042 10421028	INJ&P	Chest injury/ bruised ribs	1	22AUG2020	20/13	2	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1042 10421034	SKIN	Acne/ Acne	2	NOV2020	69/C	2	No	O	NA/TC	N	N/N
	HEPAT	Cholecystitis/ cholecystitis#	2	07FEB2021	167/3	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N
16-55/ C4591001 1042 10421035	GASTR	Diarrhoea/ Diarrhea#	3	28FEB2021	4/C	2	Yes		NA	RG	N/N
	GENRL	Chills/ Chills#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N
	MUSC	Myalgia/ Muscle Pain#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N
	NERV	Headache/ Headache#	3	28FEB2021	4/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1042 10421041	INFEC	Cystitis/ bladder infection	2	21SEP2020	27/15	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1042 10421092	NERV	Headache/ headaches	2	15SEP2020	6/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1042 10421109 16-55/ C4591001	INJ&P	Ankle fracture/ Fractured Left Ankle	2	04FEB2021	150/26	2	No	O	NA/TCN	R (01MAR2021)	N/N
1042 10421115 16-55/ C4591001	GENRL	Chills/ Chills	2	14SEP2020	6/3	1	Yes		NA	R (16SEP2020)	N/N
1042 10421125 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	14SEP2020	6/3	1	Yes		NA	R (16SEP2020)	N/N
1042 10421128 16-55/ C4591001	GENRL	Chills/ Chills#	3	03MAR2021	1/2	1	Yes		NA	R (04MAR2021)	N/N
1042 10421129 16-55/ C4591001	GENRL	Chest discomfort/ Chest Tightness#	3	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N
1042 10421129 16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	19AUG2020	1/C		No	O	NA	UNK	N/N
1042 10421140 16-55/ C4591001	METAB	Hypercholesterolaemia/ Hyperchlesterolemia	2	18DEC2020	102/C	1	No	O	NA/TC	N	N/N
1042 10421143 16-55/ C4591001	GENRL	Pyrexia/ fever	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1042 10421158	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pain/ Bodyache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Low Grade Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1042 10421161	NERV	Headache/ Headache	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ Bodyaches	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1042 10421163		Pyrexia/ Low Grade Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	INV	Blood cholesterol increased/ High Cholesterol#	2	23FEB2021	162/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1042 10421169	GENRL	Pain/ Body Aches#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever 100.9#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1042 10421175	INFEC	Sinusitis/ Sinus Infection	2	22JAN2021	124/6	1	No	O	NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1042 10421177	INJ&P	Ligament rupture/ Torn ACL Left Knee	2	04JAN2021	106/15	2	No	CND	NA/TCN	R (18JAN2021)	N/N
16-55/ C4591001 1042 10421196	INJ&P	Meniscus injury/ Torn Meniscus	2	27JAN2021	122/1	2	No	O	NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1042 10421198	MUSC	Arthralgia/ SHOULDER PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
		Neck pain/ NECK PAIN RIGHT SIDE	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1042 10421206	GENRL	Chills/ Chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1042 10421210	VASC	Hypertension/ High Blood Pressure	2	10DEC2020	74/50	1	No	O	NA/TC	R (28JAN2021)	N/N
	PSYCH	Attention deficit hyperactivity disorder/ Attention-Deficit/Hyperactivity Disorder#	4	25FEB2021	4/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1042 10421216		Pyrexia/ Fever	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1042 10421217	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy#	3	20JAN2021	3/C		No	O	NA	UNK	N/N
16-55/ C4591001 1042 10421222	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1042 10421232	RESP	Oropharyngeal pain/ Sore Throat	1	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
	RESP	Respiratory tract congestion/ Chest Congestion#	2	27JAN2021	120/8	2	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1042 10421238	VASC	Hypertension/ Hypertension	2	12OCT2020	13/C	1	No	CD	NA/TC	N	N/N
16-55/ C4591001 1042 10421243	INFEC	Ear infection/ lt ear infection	1	17SEP2020	7/C	1	No	O	NA/TC	N	N/N
	INV	Blood cholesterol increased/ High Cholesterol	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Blood potassium decreased/ Low Potassium	1	24SEP2020	14/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1042 10421259	BLOOD	Lymphadenopathy/ ENLARGED LYMPHNODES LEFT AXILLA	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1042 10421265	MUSC	Pain in extremity/ Medical Pain in Thigh (Left)	2	DEC2020	21/C	1	No	O	NA	N	N/N
16-55/ C4591001 1044 10441011	MUSC	Back pain/ low back pain	2	11SEP2020	2/1	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1044 10441028	MUSC	Myalgia/ generalized Myalgias	2	16SEP2020	2/34	2	Yes		NA/TC	R (19OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441029	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1044 10441037	MUSC	Myalgia/ generalized Myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1044 10441045	NERV	Sciatica/ Sciatica (Right side)	2	06JAN2021	114/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1044 10441048	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ generalized Myalgias	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1044 10441053	RENAL	Urinary retention/ urinary retention	2	12JAN2021	119/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1044 10441054	GENRL	Chills/ chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ FATIGUE	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441057	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/Y
16-55/ C4591001 1044 10441058	RENAL	Nephrolithiasis/ Renal Calculi	1	29AUG2020	1/36	2	No	O	NA	R (03OCT2020)	N/Y
	GASTR	Diarrhoea/ diarrhea	1	13SEP2020	3/1	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1044 10441060	SKIN	Alopecia/ hair loss	2	05OCT2020	15/C	1	No	O	NA	N	N/N
16-55/ C4591001 1044 10441069	SKIN	Dermatitis contact/ adhesive tape hypersensitivity extremities#	3	02JAN2021	16/1	1	No	O	NA/TC	R (02JAN2021)	N/N
16-55/ C4591001 1044 10441071	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Pyrexia/ fever	2	23SEP2020	2/1	3	Yes		NA/TC	R (23SEP2020)	N/N
		Arthralgia/ joint pain	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
		Myalgia/ generalized Myalgia	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441076	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1044 10441077	GASTR	Mouth ulceration/ ORAL ulcer	1	05SEP2020	3/2	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1044 10441079	GENRL	Chills/ chills	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	25SEP2020	1/32	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1044 10441086	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	1/1	1	No	O	NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1044 10441088	GENRL	Fatigue/ fatigue	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain	2	26SEP2020	2/5	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ generalized myalgia	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ headache	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
	INFEC	Sinusitis bacterial/ Bacterial sinusitis#	2	22FEB2021	151/10	1	No	O	NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1044 10441099	INFEC	Gastroenteritis/ gastroenteritis	2	05OCT2020	7/1	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C4591001 1044 10441101	INFEC	Furuncle/ boil inguinal area	1	22SEP2020	13/36	1	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1044 10441102	INJ&P	Corneal abrasion/ Corneal abrasion (left)	1	27SEP2020	18/3	1	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1044 10441119	GENRL	Chills/ chills	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
		Fatigue/ fatigue	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	1/3	1	Yes		NA/TC/TCN	R (15OCT2020)	N/N
16-55/ C4591001 1044 10441122	GENRL	Pyrexia/ fever#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441123	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	1	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1044 10441127	GENRL	Chills/ chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ General fatigue	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ fever	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia (mild) generalized	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1044 10441129	GENRL	Pyrexia/ FEVER	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia GENERALIZED	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1044 10441133	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1044 10441139	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ injection site pain	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	SKIN	Angioedema/ Angioedema face	2	16OCT2020	3/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1044 10441142	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441146	INFEC	Otitis externa/ otitis externa (left ear)	1	27SEP2020	4/8	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1044 10441152†	GASTR	Mouth ulceration/ oral Ulcer	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N
		Stomatitis/ Stomatitis	2	24OCT2020	6/3	1	No	O	NA	R (26OCT2020)	N/N
	NEOPL	Breast cancer/ breast cancer initial diagnosis	2	28DEC2020	71/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1044 10441153	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site erythema/ redness to injection site	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		Pyrexia/ fever	2	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1044 10441157	GENRL	Chills/ Chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441163	GENRL	Chills/ chills	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
		Fatigue/ fatigue	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Intervertebral disc protrusion/ Worsening of herniated disc	2	05JAN2021	72/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04MAR2021	1/1	1	Yes		NA/TC/W	R (04MAR2021)	N/N
16-55/ C4591001 1044 10441164	MUSC	Myalgia/ generalized myalgia	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ headache	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1044 10441165	GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	MUSC	Myalgia/ myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GASTR	Nausea/ nausea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
		Injection site pain/ injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
		Pyrexia/ fever	2	09NOV2020	1/2	3	Yes		NA/TC	R (10NOV2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
	INJ&P	Foreign body/ Foreign object in finger	2	20NOV2020	12/5	1	No	O	NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1044 10441166	GENRL	Injection site pain/ Injection site pain	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ fever	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1044 10441171	INFEC	Tooth abscess/ TOOTH ABSCESS	2	10NOV2020	14/9	1	No	O	NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1044 10441177	GENRL	Fatigue/ Fatigue	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ Injection site pain	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1044 10441186	GASTR	Irritable bowel syndrome/ Worsening of IBS	2	23NOV2020	28/C	1	No	O	NA	RG	N/N
	NERV	Headache/ headache	2	02DEC2020	27/1	1	No	O	NA/TC	R (02DEC2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	02DEC2020	27/1	1	No	O	NA/TC	R (02DEC2020)	N/N
16-55/ C4591001 1044 10441190		Sneezing/ sneezing	2	02DEC2020	27/1	1	No	O	NA	R (02DEC2020)	N/N
	GENRL	Fatigue/ worsening fatigue	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
		Pyrexia/ Fever	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1044 10441218	NERV	Headache/ headache	2	08NOV2020	3/3	1	Yes		NA	R (10NOV2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
		Nausea/ nausea	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
	RESP	Reflux laryngitis/ Laryngopharyngeal Reflux	2	DEC2020	1/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1044 10441234 16-55/ C4591001 1044 10441237	GENRL  NERV	Injection site pain/ injection site pain#  Headache/ headache#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1044 10441240	GASTR	Nausea/ nausea	1	09DEC2020	17/1	1	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1044 10441242	NERV  SKIN	Dizziness/ dizziness  Eczema/ Worsening of eczema (face)#	1  2	24NOV2020  26FEB2021	1/1  74/3	1	Yes  No	  O	NA  NA/TC	R  R (28FEB2021)	N/N  N/N
16-55/ C4591001 1044 10441244	GENRL	Injection site pain/ injection site pain	1	24NOV2020	1/4	1	Yes		NA	R (27NOV2020)	N/N
16-55/ C4591001 1044 10441246	INFEC	Otitis media/ otitis media (Left ear)	1	02JAN2021	6/6	1	No	O	NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1046 10461030	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1046 10461046	BLOOD	Injection site swelling/ Swollen Left Arm at Injection Site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Lymphadenopathy/ Swollen Lymph Node on left side of Neck	2	14SEP2020	7/7	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1046 10461091	NERV	Migraine/ Migraine	2	15SEP2020	2/3	2	No	O	NA	R (17SEP2020)	N/N
16-55/ C4591001 1046 10461118	ENDO	Hyperthyroidism/ Hyperthyroidism#	2	02MAR2021	170/C	1	No	O	NA/TC	N	N/N
	INJ&P	Exposure during pregnancy/ Pregnancy Exposure	2	09JAN2021	114/C		No	O	NA	UNK	N/N
16-55/ C4591001 1046 10461131	INFEC	Urinary tract infection/ Urinary Tract Infection	2	01DEC2020	75/4	2	No	O	NA	R (04DEC2020)	N/N
16-55/ C4591001 1046 10461134	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1046 10461145	METAB	Pain/ Full Body Aches#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Hypercholesterolaemia/ Hypercholesterolemia	2	05OCT2020	15/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1046 10461153	GENRL	Fatigue/ Fatigue	1	05SEP2020	5/4	3	No	O	NA	R (08SEP2020)	N/N
		Pyrexia/ Fever	1	05SEP2020	5/4	3	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1046 10461168	GENRL	Pyrexia/ Low Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1046 10461174	GENRL	Injection site pain/ Left Arm Muscle Aches at Injection Site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1046 10461175	INFEC	COVID-19/ CoVid19	2	14JAN2021	115/12	3	No	O	NA/TC	R (25JAN2021)	Y/N
16-55/ C4591001 1046 10461209	GENRL	Injection site pain/ Sore Left Arm at Injection Site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1046 10461219	GENRL	Injection site pain/ Left Arm Soreness at Injection Site#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
		Pain/ General Body Aches#	4	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1046 10461268		Injection site pain/ Sore Left Arm at Injection Site#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1046 10461280	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1046 10461332	PSYCH	Anxiety/ Anxiety Attack	2	12DEC2020	24/3	1	No	O	NA	R (14DEC2020)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies#	4	03MAR2021	37/2	1	No	O	NA	R (04MAR2021)	N/N
16-55/ C4591001 1047 10471010	GENRL	Injection site erythema/ Redness at injection site left deltoid	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ soreness of injection site left deltoid	2	08SEP2020	1/8	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1047 10471017	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1047 10471018	GASTR	Diarrhoea/ diarrhea	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Soreness Left arm post injection	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471025	GENRL	Chills/ chills#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
		Pain/ bodyaches#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Pain/ body aches	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ injection site Soreness Left Deltoid	1	25AUG2020	4/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1047 10471035		Injection site pruritus/ left arm itchiness at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
		Injection site swelling/ left arm swollen at injection site	2	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
	MUSC	Back pain/ lower back pain	2	13OCT2020	30/C	1	No	O	NA	N	N/N
	MUSC	Tendonitis/ elbow tendinitis#	2	29JAN2021	138/C	2	No	O	NA	N	N/N
16-55/ C4591001 1047 10471040	GENRL	Pain/ body aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471041	GENRL	Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ 100.4 fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ generalized muscles aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471042	GENRL	Chills/ chills#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1047 10471049	NERV	Pyrexia/ fever of 101.9#	3	22DEC2020	1/2	2	Yes		NA	R (23DEC2020)	N/N
		Headache/ headaches#	3	22DEC2020	1/2	3	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1047 10471052	RESP	Fatigue/ fatigue`#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
		Pain/ body aches#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
		Sleep apnoea syndrome/ sleep apnea	2	DEC2020	77/C	2	No	O	NA	N	N/N
16-55/ C4591001	GENRL	Pyrexia/ low grade temp post injection 99.9	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471057 16-55/ C4591001 1047 10471061	GENRL	Pain/ Body Aches generalized	2	17SEP2020	2/2	2	Yes	NA	NA	R (18SEP2020)	N/N
		Pyrexia/ Fever 102	2	17SEP2020	2/1	2	Yes	NA	NA	R (17SEP2020)	N/N
		Pyrexia/ Fever 103.0	2	17SEP2020	2/1	3	Yes	NA	NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes	NA	NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	3/2	1	Yes	NA	NA	R (19SEP2020)	N/N
16-55/ C4591001 1047 10471064	GENRL	Pain/ Body aches generalized	2	17SEP2020	2/3	1	Yes	NA	NA	R (19SEP2020)	N/N
		Pyrexia/ Temp 101	2	17SEP2020	2/1	1	Yes	NA	NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471068	GENRL	Fatigue/ fatigue#	4	11FEB2021	1/2	1	Yes	NA	NA	R (12FEB2021)	N/N
		Injection site pain/ injection site pain#	4	11FEB2021	1/2	1	Yes	NA	NA	R (12FEB2021)	N/N
16-55/ C4591001 1047 10471069	GENRL	Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes	NA	NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471070	NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ Body aches generalized	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471081		Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1047 10471088	NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	15NOV2020	56/3	1	No	O	NA/TC	R (17NOV2020)	N/N
16-55/ C4591001 1047 10471093	NERV	Tension headache/ Tension Headache	2	15NOV2020	56/3	1	No	O	NA	R (17NOV2020)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies	1	02SEP2020	3/2	1	No	O	NA	R (03SEP2020)	N/N
	RESP	Oropharyngeal pain/ intermittent Sore throat	1	02SEP2020	3/2	1	No	O	NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471095		Injection site pain/ left injection site shoulder pain.	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Neck pain/ Neck Pain	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Injection site swelling/ Injection site swelling	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	EYE	Retinal tear/ retinal tear	2	20NOV2020	58/15	3	No	O	NA	R (04DEC2020)	N/N
	SURG	Retinal operation/ Laser Surgery for Retinal tear repair	2	04DEC2020	72/1	3	No	O	NA/TCN	R (04DEC2020)	N/N
16-55/ C4591001 1047 10471106	MUSC	Arthralgia/ bilateral shoulder pain#	2	01MAR2021	159/C	2	No	O	NA	N	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headaches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1047 10471128	GENRL	Chills/ Chills	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ Bodyaches	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Pyrexia/ Fever 101.0	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Headache/ Headache	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
	RESP	Paranasal sinus discomfort/ Sinus Pressure	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1047 10471131	GENRL	Pyrexia/ fever (100.8)#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1047 10471133	GENRL	Pain/ Bodyaches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature 100.0	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1047 10471143	MUSC	Arthralgia/ Elbow pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Arthralgia/ wrist pain right arm	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
Myalgia/ muscle pain right arm		1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N	
Chills/ Chills		1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N	
Fatigue/ Fatigue		1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N	
		Injection site pain/ Injection site soreness	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471146	GENRL	Pyrexia/ fever (103.0 F)#	4	25JAN2021	1/2	3	Yes		NA	R (26JAN2021)	N/N
	NERV	Migraine/ intermittent migraines#	4	09FEB2021	16/C	2	No	O	NA	N	N/N
16-55/ C4591001 1047 10471150	GENRL	Injection site pain/ injection site pain#	2	21DEC2020	85/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	11JAN2021	22/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pain/ body aches#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1047 10471172	RENAL	Nephrolithiasis/ Kidney Stone, Right Side	2	05NOV2020	37/4	2	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 1047 10471174	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1047 10471180	GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	EAR	Ear discomfort/ Ear pressure	2	05OCT2020	1/3	1	No	O	NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1047 10471186	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	RESP	Rhinitis allergic/ Allergic Rhinitis	1	05OCT2020	25/3	1	No	O	NA/TC	R (07OCT2020)	N/N
	EAR	Ear pain/ Bilateral Otalgia	2	06OCT2020	2/3	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1047 10471189	PSYCH	Cyclothymic disorder/ cyclothyma	2	01NOV2020	32/C	2	No	O	NA	N	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Pain/ body ache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	INJ&P	Procedural pain/ post injection pain#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	NERV	Headache/ headache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	BLOOD	Lymphadenopathy/ swollen lymph node (left shoulder)#	4	21JAN2021	14/8	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1047 10471198	GENRL	Injection site pain/ injection site pain#	2	22DEC2020	83/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1047 10471201	GENRL	Injection site pain/ Left Arm soreness post injection	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471203	GENRL	Fatigue/ Fatigue*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ Left arm pain at injection site*		14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Left arm pain at injection site	1	12OCT2020	29/2	1	Yes		NA	R (13OCT2020)	N/N
	INJ&P	Fall/ fall	2	09NOV2020	29/1	2	No	O	NA	R (09NOV2020)	N/N
		Ligament sprain/ Sprained Left Foot	2	09NOV2020	29/73	2	No	O	NA	R (20JAN2021)	N/N
		Ligament sprain/ Sprained Right Foot	2	09NOV2020	29/73	2	No	O	NA	R (20JAN2021)	N/N
16-55/ C4591001 1047 10471217	SKIN	Blister/ left torso blisters	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N
		Rash/ left torso rash	2	12OCT2020	4/25	1	No	O	NA	R (05NOV2020)	N/N
16-55/ C4591001 1047 10471223	GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pain/ body aches	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N
	INV	Body temperature increased/ increased body temperture 99.1	1	08OCT2020	23/2	1	Yes		NA	R (09OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471225	EYE	Photophobia/ Light sensitivity eyes	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	06OCT2020	2/9	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pyrexia/ Fever 102.6	2	07OCT2020	3/1	3	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1047 10471232	GENRL	Injection site pain/ Injection site soreness left arm*		17SEP2020	1/8	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1047 10471236	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1047 10471238	GENRL	Injection site pain/ pain at injection site#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/Y
		Injection site pruritus/ itching at injection site#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/Y
16-55/ C4591001 1047 10471241	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
		Nausea/ Nausea	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	GENRL	Injection site pain/ Injection Site Soreness	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N	
		Pain/ Bodyaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N	
		Pyrexia/ Low Grade Fever 100.4	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N	
16-55/ C4591001 1047 10471244	GENRL	Injection site pain/ Injection site soreness left arm*		18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N	
		NERV	Headache/ Headaches	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
			GASTR	Nausea/ nausea#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)
16-55/ C4591001 1047 10471251	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
		Pain/ body ache#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
		Pyrexia/ Fever#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	NERV	Headache/ headache#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
		GENRL	Pain/ body aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1047 10471254	GASTR	Nausea/ Nausea	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471255	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	BLOOD	Lymphadenopathy/ swollen lymph node (left armpit)#	4	09JAN2021	2/28	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pain/ body aches#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site left arm*		21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ fever 101.6	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	INFEC	Localised infection/ right lower leg infection	1	26SEP2020	5/12	2	No	O	NA	R (07OCT2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	29SEP2020	8/4	2	No	O	NA	R (02OCT2020)	N/N
	INFEC	Subcutaneous abscess/ cutaneous abscess under left arM#	4	02MAR2021	13/1	1	No	O	NA	R (02MAR2021)	N/N
16-55/ C4591001 1047 10471266	SKIN	Dermatitis contact/ poison ivy#	4	02MAR2021	13/C	2	No	O	NA	N	N/N
	GASTR	Diarrhoea/ diarrhea (mild)	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	4	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
		Pain/ body aches#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1047 10471267	GENRL	Injection site pain/ soreness at injection site*		22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ low grade temperature (99.1)	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1047 10471275	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Pain/ body aches	2	14OCT2020	1/5	2	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1047 10471279	NERV	Headache/ headache#	4	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1047 10471318	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	DEC2020	30/C		No	O	NA	UNK	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1047 10471326	GENRL	Injection site pruritus/ Itchiness left arm, injection site*		21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Left arm soreness, injection site	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1047 10471331	INJ&P	Ligament sprain/ right lower leg sprain	1	02NOV2020	12/15	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1048 10481004	INJ&P	Muscle strain/ THORACIC MUSCLE STRAIN	2	24SEP2020	23/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1048 10481020	SKIN	Pruritus/ PRURITIS - LEFT FOOT	2	05OCT2020	26/2	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1048 10481025	GENRL	Fatigue/ fatigue	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ New muscle pain, generalized	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1048 10481032	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	2/5	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Intervertebral disc degeneration/ Worsening of degenerative disc disease	2	11JAN2021	119/C	1	No	O	NA/TC	N	N/N
	GASTR	Gastritis/ Worsening of gastritis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
		Impaired gastric emptying/ Worsening of gastroparesis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1048 10481040	SKIN	Rash/ RASH LEFT ANTECUBITAL	1	27AUG2020	1/4	1	No	O	NA	R (30AUG2020)	N/N
	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1048 10481044	GENRL	Cyst/ CYST ON LEFT GROIN	2	05OCT2020	20/148	2	No	O	NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1048 10481055	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
		Injection site pain/ injection site pain	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1048 10481056	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1048 10481065	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1048 10481075	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	INFEC	Nasopharyngitis/ common cold	2	18OCT2020	26/C	1	No	O	NA	N	N/N
16-55/ C4591001 1048 10481079	GENRL	Fatigue/ FATIGUE	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1048 10481083	GENRL	Chills/ chills	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Dizziness/ dizziness	1	06SEP2020	4/7	1	Yes		NA	R (12SEP2020)	N/N
		Headache/ headaches	1	06SEP2020	4/7	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1048 10481086	GENRL	Injection site pain/ muscle pain at injection site	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
	SKIN	Night sweats/ Profuse night sweating	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
	GASTR	Nausea/ nausea	1	05SEP2020	3/3	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pain/ body aches	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1048 10481088	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	20SEP2020	17/C		No	O	NA	N	N/N
16-55/ C4591001 1048 10481095	GASTR	Gastroesophageal reflux disease/ Acid reflux	2	03FEB2021	128/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1048 10481101	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1048 10481103	GENRL	Injection site pain/ Left arm pain at injection site#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1048 10481106		Pyrexia/ FEVER	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1048 10481125	INJ&P	Tooth fracture/ CRACKED TOOTH	2	05OCT2020	5/5	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1048 10481132	GENRL	Fatigue/ FATIGUE	1	12SEP2020	2/11	1	Yes		NA/TCN	R (22SEP2020)	N/N
16-55/ C4591001 1052 10521160	NERV	Headache/ intermittent headaches	1	23SEP2020	1/C	1	No	O	NA	N	N/Y
16-55/ C4591001 1052 10521172	INFEC	Infection/ infection#	4	05FEB2021	11/C	2	No	O	NA/TC	R	N/N
	METAB	Lactic acidosis/ lactic acidosis#	4	05FEB2021	11/1	2	No	O	NA/TC	R (05FEB2021)	N/N
	NERV	Seizure/ Seizure#	4	05FEB2021	11/1	1	No	O	NA/TC	R (05FEB2021)	Y/N
16-55/ C4591001 1054 10541002	GENRL	Chills/ one episode of chills	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541003	GENRL	Injection site pain/ soreness L arm injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1054 10541005	NERV	Headache/ headache	2	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	MUSC	Arthralgia/ L shoulder pain	2	04OCT2020	26/7	2	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pain/ generalized body ache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Lethargy/ lethargy#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1054 10541008	GENRL	Injection site pain/ soreness at the injection site, L arm#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ injection site pain L arm#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541011		Injection site erythema/ redness at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ soreness at L arm injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site swelling/ swelling at L arm injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1054 10541012	GASTR	Diarrhoea/ diarrhea - 1 episode	2	17SEP2020	7/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1054 10541014	GASTR	Nausea/ nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ muscle ache at injection site, L arm	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1054 10541018	GENRL	Injection site pain/ pain at injection site L arm	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	DEC2020	84/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ pain at injection site L arm#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ L arm soreness site injection#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541028	GENRL	Chills/ chills#	4	04MAR2021	1/2	1	Yes		NA	R (05MAR2021)	N/N
		Pyrexia/ fever#	4	04MAR2021	1/C	1	Yes		NA/TC	RG	N/N
	GENRL	Pain/ generalized body ache#	4	05MAR2021	2/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1054 10541032	GENRL	Injection site pain/ pain L arm at injection site	1	23AUG2020	2/3	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Back pain/ low back pain	1	23AUG2020	2/4	1	Yes		NA/TC	R (26AUG2020)	N/N
	GENRL	Injection site pain/ pain injection site	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	GASTR	Nausea/ nausea	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1054 10541034	GENRL	Fatigue/ fatigue	1	23AUG2020	2/13	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1054 10541035	INFEC	Chronic sinusitis/ worsening of chronic sinusitis	2	24SEP2020	15/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ L arm soreness at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541037	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ fever 101 degrees Fahrenheit#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1054 10541038	GENRL	Fatigue/ fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ headache#	3	13FEB2021	2/1	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1054 10541043	GENRL	Injection site pain/ soreness at injection site (LUE)	1	24AUG2020	1/5	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ headache	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1054 10541044	GENRL	Injection site pain/ L arm pain at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	SKIN	Night sweats/ night sweats#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ L arm injection site pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ intermittent chills#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		Injection site pain/ L arm injection site pain#	4	23FEB2021	2/4	2	Yes		NA	R (26FEB2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
		Myalgia/ muscle pain#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Hyperaesthesia/ diffuse skin sensitivity#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
	SKIN	Hyperhidrosis/ intermittent sweats#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1054 10541050	GENRL	Injection site pain/ pain at injection site, L deltoid	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ muscle ache L upper arm	1	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ headache	2	30SEP2020	15/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1054 10541051	NERV	Headache/ headache#	3	01FEB2021	1/1	1	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541054	NERV	Headache/ headache#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Pyrexia/ subjective fever	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Chest pain/ chest pain with deep inspiration	1	29AUG2020	4/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ tiredness#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1054 10541057		Injection site pain/ L arm soreness at injection site#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ mild headache#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ L arm soreness site injection#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1054 10541058	NERV	Headache/ headache#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Injection site pain/ soreness L arm injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1054 10541065	GASTR	Vomiting/ vomiting	1	03SEP2020	8/2	1	No	O	NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541067	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N	
	NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA/TC/TCN	R (29AUG2020)	N/N	
	NERV	Headache/ headache	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N	
	EAR	Hypoacusis/ decreased hearing R ear	2	20SEP2020	3/C	2	No	O	NA/TC	RG	N/N	
		Tinnitus/ Tinnitus R ear	2	20SEP2020	3/C	2	No	O	NA/TC	N	N/N	
		Vertigo/ vertigo	2	20SEP2020	3/3	1	No	O	NA	R (22SEP2020)	N/N	
	EAR	Ear disorder/ fluid R ear	2	22SEP2020	5/145	1	No	O	NA/TC	R (13FEB2021)	N/N	
	MUSC	Temporomandibular joint syndrome/ worsening R TMJ dysfunction#	3	12FEB2021	10/C	1	No	O	NA	RG	N/N	
	16-55/ C4591001 1054 10541068	GENRL	Pyrexia/ fever	1	17SEP2020	21/1	3	No	O	NA	R (17SEP2020)	N/N
	16-55/ C4591001 1054 10541069	GENRL	Chills/ intermittent chills	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		Pain/ diffuse body aches	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	1	29AUG2020	2/2	2	Yes		NA	R (30AUG2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541070	VASC	Hot flush/ hot flashes (worsening)	1	29AUG2020	2/8	1	Yes		NA	R (05SEP2020)	N/N
	INV	Blood testosterone decreased/ low testosterone	2	16OCT2020	8/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ pain L arm injection site	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ chills	1	18SEP2020	22/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	INFEC	Fungal skin infection/ fungal skin infection L arm	1	11SEP2020	15/62	1	No	O	NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site pain/ L arm site injection pain#	3	04FEB2021	1/4	1	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Injection site pain/ L arm pain site injection#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Pyrexia/ subjective fever, 99.8 degrees Fahrenheit#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1054 10541074	SKIN	Pruritus/ intermittent itching umbilical area	1	04SEP2020	8/16	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541078	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Pain/ body ache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Dizziness/ dizziness - intermittent	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1054 10541080		Headache/ headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INJ&P	Road traffic accident/ road accident	2	19OCT2020	29/1	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C4591001 1054 10541081	MUSC	Coccydynia/ pain in tail bone	2	19OCT2020	29/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ L arm soreness site injection#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1054 10541084	GENRL	Injection site pain/ soreness R arm injection site#	3	24DEC2020	1/2	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1054 10541085	GENRL	Injection site pain/ injection site pain L arm#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541086	GENRL	Injection site pain/ site injection pain	1	01SEP2020	1/4	1	Yes	NA		R (04SEP2020)	N/N
1054 10541087	GENRL	Asthenia/ low energy	2	23SEP2020	2/2	2	Yes	NA		R (24SEP2020)	N/N
1054 10541089		Injection site pain/ soreness L arm injection site	2	23SEP2020	2/5	1	Yes	NA		R (27SEP2020)	N/N
		Pain/ diffuse body aches	2	23SEP2020	2/2	2	Yes	NA/TC		R (24SEP2020)	N/N
		Pyrexia/ subjective fever	2	23SEP2020	2/2	1	Yes	NA		R (24SEP2020)	N/N
	NERV	Headache/ headache	2	23SEP2020	2/2	1	Yes	NA		R (24SEP2020)	N/N
16-55/ C4591001 1054 10541090	GENRL	Chills/ chills	1	01SEP2020	1/2	1	Yes	NA		R (02SEP2020)	N/N
	MUSC	Pain in extremity/ soreness R arm	1	01SEP2020	1/2	1	Yes	NA		R (02SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	1/2	1	Yes	NA		R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	22SEP2020	1/3	1	Yes	NA		R (24SEP2020)	N/N
		Pain/ diffuse soreness	2	22SEP2020	1/3	1	Yes	NA		R (24SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541091	GENRL	Injection site pain/ soreness L arm injection site#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1054 10541092	GENRL	Chills/ chills#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1054 10541094	GENRL	Fatigue/ fatigue#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ injection site pain L arm#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	4	24FEB2021	1/1	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ soreness at L arm injection site#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ fever#	4	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1054 10541096	GENRL	Chills/ intermittent chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541097		Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Iron deficiency anaemia/ anemia, iron deficiency	2	08OCT2020	16/C	1	No	CD	NA/TC	N	N/N
	GENRL	Fatigue/ fatigue	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Somnolence/ sleepiness	1	14SEP2020	13/34	1	Yes		NA	R (17OCT2020)	N/N
	VASC	Hot flush/ hot flashes	1	14SEP2020	13/23	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ intermittent headache	1	18SEP2020	17/32	1	Yes		NA/TC	R (19OCT2020)	N/N
	ENDO	Hypothyroidism/ hypothyroidism	2	25SEP2020	3/28	1	No	O	NA	R (22OCT2020)	N/N
	METAB	Dyslipidaemia/ dyslipidemia	2	25SEP2020	3/C	1	No	O	NA	N	N/N
	INFEC	Urinary tract infection/ UTI	2	03OCT2020	11/3	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
	INFEC	Pyelonephritis/ pyelonephritis	2	05OCT2020	13/13	2	No	O	NA/TC	R (17OCT2020)	N/N
	GASTR	Diverticulum intestinal/ diverticulosis of the colon	2	06OCT2020	14/C	1	No	O	NA	N	N/N
RESP	Lung infiltration/ nodular interstitial infiltrate, RLL of lung	2	06OCT2020	14/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	REPRO	Nipple pain/ bilateral nipple pain	2	15OCT2020	23/13	1	No	O	NA	R (27OCT2020)	N/N
	GASTR	Constipation/ constipation#	3	10FEB2021	3/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ injection site pain L arm#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	4	03MAR2021	3/2	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ headache#	4	03MAR2021	3/2	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1054 10541098	GENRL	Injection site pain/ pain R arm injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1054 10541100	GENRL	Injection site pain/ L arm injection site soreness#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain L arm#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ fever 101 degrees Fahrenheit#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1054 10541101	GENRL	Injection site pain/ pain L arm injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ low grade fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541104	GENRL	Pyrexia/ fever - subjective	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1054 10541106	GENRL	Injection site pain/ injection site pain L arm#	3	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1054 10541107	GENRL	Injection site pain/ injection site pain R arm#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ R arm injection site soreness#	4	24FEB2021	1/10	1	Yes		NA	R (05MAR2021)	N/N
	GENRL	Chills/ intermittent chills#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Fatigue/ fatigue#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
		Injection site erythema/ redness R arm injection site#	4	25FEB2021	2/9	1	Yes		NA	R (05MAR2021)	N/N
		Injection site swelling/ swelling R arm injection site#	4	25FEB2021	2/9	1	Yes		NA	R (05MAR2021)	N/N
	MUSC	Arthralgia/ joint pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1054 10541108	GENRL	Injection site pain/ soreness R arm injection site	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541111		Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pain/ diffuse body aches	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	METAB	Decreased appetite/ decreased appetite	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Dysgeusia/ metallic taste	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Migraine/ migraine headache	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1054 10541113	GENRL	Injection site pain/ site injection pain	1	05SEP2020	3/6	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1054 10541115	GENRL	Injection site pain/ tenderness L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
		Injection site pruritus/ itching L arm injection site	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
	MUSC	Arthralgia/ joint aches	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site bruising/ bruising L arm injection site	1	06SEP2020	3/6	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1054 10541119	MUSC	Fatigue/ fatigue	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N	
		Pain/ generalized body aches	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
		Pyrexia/ subjective fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N	
		Arthralgia/ bilateral hip joint ache	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N	
	SKIN	Night sweats/ night sweats	2	27SEP2020	3/1	1	Yes		NA	R (27SEP2020)	N/N	
	NERV	Headache/ headache	2	19OCT2020	25/1	1	No	O	NA/TC	R (19OCT2020)	N/N	
	GENRL	Injection site pain/ L arm injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ headache#	3	10FEB2021	1/1	1	Yes		NA/TC	R (10FEB2021)	N/N	
	16-55/ C4591001 1054 10541121	GASTR	Diarrhoea/ diarrhea, single episode	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N
	GENRL	Chills/ chills	1	08SEP2020	5/1	1	No	O	NA	R (08SEP2020)	N/N	
GENRL	Injection site pain/ soreness L arm (injection site)#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N		
GENRL	Injection site pain/ injection site pain L arm#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541122	NERV	Headache/ headache#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
	RESP	Nasal congestion/ nasal congestion	1	27SEP2020	20/2	1	No	O	NA/TC	R (28SEP2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ yeast vaginitis	2	13JAN2021	108/21	1	No	O	NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain L arm#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ pain L arm injection site#	4	26FEB2021	1/7	1	Yes		NA	R (04MAR2021)	N/N
	MUSC	Musculoskeletal stiffness/ generalized muscle stiffness#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1054 10541135	NERV	Lethargy/ lethargy#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
	MUSC	Back pain/ low back soreness	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Back pain/ low back soreness	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1054 10541137	GENRL	Chills/ chills#	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site bruising/ bruise L arm injection site	1	11SEP2020	2/21	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541140	GENRL	Injection site pain/ L arm injection site soreness#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ soreness injection site L arm#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1054 10541141	GENRL	Injection site pain/ muscle pain at injection site, L arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache*		10SEP2020	1/4	1	No	O	NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	30SEP2020	1/5	2	Yes		NA/TC	R (04OCT2020)	N/N
	GASTR	Nausea/ nausea	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Back pain/ upper back ache	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1054 10541144	GASTR	Abdominal pain upper/ epigastric pain	1	12SEP2020	2/5	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541145	MUSC	Myalgia/ myalgia	1	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1054 10541148	GENRL	Injection site pain/ soreness L arm injection site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Nausea/ nausea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	02OCT2020	1/9	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ fever	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
	SKIN	Rash/ rash upper abdomen	2	02OCT2020	1/5	1	Yes		NA	R (06OCT2020)	N/N
	GASTR	Nausea/ intermittent nausea	2	07OCT2020	6/4	1	Yes		NA	R (10OCT2020)	N/N
		Retching/ dry heaves	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1054 10541152	MUSC	Musculoskeletal stiffness/ neck stiffness	2	07OCT2020	6/1	1	Yes		NA	R (07OCT2020)	N/N
			2	07OCT2020	6/10	2	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	6/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Feeling abnormal/ brain fog	2	11OCT2020	10/1	1	No	O	NA	R (11OCT2020)	N/N
	GENRL	Feeling abnormal/ brain fog	2	13OCT2020	12/1	1	No	O	NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	19SEP2020	6/1	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Motor dysfunction/ L C7 motor dysfunction	2	OCT2020	1/C	1	No	O	NA/TCN	N	N/N
		Radiculopathy/ worsening of radiculopathy, both upper extremities	2	OCT2020	1/C	2	No	O	NA/TC/TCN	N	N/N
	EYE	Eye irritation/ burning sensation in eyes	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ subjective fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
MUSC	Myalgia/ diffuse muscle aches	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1054 10541153	GENRL	Injection site pain/ L arm soreness at injection site#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ L arm injection site pain#	4	17FEB2021	1/5	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1054 10541155	GENRL	Injection site pain/ soreness L arm injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1054 10541157	GENRL	Injection site pain/ site injection pain, L arm	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1054 10541158	GENRL	Injection site pain/ soreness L arm injection site#	3	26JAN2021	1/5	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	28JAN2021	3/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1054 10541160	GENRL	Injection site pain/ soreness at R arm injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GASTR	Nausea/ nausea	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
		Fatigue/ fatigue	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ muscle ache at R arm injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1054 10541170	INJ&P	Contusion/ contusion - multiple areas#	3	26FEB2021	11/5	2	No	O	NA	R (02MAR2021)	N/N
		Skin abrasion/ abrasion - multiple areas#	3	26FEB2021	11/C	2	No	O	NA/TC	RG	N/N
	MUSC	Pain in extremity/ sore L arm#	4	09MAR2021	1/5	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1054 10541171	MUSC	Pain in extremity/ L arm soreness#	3	02FEB2021	1/6	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ R arm injection site pain#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1054 10541174	GENRL	Injection site pain/ soreness R arm injection site	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ headache	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
		Somnolence/ drowsiness	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ soreness R arm injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
			2	08OCT2020	1/6	2	Yes		NA	R (13OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ generalized body aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ intermittent low grade feverw	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1054 10541178	GENRL	Injection site pain/ L arm site injection pain#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1054 10541182	BLOOD	Anaemia/ anemia	1	06OCT2020	14/C	1	No	O	NA	N	N/N
	GASTR	Dry mouth/ dry mouth	2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Thirst/ increased thirst	2	19OCT2020	5/6	1	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Injection site pain/ soreness R arm site injection#	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1054 10541184	RESP	Epistaxis/ epistaxis R nostril	1	14OCT2020	22/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ L arm injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541190	GENRL	Injection site pain/ pain at injection site, L arm	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
1054 10541191	GENRL	Fatigue/ tiredness	1	19OCT2020	1/26	1	Yes		NA	R (13NOV2020)	N/N
1054 10541197	GENRL	Injection site pain/ soreness L arm injection site	1	20OCT2020	2/23	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ soreness L arm injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1054 10541200	GENRL	Chills/ intermittent chills	1	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
		Pain/ diffuse body aches	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ headache	1	22OCT2020	1/6	1	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site swelling/ injection site swelling L arm	1	31OCT2020	10/2	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1054 10541201	GENRL	Fatigue/ tiredness	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N
		Pain/ body aches	1	22OCT2020	1/20	1	Yes		NA	R (10NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ intermittent headache	1	22OCT2020	1/20	1	Yes		NA/TC	R (10NOV2020)	N/N
	NERV	Cervical radiculopathy/ L upper extremity pain - cervicular radiculopathy	2	16DEC2020	27/9	2	No	O	NA/TC	R (24DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site, R arm#	4	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
	EYE	Lacrimation increased/ watery eyes#	4	27FEB2021	2/2	1	No	O	NA	R (28FEB2021)	N/N
	GENRL	Chills/ chills#	4	27FEB2021	2/11	1	Yes		NA	R (09MAR2021)	N/N
		Pain/ body aches#	4	27FEB2021	2/12	1	Yes		NA/TC	R (10MAR2021)	N/N
	NERV	Headache/ headache#	4	27FEB2021	2/11	1	Yes		NA	R (09MAR2021)	N/N
16-55/ C4591001 1054 10541203	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/5	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ fever (subjective)	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site erythema/ injection site erythema	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pruritus/ injection site pruritus	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain L deltoid	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1054 10541206		Injection site pain/ L arm - site injection pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ tiredness	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
		Feeling cold/ cold feeling	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N
		Injection site pain/ pain L arm injection site	2	16NOV2020	1/4	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1054 10541208	GENRL	Injection site pain/ soreness L arm injection site#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1054 10541215	GENRL	Injection site pain/ L arm soreness at the injection site#	2	28JAN2021	73/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1055 10551001	GENRL	Injection site pain/ injection site soreness#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/Y
	GENRL	Injection site pain/ injection site pain#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	12FEB2021	3/3	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551007	GENRL	Injection site pruritus/ Itching at injection site	2	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pruritus/ Injection site itching#	4	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/Y
	EAR	Vertigo/ Vertigo#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1055 10551012	BLOOD	Lymphadenopathy/ Left supraclavicular adenopathy	2	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	INFEC	Herpes zoster/ Shingles#	2	08FEB2021	161/30	2	No	O	NA/TC	R (09MAR2021)	N/N
16-55/ C4591001 1055 10551013	GENRL	Injection site pain/ injection site soreness#	3	27JAN2021	1/5	1	Yes		NA	R (31JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551026	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1055 10551028	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/4	2	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1055 10551032	GENRL	Injection site pain/ Injection Site Pain#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1055 10551034	MUSC	Injection site pain/ Injection Site Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Myalgia/ Myalgias#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
	RESP	Oropharyngeal pain/ Sore throat	2	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pruritus/ Itching at injection site	2	03SEP2020	3/5	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551037	GENRL	Fatigue/ Fatigue#	3	14JAN2021	3/1	2	Yes	NA	R	(14JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	14JAN2021	3/1	2	Yes	NA/TC	R	(14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/1	1	Yes	NA	R	(03FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	03FEB2021	2/1	1	Yes	NA	R	(03FEB2021)	N/N
16-55/ C4591001 1055 10551040	GENRL	Injection site pain/ Injection Site Pain#	3	09FEB2021	1/2	1	Yes	NA	R	(10FEB2021)	N/N
16-55/ C4591001 1055 10551045	GENRL	Injection site pain/ Injection Site Pain#	3	09FEB2021	1/1	1	Yes	NA	R	(09FEB2021)	N/N
16-55/ C4591001 1055 10551046	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	2/2	2	Yes	NA/TC	R	(14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/2	2	Yes	NA	R	(03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes	NA	R	(03FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes	NA/TC	R	(03FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	03FEB2021	2/1	2	Yes	NA/TC	R	(03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551051	GENRL	Chills/ Chills	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ Injection site pain, left	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1055 10551054	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes		NA/TC	R (18AUG2020)	N/N
	GENRL	Fatigue/ fatigue#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
NERV	Headache/ Headache#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551056	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ Fatigue#	4	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1055 10551057	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/7	2	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	2	08SEP2020	1/2	2	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	08SEP2020	1/7	1	Yes		NA/TC	R (14SEP2020)	N/N
	SKIN	Dermatitis contact/ Poison Oak Rash#	2	20FEB2021	166/15	1	No	O	NA/TC	R (06MAR2021)	N/N
16-55/ C4591001 1055 10551058	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551061	MUSC	Injection site pain/ Injection site pain	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Myalgia/ Myalgias	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Back injury/ Back pain (post-traumatic)	2	03DEC2020	87/C	2	No	O	NA/TC	N	N/N
	GENRL	Road traffic accident/ Car/pedestrian accident	2	03DEC2020	87/1	2	No	O	NA/TC	R (03DEC2020)	N/N
		Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Malaise/ Malaise#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1055 10551063	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1055 10551067	GENRL	Chills/ Chills#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551071	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	1	07SEP2020	20/6	2	No	O	NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	14SEP2020	1/4	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pains	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/4	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1055 10551072	NERV	Headache/ Headache	1	20AUG2020	2/3	1	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1055 10551073	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1055 10551074	GENRL	Fatigue/ Fatigue#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551075	GENRL	Injection site pain/ Injection Site Pain#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1055 10551076	GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		Injection site pain/ Injection site pain	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1055 10551077	GENRL	Chills/ Chills	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
		Injection site bruising/ bruising at injection site#	3	02FEB2021	2/4	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	1/5	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551078 16-55/ C4591001 1055 10551080	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	RESP	Productive cough/ Productive cough	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	RESP	Productive cough/ Productive cough	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1055 10551082	GENRL	Fatigue/ fatigue#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ injection site pain#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	12FEB2021	1/5	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/3	1	Yes		NA	R (15FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551084	NERV	Headache/ Headache#	4	13FEB2021	2/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
		Feeling hot/ Warm feeling of neck and head	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Low grade fever	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1055 10551085	INJ&P	Exposure during pregnancy/ Exposure during Partner pregnancy#	2	04FEB2021	150/C		No	O	NA	UNK	N/N
	GENRL	Fatigue/ fatigue#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ injection site pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ injection site pain#	4	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1055 10551086		Pyrexia/ fever#	4	07JAN2021	1/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	INFEC	Bacterial blepharitis/ Bacterial blepharitis	2	20SEP2020	12/51	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1055 10551087	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1055 10551089	GENRL	Injection site pain/ Pain at injection site, left	1	21AUG2020	1/5	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Injection site erythema/ Erythema at injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site erythema/ Erythema at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551092	MUSC	Myalgia/ Myalgias	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during partner pregnancy	2	03FEB2021	142/C		No	O	NA	UNK	N/N
16-55/ C4591001 1055 10551099	GENRL	Chills/ chills#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pain/ body aches#	3	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
		Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1055 10551103	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever	1	25AUG2020	1/3	2	Yes		NA/TC	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551104	GENRL	Chills/ Chills	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	15SEP2020	1/8	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/4	2	Yes		NA	R (28AUG2020)	N/N
	SKIN	Hyperhidrosis/ Diaphoresis	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Dizziness/ Dizzy	2	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	18SEP2020	3/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1055 10551105		Pyrexia/ Fever	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Disturbance in attention/ Difficulty concentrating	2	16SEP2020	2/11	2	Yes		NA	R (26SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551115	GENRL	Fatigue/ Fatigue	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	26AUG2020	1/6	2	Yes		NA/TC	R (31AUG2020)	N/N
	NERV	Dizziness/ Dizzy	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/Y
		Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/Y
	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	16SEP2020	1/5	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Injection site erythema/ Injection site redness	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pruritus/ Injection site itching	2	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1055 10551116	GENRL	Chills/ Chills	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
	SKIN	Hyperhidrosis/ Diaphoresis	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	3	Yes		NA/TC	R (15SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1055 10551117	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	2/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1055 10551118	GENRL	Injection site pain/ injection site soreness#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1055 10551121	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/4	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Dizziness/ dizziness#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
		Headache/ headache#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1055 10551125	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	SKIN	Rash/ Rash on left thigh, left calf, left forearm, right foot	1	30AUG2020	4/22	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	SKIN	Pruritus/ Itching on left anterior thigh	2	28SEP2020	1/1	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1055 10551128	GENRL	Injection site pain/ injection site pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/Y
	BLOOD	Lymphadenopathy/ Left Axillary Lymphadenopathy#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever#	4	09FEB2021	2/1	3	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	2/1	2	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1055 10551131	GENRL	Pyrexia/ Fever	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1055 10551133	GENRL	Injection site pain/ injection site pain#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ injection site pain#	4	11JAN2021	1/5	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1055 10551134	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551135	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GASTR	Nausea/ Nausea#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/8	2	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1055 10551136	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/4	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Cognitive disorder/ cognitive impairment#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	1	Yes		NA	R (31AUG2020)	N/N
	GASTR	Oral pain/ Oral Pain	1	14SEP2020	18/9	1	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Tooth abscess/ Dental Abscess	1	14SEP2020	18/1	1	No	O	NA/TC	R (14SEP2020)	N/N
GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N	
NERV	Headache/ Headache	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551138	INFEC	Tooth abscess/ Dental abscess	2	01OCT2020	16/14	2	No	O	NA/TC	R (14OCT2020)	N/N
	MUSC	Periarthritis/ frozen left shoulder	2	NOV2020	47/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site soreness#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1055 10551139	MUSC	Myalgia/ Myalgias#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ chills#	3	21JAN2021	2/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
BLOOD	Lymphadenopathy/ Right Axillary Adenopathy#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551143	GENRL	Injection site pain/ Injection Site Pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/4	2	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1055 10551144	NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
		Fatigue/ Fatigue	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	18SEP2020	1/3	2	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headaches	2	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1055 10551145	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N	
	NERV	Cerebral capillary telangiectasia/ Cerebral Capillary telangiectasia	1	26SEP2020	30/C	1	No	O	NA	N	N/N	
	MUSC	Pain in extremity/ Bilateral upper extremity pain	1	10OCT2020	44/C	1	No	O	NA/TC	N	N/N	
	GENRL	Chronic fatigue syndrome/ Chronic Fatigue Syndrome	1	05JAN2021	131/C	2	No	O	NA	N	N/N	
	MUSC	Fibromyalgia/ Fibromyalgia	1	05JAN2021	131/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1055 10551146	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
		Injection site pain/ Injection Site Pain	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
	MUSC	Myalgia/ Myalgias	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1055 10551151	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/5	2	Yes		NA	R (04SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NEOPL	Lipoma/ Lipoma	1	14SEP2020	15/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1055 10551157	GENRL	Injection site pain/ Injection site pain#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1055 10551161	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	22SEP2020	1/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551162	GENRL	Fatigue/ Fatigue	2	28SEP2020	5/2	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551165	GENRL	Pyrexia/ Fever	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1055 10551168		Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551169	MUSC	Myalgia/ Myalgias	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Dizziness/ Dizziness#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	3/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1055 10551171	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	2	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1055 10551173	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Dizziness/ Lightheaded	1	04SEP2020	2/2	2	Yes		NA	R (05SEP2020)	N/N
		Headache/ Headache	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ headache#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ injection site pain#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Headache/ headache#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1055 10551174	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1055 10551175	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551176	CARD	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N
16-55/ C4591001 1055 10551177	GENRL	Injection site pain/ Injection Site Tenderness	1	03SEP2020	1/5	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	1/8	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1055 10551179	MUSC	Myalgia/ Generalized Muscle Aches	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1055 10551181	EAR	Vertigo/ Vertigo	2	23FEB2021	155/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551184	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/3	1	Yes	NA	R	(03FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/2	1	Yes	NA	R	(24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes	NA/TC	R	(23FEB2021)	N/N
16-55/ C4591001 1055 10551186	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes	NA	R	(06SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	12FEB2021	2/3	1	Yes	NA	R	(14FEB2021)	N/N
16-55/ C4591001 1055 10551190	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/3	2	Yes	NA/TC	R	(06SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	1	Yes	NA/TC	R	(26SEP2020)	N/N
16-55/ C4591001 1055 10551193	GENRL	Fatigue/ Fatigue#	3	25FEB2021	1/2	1	Yes	NA/TC	R	(26FEB2021)	N/N
	NERV	Headache/ Headache#	3	25FEB2021	1/2	1	Yes	NA	R	(26FEB2021)	N/N
16-55/ C4591001 1055 10551195	GENRL	Fatigue/ Fatigue	1	04SEP2020	1/2	1	Yes	NA	R	(05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ Lightheaded	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y
	GENRL	Fatigue/ fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1055 10551198	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1055 10551200	GENRL	Chest discomfort/ Chest tightness	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	09SEP2020	2/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chest discomfort/ Chest tightness	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	23OCT2020	25/C	1	No	O	NA	N	N/N
16-55/ C4591001 1055 10551202	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1055 10551203	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	2	Yes		NA	R (18DEC2020)	N/N
	MUSC	Myalgia/ Myalgias#	3	18DEC2020	2/2	2	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1055 10551204	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ Chills	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	1	13SEP2020	5/1	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	13SEP2020	5/1	2	Yes		NA	R (13SEP2020)	N/N
	MUSC	Costochondritis/ costochondritis	2	02OCT2020	3/4	2	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551206	SKIN	Rash maculo-papular/ Maculopapular rash	1	20SEP2020	12/48	1	No	CD	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
1055 10551207	MUSC	Myalgia/ Generalized Myalgias	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
1055 10551208	MUSC	Arthralgia/ Arthralgias	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
1055 10551211	GENRL	Injection site pain/ pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551215	GENRL	Chills/ chills#	3	31DEC2020	2/1	1	Yes	NA	R	(31DEC2020)	N/N
		Injection site pain/ injection site pain#	3	31DEC2020	2/3	1	Yes	NA	R	(02JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	01JAN2021	3/3	1	Yes	NA	R	(03JAN2021)	N/N
	NERV	Headache/ headache#	3	01JAN2021	3/3	1	Yes	NA/TC	R	(03JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	20JAN2021	2/1	1	Yes	NA	R	(20JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	2/1	1	Yes	NA/TC	R	(20JAN2021)	N/N
	NERV	Headache/ headache#	4	20JAN2021	2/1	1	Yes	NA/TC	R	(20JAN2021)	N/N
16-55/ C4591001 1055 10551219	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes	NA	R	(14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes	NA	R	(13SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	01OCT2020	1/3	2	Yes	NA/TC	R	(03OCT2020)	N/N
	GENRL	Chills/ Chills	2	02OCT2020	2/1	2	Yes	NA	R	(02OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	2/4	2	Yes	NA	R	(05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551220	MUSC	Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Arthralgia/ Generalized Joint aches	2	02OCT2020	2/2	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site bruising/ bruising at injection site#	3	16JAN2021	2/C	1	Yes		NA	N	N/N
		Injection site pain/ injection site soreness#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1055 10551221	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1055 10551221	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1055 10551222	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site soreness#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
	MUSC	Fatigue/ Fatigue#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Muscle fatigue/ Muscle fatigue	1	12SEP2020	2/11	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1055 10551223	GASTR	Gastrointestinal disorder/ Gastrointestinal frequency	1	13SEP2020	3/11	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1055 10551224	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1055 10551225	NERV	Hyperaesthesia/ Hyperaesthesia	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1055 10551226	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	2	Yes		NA	R (03OCT2020)	N/N
	INJ&P	Facial bones fracture/ Fractured nose	2	26OCT2020	25/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551228	GENRL	Pyrexia/ fever#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N
	NERV	Headache/ headache#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ injection site pain#	4	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	INFEC	Infected cyst/ infected right leg cyst#	4	02FEB2021	14/16	2	No	O	NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24DEC2020	4/3	1	Yes		NA	R (26DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	11JAN2021	1/6	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	16-55/ C4591001 1055 10551229	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/5	2	Yes		NA/TC	R (18SEP2020)
GENRL	Malaise/ Malaise	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N	
GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551230	MUSC	Malaise/ Malaise	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
		Arthralgia/ Generalized joint pain	2	06OCT2020	2/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1055 10551231	GENRL	Chills/ Chills	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1055 10551232	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	2	06OCT2020	1/4	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551233	MUSC	Myalgia/ Generalized myalgias	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
	PSYCH	Insomnia/ insomnia#	4	11JAN2021	1/7	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1055 10551235		Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	15SEP2020	1/6	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551237	MUSC	Pyrexia/ Fever	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
		Myalgia/ Generalized myalgias	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
		Nausea/ Nausea	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
Fatigue/ Fatigue		2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1055 10551238	GENRL	Injection site pain/ Injection Site Pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y
16-55/ C4591001 1055 10551239	GENRL	Injection site pain/ injection site pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Pyrexia/ Fever	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	NOV2020	25/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site soreness#	3	28JAN2021	1/5	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Pyrexia/ low grade fever#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	30JAN2021	3/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	17FEB2021	1/4	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1055 10551240	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1055 10551243	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
		Injection site pain/ injection site soreness#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	3	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551244	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	09FEB2021	2/2	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pains	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1055 10551245	NERV	Headache/ Headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/4	1	Yes		NA/TC	R (16NOV2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1055 10551246	GENRL	Injection site pain/ injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	PSYCH	Sleep disorder/ Disturbed sleep#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1055 10551247	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1055 10551249	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561013	GENRL	Chills/ CHILLS	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
16-55/ C4591001 1056 10561016	INJ&P	Contusion/ MULTIPLE CONTUSION	2	26SEP2020	18/34	2	No	O	NA/TC	R (29OCT2020)	N/N
		Road traffic accident/ CAR ACCIDENT	2	26SEP2020	18/1	2	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1056 10561022	BLOOD	Lymphadenopathy/ SWOLLEN LEFT AXILLARY LYMPH NODES	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site erythema/ INJECTION SITE ERYTHEMA	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1056 10561039	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1056 10561058	GENRL	Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1056 10561059	GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1056 10561071	GENRL	Chills/ CHILLS#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ FEVER#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1056 10561089	GENRL	Injection site pain/ LEFT ARM INJECTION SITE MUSCLE PAIN	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1056 10561108	GENRL	Injection site swelling/ INJECTION SITE SWELLING	1	04SEP2020	4/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1056 10561121	GENRL	Chills/ CHILLS#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561146 16-55/ C4591001 1056 10561177	GENRL	Chills/ CHILLS	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ INJECTION SITE MUSCLE PAIN	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ FEVER	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1056 10561187	GENRL	Injection site pain/ RIGHT ARM INJECTION SITE MUSCLE PAIN	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1056 10561213	GENRL	Fatigue/ TIREDNESS	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1056 10561219	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1056 10561251	GENRL	Fatigue/ TIREDNESS	1	16SEP2020	1/4	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561252	GENRL	Pyrexia/ FEVER	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ PAIN AR THE INJECTION SITE	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1056 10561262	GENRL	Chills/ CHILLS	1	01OCT2020	16/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1056 10561263	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	01MAR2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1056 10561277	GENRL	Injection site pain/ MUSCLE PAIN (INJECTION SITE LEFT)	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1056 10561315		Pyrexia/ FEVER	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	RESP	Nasal congestion/ NASAL CONGESTION	1	30SEP2020	9/4	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ CHILLS	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561327	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	27SEP2020	4/4	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE (LEFT)#	3	10FEB2021	3/7	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	10FEB2021	3/8	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1056 10561330	GENRL	Chills/ Chills#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1056 10561360	GENRL	Pyrexia/ FEVER	2	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1056 10561375	GENRL	Chills/ CHILLS	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561396	NERV	Headache/ HEADACHE	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1056 10561400	NERV	Headache/ HEADACHE	1	11OCT2020	7/2	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Chills/ CHILLS	1	12OCT2020	8/2	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ FEVER#	3	06FEB2021	2/5	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1056 10561401	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	06FEB2021	2/5	1	Yes		NA/TC	R (10FEB2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	3	06FEB2021	2/13	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1056 10561442	GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1056 10561444	GENRL	Pyrexia/ FEVER	1	09OCT2020	2/7	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1056 10561453	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	09OCT2020	2/8	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
		Pyrexia/ FEVER	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	2	29OCT2020	2/9	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN	1	13OCT2020	2/11	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	1	13NOV2020	25/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1056 10561558	GENRL	Injection site pain/ Pain At Site Of Injection (Left)#	4	23FEB2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1056 10561594	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1056 10561600	GASTR	Diarrhoea/ DIARRHEA	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Pyrexia/ FEVER	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ HEADACHE	1	29OCT2020	3/4	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1056 10561622	GENRL	Chills/ CHILLS	1	31OCT2020	4/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1056 10561635	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
	MUSC	Arthralgia/ GENERALIZED JOINT PAIN	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ CHILLS#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1056 10561642		Pyrexia/ FEVER#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1057 10571002	GENRL	Injection site pain/ PAIN AT INJECTION SITE ON LEFT ARM#	3	27JAN2021	1/4	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1057 10571018	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1057 10571032	GENRL	Chills/ CHILLS#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1057 10571065	HEPAT	Cholecystitis acute/ ACUTE CHOLECYSTITIS#	2	05FEB2021	150/4	3	No	O	NA/TCN	R (08FEB2021)	Y/N
	HEPAT	Steatohepatitis/ STEATOHEPATITIS#	2	07FEB2021	152/C	2	No	O	NA/TCN	N	N/N
	INFEC	Postoperative abscess/ POST CHOLECYSTECTOMY ABSCESS#	2	12FEB2021	157/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1057 10571074	GENRL	Fatigue/ FATIGUE#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1057 10571083	GASTR	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N	
		Pain/ BODY ACHES#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N	
		Nausea/ NAUSEA	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
		Vomiting/ VOMITTING	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
		INV	Blood pressure increased/ INCREASED BLOOD PRESSURE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		NERV	Headache/ HEADACHE	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		GASTR	Vomiting/ VOMITTING	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		GENRL	Chills/ CHILLS	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		INV	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		INV	Blood pressure increased/ INCREASED BLOOD PRESSURE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1057 10571100	GASTR	Headache/ HEADACHE	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N	
		Nausea/ NAUSEA#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571120	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Pain/ BODY ACHES#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ HEADACHES#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN RIGHT ARM#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	RESP	Throat irritation/ THROAT IRRITATION	2	19SEP2020	4/1	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Vomiting/ Vomiting	1	08SEP2020	8/2	1	No	O	NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ INJECTIONS SITE PAIN LEFT ARM#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N
	GENRL	Fatigue/ FATIGUE#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1057 10571152	MUSC	Pyrexia/ FEVER#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N	
		NERV	Myalgia/ MUSCLE SORENESS#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
			Headache/ HEADACHE#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE LEFT ARM#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N	
	GASTR	Diarrhoea/ DIARRHEA	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTIONS SITE ON LEFT ARM#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N	
	NERV	Dizziness/ DIZZINESS	2	07OCT2020	1/C	2	Yes		NA	N	N/N	
	EAR	Deafness unilateral/ HEARING LOSS IN RIGHT EAR	2	08OCT2020	2/C	1	Yes		NA	N	N/N	
INJ&P	Fall/ FALL	2	24NOV2020	49/1	2	Yes		NA	R (24NOV2020)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571238	GENRL	Upper limb fracture/ BROKEN RIGHT ARM	2	24NOV2020	49/C	1	Yes		NA/TCN	N	N/N
		Fatigue/ FATIGUE#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ BODY ACHES#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		NERV Headache/ HEADACHES#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pain/ BODY ACHES#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1057 10571239	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	2/8	2	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1057 10571241	GENRL	Injection site pain/ SORENESS INJECTION SITE LEFT ARM	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ BODY ACHES	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1057 10571246	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	25SEP2020	1/6	2	Yes		NA	R (30SEP2020)	N/N
		Pain/ BODY ACHES	1	25SEP2020	1/6	1	Yes		NA	R (30SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571263	RESP	Nasal congestion/ Nasal Congestion	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1057 10571265	METAB	Type 2 diabetes mellitus/ Type 2 Diabetes mellitus	2	29DEC2020	61/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1057 10571273	GENRL	Injection site pruritus/ Itchiness on Left Arm at Injection Site	1	08OCT2020	2/5	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1057 10571278	GENRL	Injection site pain/ Pain at Injection Site	1	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1057 10571294	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1057 10571295	GASTR	Nausea/ NAUSEA	2	25NOV2020	23/4	1	No	O	NA	R (28NOV2020)	N/N
16-55/ C4591001 1057 10571312	NERV	Dizziness/ Dizziness	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571316	INV	Body temperature increased/ ELEVATED TEMPERATURE	2	04NOV2020	2/2	2	Yes		NA	R (05NOV2020)	N/N
16-55/ C4591001 1057 10571319	GENRL	Pain/ BODY ACHES	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Neck pain/ NECK PAIN	2	14NOV2020	3/C	1	No	O	NA	N	N/N
16-55/ C4591001 1057 10571320	GENRL	Chills/ CHILLS	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		Injection site pain/ Injection site pain	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1057 10571331	GENRL	Chills/ CHILLS	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
		Fatigue/ FATIGUE	2	06NOV2020	1/5	1	Yes		NA	R (10NOV2020)	N/N
		Pyrexia/ FEVER	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571332†	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1057 10571333	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1057 10571339	GASTR	Nausea/ NAUSEA	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1057 10571373	GENRL	Injection site pain/ INJECTION SITE PAIN ON LEFT ARM#	3	26JAN2021	1/3	2	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1066 10661019	GENRL	Fatigue/ fatigue	1	18AUG2020	7/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1066 10661020	GENRL	Fatigue/ fatigue	1	13AUG2020	2/2	1	Yes		NA	R (14AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661026	GENRL	Injection site pain/ pain at injection site	1	13AUG2020	2/3	1	Yes		NA	R (15AUG2020)	N/N
		Fatigue/ fatigue	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
	NERV	Headache/ headache	1	16AUG2020	4/2	1	Yes		NA	R (17AUG2020)	N/N
16-55/ C4591001 1066 10661027	GENRL	Fatigue/ fatigue	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	16AUG2020	4/5	2	Yes		NA	R (20AUG2020)	N/N
	GENRL	Chills/ chills	1	17AUG2020	5/4	2	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1066 10661037	NERV	Headache/ headache	1	17AUG2020	5/4	2	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Pain/ body aches#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	30JAN2021	2/3	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1066 10661059	GENRL	Fatigue/ fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661081	GENRL	Pain/ body aches#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ pain at injection site#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Pain/ Body aches#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1066 10661086	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	11JAN2021	1/8	1	Yes		NA	R (18JAN2021)	N/N
	NERV	Headache/ headache#	4	11JAN2021	1/8	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1066 10661095	MUSC	Back pain/ lower back pain	2	06OCT2020	23/3	2	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1066 10661106	GENRL	Pain/ body aches	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001	GENRL	Pain/ body aches#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661116		Pyrexia/ fever#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1066 10661129	GENRL	Injection site pain/ pain at injection site#	3	16JAN2021	2/3	1	Yes		NA	R (18JAN2021)	N/N
16-55/ C4591001 1066 10661138	GENRL	Injection site pain/ pain at injection site#	3	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pain/ body aches#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	METAB	Decreased appetite/ lack of appetite#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1066 10661182	GENRL	Fatigue/ fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ body aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1066 10661192	INFEC	Diverticulitis/ diverticulitis	2	07NOV2020	44/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661202	BLOOD	Lymphadenopathy/ L side axillary lymph node swelling#	4	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	08JAN2021	1/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1066 10661203	GENRL	Pain/ body aches	1	07SEP2020	1/3	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ fever	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Chills/ chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Pain/ body aches	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ fever	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1066 10661226	VASC	Hot flush/ hot flashes	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	2/4	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661235	GENRL	Pain/ body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1066 10661242	RESP	Pleuritic pain/ pleuritic chest pain#	4	15FEB2021	6/8	2	No	O	NA/TC	R (22FEB2021)	N/N
		Pulmonary embolism/ Pulmonary Embolism with bilateral lower lobe Pulmonary embolisms#	4	15FEB2021	6/2	3	No	O	NA/TC	RS (16FEB2021)	Y/N
16-55/ C4591001 1066 10661253	GENRL	Pain/ body aches#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1066 10661261	GENRL	Chills/ chills#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
		Pain/ body aches#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Pyrexia/ fever#	4	04JAN2021	1/3	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661264	GENRL	Fatigue/ fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1066 10661265	GENRL	Chills/ chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Pain/ body aches#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ fever#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1066 10661275	INFEC	Herpes zoster/ Herpes zoster	2	24OCT2020	16/14	2	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1066 10661279	GASTR	Nausea/ nausea	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		Pain/ body aches	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1066 10661282	GENRL	Fatigue/ fatigue#	4	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661294	NERV	Headache/ headache#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pain/ body aches	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1066 10661308		Pyrexia/ fever	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1066 10661315	GENRL	Injection site pain/ pain at injection site	1	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1066 10661323	GENRL	Chills/ chills	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ chills	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1066 10661324	INFEC	Localised infection/ infection left middle finger	2	29NOV2020	28/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1066 10661331	GENRL	Chills/ chills	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Pain/ body aches	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1066 10661337	GENRL	Injection site pain/ pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1066 10661342	GENRL	Pyrexia/ Fever#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1066 10661345	GENRL	Fatigue/ fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
		Injection site pain/ pain at injection site	2	07NOV2020	2/4	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1066 10661379		Pain/ body aches	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1066 10661388	GENRL	Injection site pain/ pain at injection site	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1066 10661396	GENRL	Injection site pain/ pain at injection site#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	MUSC	Myalgia/ muscle pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	NERV	Headache/ headache#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1068 10681002	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	2/4	2	Yes		NA/TC/TCN	R (22AUG2020)	N/N
	NERV	Dizziness/ lightheadedness	1	19AUG2020	2/4	1	Yes		NA/TC/TCN	R (22AUG2020)	N/N
		Headache/ Headache	1	19AUG2020	2/4	2	Yes		NA/TC/TCN	R (22AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1068 10681013	MUSC	Arthralgia/ Joint Aches	2	10SEP2020	2/2	2	Yes		NA/TC/TCN	R (11SEP2020)	N/N	
		Myalgia/ Muscle Aches	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ headache#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/Y	
	16-55/ C4591001 1068 10681021	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		GENRL	Chills/ chills	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
			Pyrexia/ fever	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	16-55/ C4591001 1068 10681024	GENRL	Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC/TCN	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
	NERV	Headache/ Headache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681025	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Pain/ body aches#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1068 10681026	GENRL	Injection site pain/ Injection Site pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1068 10681027	GENRL	Injection site pain/ Pain at the injection site	1	21AUG2020	1/2	1	Yes		NA/TC	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	22AUG2020	2/1	1	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1068 10681031	GASTR	Nausea/ nausea#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1068 10681035	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	22/4	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Joint Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
		Myalgia/ Muscle Aches	2	15SEP2020	2/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1068 10681036	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	NERV	Headache/ headache#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
		Dyspnoea/ shortness of breath	1	29AUG2020	6/10	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C4591001 1068 10681037	RESP								NA		
	GENRL	Wheezing/ wheezing	1	29AUG2020	6/10	1	No	O	NA	R (07SEP2020)	N/N
		Fatigue/ fatigue#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	MUSC	Myalgia/ left arm muscle aches#	3	24FEB2021	1/3	2	Yes		NA	R (26FEB2021)	N/N
		Nausea/ Nausea	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001	GASTR								NA		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1068 10681042	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1068 10681046	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	16SEP2020	22/1	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	22/3	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	EYE	Eye pruritus/ Right Eye Itching	2	17OCT2020	32/2	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1068 10681052	MUSC	Tendonitis/ Tendonitis of the right forearm	1	15SEP2020	20/C	1	No	O	NA/TC	RG	N/N
	NERV	Headache/ headache#	3	30DEC2020	3/5	2	Yes		NA	R (03JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681053	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Joint range of motion decreased/ Decreased left shoulder mobility	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ injection Site Pain	1	05SEP2020	10/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1068 10681058	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1068 10681060	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	2	Yes		NA/TC/TCN	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
		Pain/ Body aches	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1068 10681064	GASTR	Nausea/ Nausea	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681066	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left swollen cervical lymph node	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GASTR	Gingival swelling/ Gum Swelling	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Chills/ chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1068 10681071		Pain/ body aches#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
		Injection site pain/ pain at the injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
		Pain/ body aches#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1068 10681074	NERV	Headache/ headache#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ chills#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681077	NERV	Pain/ body aches#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Headache/ headache#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1068 10681080	GASTR	Nausea/ nausea#	4	12MAR2021	1/2	1	Yes		NA/TC	R (13MAR2021)	N/N
	GENRL	Chills/ chills#	4	12MAR2021	1/2	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1068 10681083	GENRL	Chills/ chills#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1068 10681086	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pain/ body aches	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/5	2	Yes		NA	R (07SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1068 10681098	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/1	1	Yes	NA	NA	R (04SEP2020)	N/N
		Pain/ Body Aches	1	04SEP2020	2/1	2	Yes	NA/TC	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1068 10681100	GENRL	Fatigue/ Fatigue	1	06SEP2020	4/9	1	Yes	NA/TC	NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	06SEP2020	4/3	1	Yes	NA	NA	R (08SEP2020)	N/N
	NERV	Headache/ headache	1	06SEP2020	4/3	1	Yes	NA	NA	R (08SEP2020)	N/N
16-55/ C4591001 1068 10681106	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes	NA/TC	NA/TC	R (26SEP2020)	N/N
		Injection site pain/ injection site pain	2	25SEP2020	1/2	1	Yes	NA/TC	NA/TC	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes	NA/TC	NA/TC	R (26SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	26SEP2020	2/1	1	Yes	NA/TC	NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1068 10681109	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	2	Yes	NA/TC	NA/TC	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1068 10681110	SKIN	Urticaria/ Left forearm hives	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1068 10681113	SKIN	Rash/ Rash on arm	1	11SEP2020	4/3	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Nausea/ nausea	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Presyncope/ near syncope	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1068 10681114	INFEC	Sinusitis/ Maxillary Sinusitis	1	26SEP2020	19/10	1	No	O	NA	R (05OCT2020)	N/N
16-55/ C4591001 1068 10681117	GENRL	Chills/ rigors#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1068 10681119	GENRL	Chills/ chills	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ fever	2	02OCT2020	2/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1068 10681121	GENRL	Injection site pain/ injection site pain in left arm	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ muscle aches in back	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	NERV	Headache/ headache	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ chest tightness consistent with skeletal pain	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1071 10711004	RESP	Oropharyngeal pain/ SORE THROAT	2	23SEP2020	21/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1071 10711019	NERV	Headache/ HEADACHE	2	07SEP2020	6/4	2	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711022	GENRL	Pain/ BODY ACHES#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1071 10711027	PSYCH	Irritability/ IRRITABILITY	1	12AUG2020	1/8	1	No	O	NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	13AUG2020	2/7	1	No	O	NA	R (19AUG2020)	N/N
16-55/ C4591001 1071 10711028	MUSC	Pain in extremity/ SORE ARM#	4	11FEB2021	2/6	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1071 10711039	GENRL	Fatigue/ FATIGUE	2	09SEP2020	6/13	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	09SEP2020	6/13	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1071 10711042	GENRL	Chills/ CHILLS#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N
	INV	Body temperature increased/ ELEVATED TEMPERATURE#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	15FEB2021	2/2	1	Yes		NA	R (16FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711055	MUSC	Myalgia/ MUSCLE ACHES#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Pain in extremity/ SORE ARM#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1071 10711056	MUSC	Arthralgia/ RIGHT SHOULDER PAIN	2	17SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C4591001 1071 10711057	MUSC	Neck pain/ SORENESS, RIGHT SIDE, BASE OF NECK#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
		Pain in extremity/ RIGHT ARM SORENESS#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ BODY ACHES#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ GENERALIZED BODY ACHES#	4	14FEB2021	1/3	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1071 10711061	GENRL	Injection site pain/ INJECTION SITE SORENESS	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ GENERALIZED BODY PAIN	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1071 10711065	NERV	Headache/ HEADACHE	2	15SEP2020	7/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1071 10711080	MUSC	Neck pain/ NECK PAIN	1	04SEP2020	14/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1071 10711083	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		Vomiting/ VOMITTING	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Chills/ CHILLS	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Back pain/ WORSENING OF BACK PAIN	1	28AUG2020	5/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1071 10711097	GENRL	Chills/ CHILLS#	4	14FEB2021	4/2	1	Yes		NA	R (15FEB2021)	N/N
		Fatigue/ FATIGUE#	4	14FEB2021	4/2	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1071 10711119	MUSC	Myalgia/ GENERAL MUSCLE PAIN	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711124	MUSC	Myalgia/ MUSCLE ACHES#	4	22FEB2021	3/7	1	No	O	NA	R (28FEB2021)	N/N
16-55/ C4591001 1071 10711125	GENRL	Chills/ CHILLS	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ GENERAL BODY ACHES	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1071 10711133	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ FEVER AFTER INJECTION	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1071 10711138	GENRL	Pyrexia/ FEVER AFTER INJECTION	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	SKIN	Night sweats/ NIGHT SWEATS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1071 10711151	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711153	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	2	01OCT2020	3/4	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1071 10711156	MUSC	Pain in extremity/ SORE ARM#	3	20FEB2021	1/15	1	Yes		NA	R (06MAR2021)	N/N
	NERV	Paraesthesia/ TINGLING IN IMMUNIZATION ARM#	3	20FEB2021	1/15	1	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1071 10711159	GENRL	Fatigue/ FATIGUE	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1071 10711160	NEOPL	Lipoma/ BENIGN LIPOMA LEFT ARM	1	28SEP2020	18/5	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1071 10711167	INJ&P	Contusion/ BRUISING LEFT ARM	1	18SEP2020	4/13	2	Yes		NA	R (30SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1071 10711171	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODE UNDER LEFT ARMPIT	2	07OCT2020	3/6	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1071 10711176	GENRL	Injection site pain/ MUSCLE PAIN AT INJECTION SITE	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1071 10711183	NERV	Headache/ HEADACHE	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1071 10711193	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C4591001 1071 10711199	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1071 10711200	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1071 10711206	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	28SEP2020	3/1	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1071 10711215 16-55/ C4591001	MUSC	Myalgia/ MUSCLE PAIN	1	02NOV2020	19/15	2	No	O	NA	R (16NOV2020)	N/N
1071 10711227 16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
1071 10711230	GENRL	Fatigue/ FATIGUE	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N
1071 10711250 16-55/ C4591001	GASTR	Nausea/ Nausea	1	22AUG2020	6/2	1	No	O	NA	R (23AUG2020)	N/N
1072 10721001	GENRL	Malaise/ General Malaise	1	22AUG2020	6/2	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001	MUSC	Metatarsalgia/ metatarsalgia	2	SEP2020	1/C	1	No	O	NA	N	N/N
1072 10721022 16-55/ C4591001	METAB	Hypercholesterolaemia/ HYPERCHOLESTERemia	2	DEC2020	79/C	1	No	CD	NA/TC	N	N/N
1072 10721031											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ HYPERTENSION	2	DEC2020	79/C	1	No	CD	NA/TC	N	N/N
16-55/ C4591001 1072 10721035	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1072 10721084	INFEC	Gingival abscess/ gum abscess	2	21NOV2020	60/4	1	No	O	NA/TC	R (24NOV2020)	N/N
	SURG	Endodontic procedure/ Root Canal Procedure	2	21NOV2020	60/1	2	No	O	NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1072 10721099	SKIN	Dermatitis atopic/ (Atopic Dermatitis) rash on arms, abd, head	2	DEC2020	64/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771003	GASTR	Coeliac disease/ CELIACS DISEASE	2	15OCT2020	46/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1077 10771004	MUSC	Pain in extremity/ BILATERAL HAND PAIN	2	07SEP2020	8/6	1	No	O	NA/TC	R (12SEP2020)	N/N
	INFEC	Diverticulitis/ FLARE OF DIVERTICULITIS	2	02OCT2020	33/6	1	No	O	NA/TC	R (07OCT2020)	N/N
	MUSC	Arthralgia/ WORSENING RIGHT KNEE PAIN	2	01DEC2020	93/C	2	No	O	NA	N	N/N
16-55/ C4591001	GENRL	Pyrexia/ FEVER OF 101.0	1	17AUG2020	8/2	1	Yes		NA/TC	R (18AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1077 10771007	RESP	Sinus congestion/ SINUS CONGESTION	1	17AUG2020	8/3	2	Yes		NA	R (19AUG2020)	N/N
	NERV	Dizziness/ DIZZINESS	2	02OCT2020	29/1	2	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1077 10771009	NEOPL	Lipoma/ LiPOMA, LOWER BACK	2	05JAN2021	128/11	1	No	O	NA/TCN	R (15JAN2021)	N/N
16-55/ C4591001 1077 10771013	PSYCH	Depression/ WORSENING DEPRESSION	1	21AUG2020	12/C	2	No	O	NA/TC	N	N/N
	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	26SEP2020	27/47	1	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1077 10771014	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE#	4	17FEB2021	3/4	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1077 10771038	VASC	Haematoma/ HEMATOMA LEFT ARM	2	01OCT2020	30/18	2	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1077 10771041	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1077 10771042	GENRL	Fatigue/ FATIGUE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C4591001 1077 10771044	INFEC	Herpes zoster/ ZOSTER WITHOUT COMPLICATIONS	2	26SEP2020	19/12	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1077 10771045	GENRL	Fatigue/ FATIGUE	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	METAB	Type 2 diabetes mellitus/ TYPE II DIABETES	2	09OCT2020	30/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771054	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/4	1	Yes		NA	R (20AUG2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE- LEFT ARM	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Nasopharyngitis/ COMMON COLD	1	29AUG2020	13/7	1	No	O	NA	R (04SEP2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION	1	06SEP2020	21/11	2	No	O	NA/TC	R (16SEP2020)	N/N
	REPRO	Polycystic ovaries/ POLYCYSTIC OVARIAN SYNDROME	2	01OCT2020	23/C	1	No	O	NA	N	N/N
	METAB	Glucose tolerance impaired/ PRE-DIABETIC MELLITUS#	2	20FEB2021	165/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771058	GASTR	Nausea/ NAUSEA	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N
		Vomiting/ INTERMITTENT VOMITING	1	21AUG2020	5/15	2	No	CD	NA	R (04SEP2020)	N/N
16-55/ C4591001 1077 10771089	NERV	Dizziness/ DIZZINESS	2	12OCT2020	29/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1077 10771120	PSYCH	Attention deficit hyperactivity disorder/ ATTENTION DEFICIT HYPERACTIVITY DISORDER	2	11FEB2021	149/C	1	No	O	NA	N	N/N
16-55/ C4591001 1077 10771126	PSYCH	Anxiety/ WORSENING ANXIETY	1	09SEP2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	METAB	Type 2 diabetes mellitus/ WORSENING OF TYPE II DIABETES	2	12JAN2021	118/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1077 10771128 16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
1077 10771132 16-55/ C4591001	INFEC	Herpes zoster/ SHINGLES	2	23NOV2020	68/7	1	No	O	NA/TC	R (29NOV2020)	N/N
1077 10771134 16-55/ C4591001	GASTR	Diarrhoea/ DIARRHEA	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
1077 10771137	GENRL	Fatigue/ FATIGUE	1	28AUG2020	2/3	2	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE- LEFT ARM	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	30AUG2020	4/2	1	Yes		NA	R (31AUG2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	30AUG2020	4/2	1	Yes		NA	R (31AUG2020)	N/N
	INJ&P	Tibia fracture/ LEFT TIBIAL PLATEAU FRACTURE	2	28JAN2021	134/C	2	No	O	NA/TC/TCN	RG	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1077 10771140	NEOPL	Skin papilloma/ SCALP VIRAL WART#	4	20FEB2021	17/7	1	No	O	NA/TCN	R (26FEB2021)	N/N
16-55/ C4591001 1077 10771169	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	07OCT2020	17/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771171	PSYCH	Anxiety/ WORSENING ANXIETY	2	02OCT2020	10/C	1	No	O	NA/TC	N	N/N
	REPRO	Postmenopausal haemorrhage/ POSTMENOPAUSAL BLEEDING	2	20NOV2020	59/11	2	No	O	NA/TCN	R (30NOV2020)	N/N
16-55/ C4591001 1077 10771178	SKIN	Dermatitis contact/ POISON IVY RASH	2	10OCT2020	17/28	1	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1077 10771184	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	22OCT2020	28/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771188	NERV	Seizure like phenomena/ Subject reports Seizure like activity#	2	27FEB2021	157/1	2	No	O	NA	R (27FEB2021)	N/N
16-55/ C4591001 1077 10771189	SKIN	Urticaria/ URTICARIA	1	08SEP2020	6/2	2	No	O	NA/TC	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Lyme disease/ LYME'S DISEASE	2	19OCT2020	28/7	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1077 10771193	MUSC	Intervertebral disc protrusion/ HERNIATED DISK L5	2	07JAN2021	105/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771201	MUSC	Periarthritis/ LEFT SHOULDER ADHESIVE CAPSULITIS#	2	18JAN2021	118/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1077 10771209	GENRL	Fatigue/ FATIGUE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1077 10771238	INFEC	Ear infection/ LEFT EAR INFECTION	1	02OCT2020	15/10	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1077 10771247	INFEC	Hepatitis A/ HEPATITIS A	1	30OCT2020	12/C	1	No	O	NA	N	N/N
16-55/ C4591001 1077 10771248	GENRL	Injection site pain/ PAIN AT INJECTION SITE- LEFT ARM	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001	INFEC	Impetigo/ IMPETIGO	2	01DEC2020	22/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1077 10771261 16-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N
16-55/ C4591001 1079 10791010	RESP	Productive cough/ Wet Cough	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N
16-55/ C4591001 1079 10791143	SKIN	Rhinorrhoea/ Runny Nose Dermatitis contact/ Poison Ivy RASH (Arms and Legs)	1	30JUL2020	1/1	1	No	O	NA	R (30JUL2020)	N/N
16-55/ C4591001 1079 10791143	SKIN	Dermatitis contact/ Poison Ivy RASH (Arms and Legs)	1	08SEP2020	22/11	2	No	O	NA/TC/TCN	R (18SEP2020)	N/N
16-55/ C4591001 1079 10791199	NERV	Seizure/ Seizure#	2	03MAR2021	169/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1079 10791245	GENRL	Non-cardiac chest pain/ NON CARDIAC CHEST PAIN	2	05OCT2020	13/3	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1079 10791290	PSYCH	Attention deficit hyperactivity disorder/ ADHD (Difficulty Focusing)	2	18NOV2020	45/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1079 10791296	PSYCH	Attention deficit hyperactivity disorder/ ADHD diagnosis#	3	14JAN2021	24/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1080 10801002	GASTR	Gastric ulcer haemorrhage/ Bleeding Ulcers (Stomach)	1	11AUG2020	2/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1080 10801004	GENRL	Injection site pain/ Injection site pain#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N	
	NERV	Headache/ Headache#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N	
16-55/ C4591001 1080 10801017	MUSC	Pain in extremity/ Sore arm#	3	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N	
16-55/ C4591001 1080 10801032	GASTR	Abdominal discomfort/ GI Distress#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	
		Diarrhoea/ Diarrhea#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N	
	NERV	Headache/ Headache#	4	05MAR2021	2/1	2	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1080 10801033	GENRL	Chills/ Chills#	4	05MAR2021	2/1	1	Yes		NA	R (05MAR2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1080 10801045	GASTR	Fatigue/ Fatigue#	4	05MAR2021	2/1	1	Yes		NA	R (05MAR2021)	N/N
		Diarrhoea/ diarrhea	2	08SEP2020	1/1	1	Yes		NA/TC	R (08SEP2020)	N/N
		Nausea/ Nausea	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1080 10801051	GENRL	Injection site pain/ Injection site pain - Right Arm	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
	SKIN	Erythema/ Redness in Right arm	2	09SEP2020	2/5	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Chest discomfort/ Chest Pressure	1	22AUG2020	6/2	2	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1080 10801057	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	09SEP2020	1/7	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1080 10801059	PSYCH	Anxiety/ Anxiety	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	INFEC	Appendicitis/ Appendicitis	2	09FEB2021	153/1	3	No	O	NA/TCN	R (09FEB2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1080 10801068	GASTR	Nausea/ Nausea	2	10SEP2020	1/6	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/6	2	Yes		NA	R (15SEP2020)	N/N
	REPRO	Menstruation irregular/ Irregular Menses	2	10SEP2020	1/C	1	No	O	NA	N	N/N
	GASTR	Noninfective gingivitis/ Inflamed Gums	2	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1080 10801081	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1080 10801082	GENRL	Injection site pain/ Soreness at injection site	2	16SEP2020	3/7	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	3/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1080 10801096	GENRL	Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1080 10801100	GENRL	Injection site pain/ Injection site arm pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1080 10801109	GENRL	Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1080 10801114	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Pain in extremity/ injection arm pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	NERV	Headache/ headache#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1080 10801117	GENRL	Injection site pain/ Soreness at injection site	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1080 10801131	GENRL	Pyrexia/ fever#	4	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1080 10801153	MUSC	Pain in extremity/ Sore arm#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1080 10801159	GASTR	Diarrhoea/ Diarrhea	2	01OCT2020	7/1	1	No	O	NA	R (01OCT2020)	N/N
	GENRL	Pain/ Body Aches#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Low-grade fever 99.3#	4	12MAR2021	2/1	2	Yes		NA	R (12MAR2021)	N/N
16-55/ C4591001 1080 10801180	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1080 10801183	GENRL	Injection site mass/ Lump at injection site	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1080 10801212	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body Aches#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever of 100.8 F#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1080 10801221	GENRL	Pain/ body aches#	3	20JAN2021	2/2	2	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1081 10811009	GASTR	Nausea/ Nausea#	3	07FEB2021	5/1	2	Yes		NA	R (07FEB2021)	N/N
		Vomiting/ Vomiting#	3	07FEB2021	5/2	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1081 10811012	GENRL	Injection site pain/ pain at site of injection (left deltoid)#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
	GASTR	Diarrhoea/ diarrhea (one episode)#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
	GENRL	Chills/ chills#	3	02MAR2021	2/1	1	Yes		NA	R (02MAR2021)	N/N
		Pyrexia/ fever (101.9)#	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1081 10811036	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N
	BLOOD	Anaemia/ Anemia	2	02NOV2020	61/C	2	No	O	NA	N	N/N
16-55/ C4591001 1081 10811046	METAB	Diabetic ketoacidosis/ Diabetic Ketoacidosis	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1081 10811075	RESP	Paranasal sinus discomfort/ sinus nasal pressure	2	03OCT2020	24/2	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1081 10811085	GENRL	Fatigue/ fatigue	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1081 10811086	GENRL	Malaise/ Malaise#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ Fever#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA	R (12MAR2021)	N/N
16-55/ C4591001 1081 10811096	RENAL	Nephrolithiasis/ Kidney Stone	1	06SEP2020	13/1	2	No	O	NA	R (06SEP2020)	N/N
16-55/ C4591001 1081 10811119	NERV	Syncope/ Episode of Syncopy	2	29SEP2020	15/1	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1081 10811127	GASTR	Diarrhoea/ Diarrhea#	4	13MAR2021	2/C	1	Yes		NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
		Pyrexia/ Fever#	4	13MAR2021	2/1	1	Yes		NA	R (13MAR2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1081 10811133	INJ&P	Foreign body in eye/ Foreign body eye	2	04OCT2020	13/1	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1081 10811134	NERV	Headache/ Headache	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N
	RESP	Oropharyngeal pain/ Sore throat	2	12OCT2020	21/2	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C4591001 1081 10811135	VASC	Essential hypertension/ New onset Essential Hypertension*		31AUG2020	1/C	2	No	O	NA/TC	RG	N/N
	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/8	4	No	O	NA/TC/TCN	RS (28OCT2020)	Y/N
	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus	2	27OCT2020	36/C	3	No	O	NA/TC	RG	Y/N
	METAB	Hyperlipidaemia/ New onset Unspecified Hyperlipidemia	2	29OCT2020	38/C	2	No	O	NA/TC	RG	N/N
	CARD	Coronary artery disease/ Coronary Artery disease	2	04NOV2020	44/C	2	No	O	NA/TC/TCN	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1081 10811141	NERV	Migraine/ Migraine	2	07DEC2020	77/1	2	No	O	NA	R (07DEC2020)	N/N
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N
16-55/ C4591001 1081 10811196	INFEC	Hordeolum/ left eye lower lid sty	2	03OCT2020	3/11	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1081 10811198	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Pain/ Body Aches	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1081 10811206	GENRL	Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1082 10821011	INJ&P	Ligament rupture/ left knee ACL rupture#	2	17FEB2021	176/8	2	No	O	NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1082 10821028	HEPAT	Cholecystitis/ cholecystitis	2	05JAN2021	134/1	2	No	O	NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1082 10821083	CARD	Myocardial infarction/ myocardial infarction	2	28OCT2020	62/8	4	No	O	NA	R (04NOV2020)	Y/N
16-55/ C4591001 1082 10821149	MUSC	Neck pain/ neck pain	1	21SEP2020	19/C	1	No	O	NA/TC	N	N/N
	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N
16-55/ C4591001 1082 10821163	CARD	Ventricular tachycardia/ paroxysmal ventricular tachycardia (etiology unknown)	2	06NOV2020	26/2	2	No	O	NA	R (07NOV2020)	N/N
16-55/ C4591001 1082 10821195	INFEC	Tooth abscess/ dentoalveolar abscess tooth #15	1	20OCT2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1082 10821198	INFEC	Abscess/ abscess of lower lip	2	24NOV2020	23/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1083 10831001	INJ&P	Fall/ Fall	2	26AUG2020	6/1	2	No	O	NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fibula fracture/ Fibula fracture	2	26AUG2020	6/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831004	SKIN	Hangnail/ Hang Nail	1	31JUL2020	3/8	1	No	O	NA/TC	R (07AUG2020)	N/N
16-55/ C4591001 1083 10831013	INV	Heart rate increased/ Rapid Heart Beat	1	31JUL2020	2/1	1	No	O	NA	R (31JUL2020)	N/N
	MUSC	Scoliosis/ Increased Back Pain secondary to Scoliosis	2	06OCT2020	48/11	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1083 10831017	GENRL	Injection site pain/ Injection Site Pain-Left Arm#	2	26FEB2021	192/3	1	Yes		NA	R (28FEB2021)	N/N
	NERV	Headache/ Headache#	3	27FEB2021	2/1	2	Yes		NA/TC	R (27FEB2021)	N/N
16-55/ C4591001 1083 10831029	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N
	CARD	Left ventricular hypertrophy/ Left Ventricular Hypertrophy	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
	VASC	Hypertension/ Hypertension	1	24AUG2020	21/C	1	No	O	NA/TC	N	N/N
	INJ&P	Skin laceration/ Laceration-Left Index Finger	1	01SEP2020	29/15	2	No	O	NA/TCN	R (15SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	CARD	Atrial flutter/ Atrial Flutter	1	02SEP2020	30/7	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N	
	CARD	Myocardial infarction/ Prior Septual Myocardial Infarction	1	08SEP2020	36/1	1	No	O	NA	R (08SEP2020)	N/N	
	CARD	Left atrial enlargement/ Left Atrial Enlargement	1	09SEP2020	37/C	1	No	O	NA	N	N/N	
		Mitral valve incompetence/ Mitral Regurgitation	1	09SEP2020	37/C	1	No	O	NA	RG	N/N	
		Mitral valve prolapse/ Bileaflet mitral valve prolapse	1	09SEP2020	37/C	1	No	O	NA	N	N/N	
	EAR	Ear pain/ Ear Pain	1	04DEC2020	123/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1083 10831040	PSYCH	Anxiety/ Situational Anxiety	2	27AUG2020	3/C	1	No	O	NA/TC	N	N/N	
	NEOPL	Uterine leiomyoma/ Worsening of Uterine Fibroids	2	16SEP2020	23/9	1	No	O	NA/TCN	R (24SEP2020)	N/N	
16-55/ C4591001 1083 10831046	GENRL	Injection site pain/ Pain at Injection Site-Right	2	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N	
	NEOPL	Benign uterine neoplasm/ Benign Uterine Mass	2	07DEC2020	105/1	2	No	O	NA/TCN	R (07DEC2020)	N/N	
16-55/ C4591001 1083 10831057	INFEC	Diverticulitis/ Diverticulitis Flare	1	09AUG2020	5/11	2	No	O	NA	R (19AUG2020)	N/N	
16-55/ C4591001	GASTR	Abdominal pain/ Worsening of Abdominal Pain	1	14AUG2020	9/11	4	No	O	NA/TC	R (24AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831060		Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
	INJ&P	Postoperative ileus/ Post Operative Ileus	1	18AUG2020	13/6	2	No	O	NA/TC	R (23AUG2020)	N/N
	GASTR	Small intestinal obstruction/ Small Bowel Obstruction	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N
	INFEC	Cellulitis/ Phlegmon Formation	1	20AUG2020	15/1	3	No	O	NA/TC/TCN	R (20AUG2020)	N/N
		Diverticulitis/ Diverticulitis	1	20AUG2020	15/6	4	No	O	NA/TC/TCN	R (25AUG2020)	N/N
	INFEC	Diverticulitis/ Diverticulitis	1	26AUG2020	21/C	3	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N
		Injection site pain/ Injection Site Pain-Left#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N
	NERV	Headache/ Slight Headache#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N
16-55/ C4591001 1083 10831068	INFEC	Cellulitis/ Left Ear Cellulitis	2	20NOV2020	82/C	1	No	O	NA/TC	N	N/N
	IMMUN	Drug hypersensitivity/ Allergic Reaction to Ear Drops-left ear	2	22NOV2020	84/C	1	No	CD	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831070	MUSC	Tendonitis/ Tendentitis-Right Knee#	2	05MAR2021	187/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831074	GASTR	Diarrhoea/ Diarrhea	1	16AUG2020	7/46	2	No	O	NA/TC	R (30SEP2020)	N/N
	GASTR	Toothache/ Toothache	1	18AUG2020	9/32	2	No	O	NA/TC	R (18SEP2020)	N/N
	IMMUN	Drug hypersensitivity/ Oral Penicillin Reaction	1	25AUG2020	16/3	1	No	O	NA	R (27AUG2020)	N/N
	GASTR	Pancreatic failure/ Exocrine pancreatic insufficiency	2	12SEP2020	13/C	1	No	O	NA	N	N/N
	GASTR	Submaxillary gland enlargement/ Swollen Submandibular Gland Neck Right Side#	3	08JAN2021	1/2	1	No	O	NA	R (09JAN2021)	N/N
	GASTR	Submaxillary gland enlargement/ Submandibular Gland facial swelling-Right side#	4	28JAN2021	1/2	1	No	O	NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	21/3	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1083 10831084	INJ&P	Meniscus injury/ Torn Meniscus-Right	1	17AUG2020	7/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1083 10831086	MUSC	Arthralgia/ Wrist Pain	1	29AUG2020	19/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	IMMUN	Seasonal allergy/ Worsening of Seasonal Allergies	2	26DEC2020	118/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831098	MUSC	Neck pain/ Neck Pain	1	17AUG2020	5/4	2	No	O	NA/TC	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	6/3	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1083 10831101	INV	Body temperature increased/ Elevated Temperature	1	14AUG2020	2/1	1	Yes		NA	R (14AUG2020)	N/N
	GASTR	Abdominal pain upper/ Intermittent Pain-Left Upper Quadrant	1	19AUG2020	7/C	2	No	O	NA/TC	RG	N/N
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	19AUG2020	7/42	2	No	O	NA/TC	R (29SEP2020)	N/N
	GASTR	Constipation/ Constipation	2	29SEP2020	29/C	1	No	O	NA	RG	N/N
	GASTR	Gastrointestinal disorder/ Gastrointestinal Issue	2	29SEP2020	29/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1083 10831105	GASTR	Cheilitis/ Cheilitis	2	02OCT2020	25/15	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1083 10831113	NERV	Syncope/ Syncope*		18AUG2020	1/1	1	No	O	NA	R (18AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831118	MUSC	Myalgia intercostal/ Intercostal Muscle Pain-Left	2	07DEC2020	91/4	2	No	O	NA/TC	R (10DEC2020)	N/N
16-55/ C4591001 1083 10831119	GASTR	Toothache/ Toothache -Lower Left Side Wisdom tooth	1	04SEP2020	18/19	2	No	O	NA/TC	R (22SEP2020)	N/N
	SURG	Wisdom teeth removal/ Tooth Extraction-Lower Left Side Wisdom tooth	2	22SEP2020	13/1	2	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1083 10831122	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
		Injection site pain/ Injection Site Soreness-Left#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1083 10831123	GENRL	Injection site pain/ Pain at injection site*		19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09SEP2020	22/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	1	09SEP2020	22/4	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	09SEP2020	22/2	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001	VASC	Varicose vein/ pain secondary to varicose vein in left thigh	2	06OCT2020	28/15	1	No	O	NA/TC	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1083 10831124	INJ&P	Stress fracture/ StressFracture-Right Foot	2	14JAN2021	128/C	1	No	O	NA	RG	N/N
	NERV	Headache/ Headache#	2	06MAR2021	179/3	1	Yes		NA/TC	R (08MAR2021)	N/N
	BLOOD	Lymphadenopathy/ Enlarged Lymph Node-Left Side#	3	07MAR2021	2/C	1	Yes		NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	07MAR2021	2/2	1	Yes		NA/TC	R (08MAR2021)	N/N
		Injection site erythema/ Injection Site Redness-5.5 centimeters#	3	07MAR2021	2/C	2	Yes		NA	RG	N/N
		Injection site pain/ Injection Site Pain-Left#	3	07MAR2021	2/2	1	Yes		NA	R (08MAR2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	07MAR2021	2/2	1	Yes		NA/TC	R (08MAR2021)	N/N
16-55/ C4591001 1083 10831127	GENRL	Injection site pain/ Injection Site Soreness-Left Arm#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1083 10831140	NERV	Headache/ Headache	1	10SEP2020	21/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831142	INFE	Pain/ Body Aches	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Sinusitis/ Sinus Infection	2	16NOV2020	68/C	2	No	O	NA/TC	RG	N/N
	PSYCH	Panic attack/ Worsening of Panic Attacks	1	31AUG2020	8/C	2	No	O	NA/TC	N	N/N
	SURG	Dental implantation/ Upper Dental Implant Surgery- Cosmetic	2	01OCT2020	18/1	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1083 10831143	MUSC	Pain in extremity/ Toe Pain- Right 5th toe	2	11NOV2020	59/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1083 10831148	EAR	Vertigo/ Vertigo	2	13JAN2021	122/8	1	No	O	NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1083 10831152	NERV	Headache/ Headache#	3	06MAR2021	1/C	1	Yes		NA	RG	N/Y
	SKIN	Dermatitis acneiform/ Acneiform Rash- Torso,Thighs,Upper Arms	1	03SEP2020	10/38	1	No	O	NA/TC	R (10OCT2020)	N/N
	SKIN	Eczema/ eczema	1	01OCT2020	38/C	1	No	O	NA/TC	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1083 10831162	GASTR	Abdominal pain upper/ Worsening of Right Upper Quadrant Pain	1	14SEP2020	20/C	1	No	O	NA	RG	N/N	
	GASTR	Vomiting/ Vomiting	2	18SEP2020	3/3	2	No	O	NA	R (20SEP2020)	N/N	
	PREG	Abortion spontaneous/ Miscarriage	2	04DEC2020	80/2	2	No	O	NA	R (05DEC2020)	Y/N	
16-55/ C4591001 1083 10831163	GENRL	Pain/ Body Aches#	3	25JAN2021	21/2	1	Yes		NA	R (26JAN2021)	N/N	
		Pyrexia/ Fever 100.4#	3	25JAN2021	21/2	1	Yes		NA	R (26JAN2021)	N/N	
16-55/ C4591001 1083 10831179	GASTR	Diarrhoea/ Diarrhea-Intermittent	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N	
	MUSC	Back pain/ Worsening of Lumbar Back Pain	1	18SEP2020	19/C	1	No	O	NA/TC	RG	N/N	
	GASTR	Intra-abdominal fluid collection/ Water Retention in the abdomen	2	01DEC2020	72/C	1	No	O	NA/TC	RG	N/N	
	MUSC	Muscle spasms/ Chest Muscle Spasm causing Chest Pain	2	01DEC2020	72/5	1	No	O	NA	R (05DEC2020)	N/N	
16-55/ C4591001 1083 10831181	INFEC	Urinary tract infection/ Urinary tract infection	1	01SEP2020	2/7	1	No	O	NA/TC	R (07SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831194	INFEC	Oral herpes/ Lip Fever Blister	2	03DEC2020	74/22	2	No	O	NA/TC	R (24DEC2020)	N/N
	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N
		Mitral valve incompetence/ Trivial Mitral Regurgitation	2	26OCT2020	34/C	1	No	O	NA/TC	N	N/N
		Palpitations/ Heart Palpitations	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1083 10831197	GENRL	Chest pain/ Chest Pain	2	26OCT2020	34/3	2	No	O	NA/TC	R (28OCT2020)	N/N
	BLOOD	Lymphadenitis/ Inflamed lymph nodes left breast	1	22SEP2020	19/C	1	No	O	NA	N	N/N
	INV	Mammogram abnormal/ Abnormal breast tissue on mammogram-left breast	1	22SEP2020	19/C	1	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1083 10831205		Pyrexia/ Low Grade Temperature	1	22OCT2020	49/2	1	Yes		NA	R (23OCT2020)	N/N
	ENDO	Autoimmune thyroiditis/ Hashimotos	2	19NOV2020	29/C	1	No	O	NA	N	N/N
	RENAL	Pollakiuria/ Urinary Frequency	1	29SEP2020	21/3	1	No	O	NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Insomnia/ Trouble Sleeping	2	01NOV2020	32/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831207	PSYCH	Depression/ Worsening of Situational Depression	2	04NOV2020	37/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831249	GENRL	Injection site pain/ Left Arm Pain at Injection Site	2	03OCT2020	2/4	2	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ Fever 101.0 degree fahrenheit	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/3	2	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1083 10831254	GENRL	Chills/ Chills	1	14OCT2020	23/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1083 10831262	INJ&P	Contusion/ Bruised Right Knee	2	29OCT2020	15/24	1	No	O	NA	R (21NOV2020)	N/N
		Fall/ Fall	2	29OCT2020	15/1	1	No	O	NA	R (29OCT2020)	N/N
		Joint injury/ Ankle Strain-Left	2	29OCT2020	15/5	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C4591001 1083 10831268	MUSC	Arthralgia/ Knee Pain-Right	2	02NOV2020	19/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Wrist Pain-Right	2	02JAN2021	80/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1083 10831272	RESP	Nasal discomfort/ Bilateral Nostril Irritation	1	22OCT2020	2/23	1	No	O	NA	R (13NOV2020)	N/N
	GASTR	Vomiting/ Vomiting	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Pyrexia/ Fever-102.0	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1083 10831276	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Low Grade Temperature 99.0 Fahrenheit	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1083 10831278	GENRL	Injection site pain/ Site Injection Pain-Left Arm#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1083 10831281	GENRL	Pyrexia/ Fever-100.3 Fahrenheit	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Joint Pain-Bilateral Shoulders, Bilateral Hips, Right Ankle and Right Elbow	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831282	INJ&P	Skin laceration/ Third Finger Laceration- Left Hand	1	30OCT2020	9/1	1	No	O	NA/TC	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Site Injection Pain-Left Eye#	2	23DEC2020	42/2	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1083 10831284	GENRL	Fatigue/ Fatigue#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N
		Injection site bruising/ Injection Site Bruising-Left#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N
		Injection site pain/ Injection Site Pain-Left#	2	02MAR2021	111/2	1	Yes		NA	R (03MAR2021)	N/N
	SKIN	Hyperhidrosis/ Hyperhidrosis#	2	02MAR2021	111/9	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001 1084 10841004	SKIN	Rash/ rash all over body	1	14AUG2020	8/13	2	No	O	NA/TC	R (26AUG2020)	N/N
	GASTR	Dental caries/ tooth cavity	2	OCT2020	35/	2	No	O	NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1084 10841056	GENRL	Fatigue/ Fatigue	2	26AUG2020	1/8	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1084 10841062	INJ&P	Fall/ Fall	1	28AUG2020	22/1	1	No	O	NA	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ BILATERAL ANKLE PAIN	1	28AUG2020	22/30	2	No	O	NA	R (26SEP2020)	N/N
16-55/ C4591001 1084 10841090	INFEC	Tooth infection/ Left Upper Tooth Infection	2	28SEP2020	32/15	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1084 10841095	INFEC	Ear infection/ left ear infection#	2	09FEB2021	163/C	2	No	O	NA/TC	N	N/N
	SKIN	Rash/ generalized rash on torso#	2	20FEB2021	174/C	1	No	O	NA	N	N/N
16-55/ C4591001 1084 10841099	PSYCH	Anxiety/ anxiety	2	OCT2020	32/C	2	No	O	NA/TC	RG	N/N
	GASTR	Nausea/ nausea#	3	08FEB2021	20/3	1	No	O	NA	R (10FEB2021)	N/N
16-55/ C4591001 1084 10841100	PSYCH	Depression/ increased depression#	2	18DEC2020	108/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1084 10841102	MUSC	Osteoarthritis/ OSTEO ARTHRITIS	2	15SEP2020	16/C	1	No	O	NA	N	N/N
	NERV	Radiculopathy/ radiculopathy (femoral nerve)	2	15SEP2020	16/C	2	No	O	NA	N	N/N
16-55/ C4591001	INFEC	Sinusitis/ Sinusitis	2	28SEP2020	29/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841107 16-55/ C4591001 1084 10841117	INFEC	Cellulitis/ Cellulitis FRONT OF ABDOMEN	1	24AUG2020	15/3	2	No	O	NA	R (26AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	13SEP2020	14/7	1	Yes		NA	R (19SEP2020)	N/N
	INV	Alanine aminotransferase increased/ Elevated ALT#	3	18JAN2021	6/C	1	No	O	NA	N	N/N
		Aspartate aminotransferase increased/ Elevated AST#	3	18JAN2021	6/C	1	No	O	NA	N	N/N
16-55/ C4591001 1084 10841118	INV	Weight decreased/ Weight-Loss	2	01SEP2020	5/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1084 10841121	NERV	Ageusia/ LOSS OF TASTE	2	05SEP2020	2/7	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1084 10841136	MUSC	Pain in jaw/ Right Jaw Pain	1	12AUG2020	1/2	2	Yes		NA	R (13AUG2020)	N/N
16-55/ C4591001 1084 10841141	INFEC	Appendicitis/ Appendicitis	2	20DEC2020	110/3	3	No	O	NA/TC/TCN	R (22DEC2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841182	GENRL	Injection site pain/ Injection Site Pain	1	15AUG2020	2/2	1	Yes		NA	R (16AUG2020)	N/N
16-55/ C4591001 1084 10841189	GENRL	Injection site pain/ Injection Site Pain	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
16-55/ C4591001 1084 10841197	GASTR	Vomiting/ Vomiting	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
	GENRL	Chills/ Chills	1	17AUG2020	1/1	1	Yes		NA	R (17AUG2020)	N/N
		Fatigue/ Fatigue	1	17AUG2020	1/4	2	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	17AUG2020	1/2	2	Yes		NA	R (18AUG2020)	N/N
	NERV	Headache/ Headache	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Chills/ Chills	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	18AUG2020	2/1	2	Yes		NA/TC	R (18AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	3/3	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841200	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1084 10841208	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	2	Yes		NA	R (18AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	19AUG2020	3/1	1	Yes		NA	R (19AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	3/1	3	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1084 10841209	GENRL	Injection site erythema/ Redness at Injection Site	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	INFEC	Pharyngitis streptococcal/ Strep Throat	2	16SEP2020	8/8	2	No	O	NA/TC	R (23SEP2020)	N/N
	VASC	Hypertension/ Hypertension#	2	10JAN2021	124/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1084 10841215	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841228	GENRL	Fatigue/ Fatigue	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
		Injection site erythema/ Redness at Injection Site	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	20AUG2020	2/1	2	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	3/2	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22AUG2020	4/1	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	23AUG2020	5/3	2	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	24AUG2020	6/1	2	Yes		NA	R (24AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
		Vomiting/ Vomiting	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Chills/ Chills	1	25AUG2020	7/1	1	Yes		NA	R (25AUG2020)	N/N
	NERV	Headache/ Headache	1	25AUG2020	7/1	2	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	11SEP2020	24/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	21AUG2020	3/3	1	Yes		NA	R (23AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841241 16-55/ C4591001 1084 10841268	INFEC	Urinary tract infection/ Urinary Tract Infection	2	11DEC2020	92/3	2	No	O	NA/TC	R (13DEC2020)	N/N
16-55/ C4591001 1084 10841269	INFEC	Urinary tract infection/ Urinary Tract Infection	2	29SEP2020	19/9	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1084 10841283	SKIN	Rash/ Left Inner Forearm Rash#	3	14JAN2021	2/4	1	Yes		NA/TC	R (17JAN2021)	N/N
16-55/ C4591001 1084 10841287	MUSC	Pain in extremity/ right hand and foot pain	2	23OCT2020	29/4	2	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1084 10841294	METAB	Vitamin D deficiency/ vitamin d deficiency#	3	15FEB2021	18/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1084 10841301	INJ&P	Fall/ Fall	1	04SEP2020	10/1	2	No	O	NA/TC	RS (04SEP2020)	N/N
16-55/ C4591001 1084 10841301	INJ&P	Ligament sprain/ Left Ankle Sprain	1	04SEP2020	10/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1084 10841301	INJ&P	Ligament sprain/ Right Ankle Sprain	2	14OCT2020	29/C	2	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841306	NERV	Headache/ Headache in Frontal Lobe	2	12OCT2020	27/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1084 10841307	GENRL	Peripheral swelling/ Bilateral Leg Swelling	1	29AUG2020	4/8	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1084 10841309	NERV	Headache/ Headache	1	29AUG2020	2/1	1	No	O	NA	R (29AUG2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection#	2	27FEB2021	163/6	1	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1084 10841315	MUSC	Back pain/ Back pain	2	15OCT2020	28/2	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1084 10841316	INFEC	Sinusitis/ Sinus Infection	1	01SEP2020	5/23	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1084 10841317	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N
16-55/ C4591001 1084 10841321	SKIN	Rash/ rash on right side of abdomen#	2	19DEC2020	90/3	1	No	O	NA/TC	R (21DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1084 10841327	RESP	Nasal congestion/ Worsening of Nasal Congestion	2	22SEP2020	2/21	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1084 10841376	NERV	Parosmia/ olfactory hallucinations (phantosmia)	1	12SEP2020	2/35	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1084 10841381	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15SEP2020	5/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1084 10841384	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Injection site erythema/ Redness at Injection Site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Injection site swelling/ Swelling at Injection Site	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841391	GASTR	Gastrooesophageal reflux disease/ Gerd	1	17SEP2020	4/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1084 10841393	RENAL	Haematuria/ haematuria	2	08OCT2020	2/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1084 10841404	INFEC	Ear infection/ left ear infection	1	01OCT2020	18/4	2	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1084 10841422	INJ&P	Ligament rupture/ Torn Ligament in Right Arm	1	07OCT2020	20/97	2	No	O	NA	R (11JAN2021)	N/N	
16-55/ C4591001 1084 10841428	INJ&P	Arthropod sting/ Wasp Sting on right forearm	1	25SEP2020	8/2	1	No	O	NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1084 10841429	MUSC	Back pain/ WORSERING BACK PAIN	2	12NOV2020	30/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1084 10841449	GENRL	Injection site pain/ injection site tenderness left arm	2	15OCT2020	2/C	1	Yes		NA	N	N/N	
16-55/ C4591001	GASTR	Nausea/ Post dose Nausea	2	16OCT2020	1/1	1	No	O	NA	R (16OCT2020)	N/Y	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841454 16-55/ C4591001 1084 10841464	INJ&P	Fall/ Fall	2	16NOV2020	29/1	1	No	O	NA	R (16NOV2020)	N/N
	MUSC	Arthralgia/ Left shoulder pain	2	16NOV2020	29/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1084 10841480	CARD	Acute coronary syndrome/ Acute Coronary Syndrome	1	26OCT2020	13/1	3	No	O	NA/TC/TCN	R (26OCT2020)	N/N
		Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N
	INV	Blood creatinine increased/ Elevated Creatinine	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N
	METAB	Hyperglycaemia/ Hyperglycemia	1	26OCT2020	13/2	1	No	O	NA	R (27OCT2020)	N/N
	VASC	Hypertensive urgency/ Hypertensive Urgency	1	26OCT2020	13/4	2	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1084 10841484	RESP	Pleuritic pain/ bilateral Pleuritic lung pain	1	01NOV2020	19/C	1	No	O	NA	N	N/N
16-55/ C4591001 1084 10841499	INFEC	Ear infection/ Right Ear Infection#	3	25JAN2021	13/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1084 10841511	INJ&P	Concussion/ concussion	2	03DEC2020	23/4	1	No	O	NA	R (06DEC2020)	N/N	
		Road traffic accident/ motor vehicle accident	2	03DEC2020	23/1	1	No	O	NA	R (03DEC2020)	N/N	
16-55/ C4591001 1084 10841526	INFEC	Labyrinthitis/ left inner ear infection#	2	15JAN2021	66/24	1	No	O	NA/TC	R (07FEB2021)	N/N	
16-55/ C4591001 1084 10841538	PSYCH	Bipolar I disorder/ Bipolar I#	2	31JAN2021	63/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1085 10851018	REPRO	Endometrial thickening/ Endometrial thickening#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
		Endometriosis/ Endometriosis#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1085 10851023	RESP	Respiratory tract congestion/ CHEST CONGESTION#	2	22JAN2021	152/15	2	No	O	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1085 10851129	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	23DEC2020	105/C		No	O	NA/W	N	N/N	
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1085 10851142		Pyrexia/ low grade fever	2	21SEP2020	6/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1085 10851178	INFEC	Sinusitis/ sinus infection#	3	07FEB2021	13/16	2	No	O	NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1085 10851191	INFEC	Gastrointestinal infection/ Gastrointestinal Infection	2	24NOV2020	70/25	1	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001 1085 10851225	GENRL	Injection site pain/ Injection Site Pain	2	26SEP2020	3/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1085 10851246	INJ&P	Radius fracture/ fracture left radius#	2	17FEB2021	147/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1085 10851248	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	19OCT2020	25/C		No	O	NA	UNK	N/N
16-55/ C4591001 1085 10851248	GENRL	Chills/ Chills	2	22SEP2020	2/6	1	Yes		NA	R (27SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	26SEP2020	6/2	1	Yes		NA	R (27SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1085 10851250	INFEC	Conjunctivitis/ conjunctivitis	1	16SEP2020	14/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1085 10851253	GASTR	Diarrhoea/ Diarrhea	2	28OCT2020	35/1	1	No	CND	NA	R (28OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	05NOV2020	43/1	1	No	CND	NA	R (05NOV2020)	N/N
16-55/ C4591001 1085 10851280	GENRL	Chills/ CHILLS	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ BODY ACHES	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1085 10851304	GENRL	Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1085 10851337	GENRL	Chills/ Chills	2	08OCT2020	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1085 10851361	GENRL	Injection site pain/ Injection site tenderness	1	10OCT2020	6/4	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1085 10851364	MUSC	Myalgia/ Muscle pain	2	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1087 10871020	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
		Myalgia/ Generalized muscle pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
		Myalgia/ Generalized Muscle Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1087 10871045	IMMUN	Food allergy/ Egg White/Yolk Allergy - Allergy Test Finding	1	28AUG2020	19/C	1	No	O	NA	N	N/N
		Food allergy/ Kidney Bean Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N
		Milk allergy/ Dairy Allergy - Allergy Test Findings	1	28AUG2020	19/C	1	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N
		Pyrexia/ Fever#	4	12MAR2021	2/2	1	Yes		NA/TC	R (13MAR2021)	N/N
16-55/ C4591001 1087 10871046	GASTR	Toothache/ TOOTH ACHE	2	02SEP2020	3/27	2	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C4591001 1087 10871053	GENRL	Pain/ Body Ache#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871064	INFEC	Tooth infection/ Wisdom Teeth Infection - Right lower quadrant	2	15JAN2021	136/15	2	No	O	NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1087 10871078	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	02FEB2021	156/C	1	No	O	NA/TC	N	N/N
	EYE	Blepharitis/ Blepharitis - Right Eye#	2	19FEB2021	173/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871089	CARD	Tachycardia/ TACHYCARDIA	1	24SEP2020	39/7	2	No	O	NA/TC	R (30SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1087 10871094	INFEC	Cellulitis/ CELLULITIS LEFT KNEE	1	03SEP2020	17/11	2	No	O	NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1087 10871103	GENRL	Pain/ Body Ache#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
	NERV	Lethargy/ Lethargy#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1087 10871109	RESP	Nasal congestion/ NASAL CONGESTION	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N	
16-55/ C4591001 1087 10871113	GENRL	Injection site pain/ Pain at injection site - Left deltoid#	3	15JAN2021	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1087 10871114	IMMUN	Seasonal allergy/ WORSENING OF SEASONAL ALLERGIES	2	27SEP2020	19/8	1	No	O	NA/TC	R (04OCT2020)	N/N	
	GASTR	Nausea/ NAUSEA	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N	
		Vomiting/ VOMITING	2	08OCT2020	30/2	1	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1087 10871127	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	20NOV2020	74/C	1	No	O	NA/TC	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871146	PSYCH	Anxiety/ ANXIETY	1	09SEP2020	21/C	1	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1087 10871148	GENRL	Pain/ Aches (generalized body)	2	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1087 10871149	INJ&P	Muscle rupture/ LEFT BICEP TEAR	2	29SEP2020	19/1	2	No	O	NA/TCN	R (29SEP2020)	N/N
16-55/ C4591001 1087 10871152	BLOOD	Lymphadenopathy/ SWOLLEN LYMPH NODES IN LEFT AXILLA	2	12SEP2020	2/23	2	Yes		NA	R (04OCT2020)	N/N
	SKIN	Acne cystic/ Cystic Acne	2	14OCT2020	34/C	3	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871153	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Injection Site Pain - Left Deltoid#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871171	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871172	GENRL	Injection site pain/ INJECTION SITE PAIN	2	15SEP2020	2/5	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ FEVER	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1087 10871181	MUSC	Myalgia/ generalized muscle Soreness	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1087 10871186	INJ&P	Muscle strain/ RIGHT FOOT PAIN DUE TO STRAINING FOOT	1	05SEP2020	12/7	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1087 10871191	GENRL	Pyrexia/ Fever#	4	01MAR2021	1/1	2	Yes		NA	R (01MAR2021)	N/N
	BLOOD	Lymphadenopathy/ Swollen Lymph Nodes - Left Axillary Region#	4	02MAR2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1087 10871214	INJ&P	Upper limb fracture/ Arm Fracture - Left	2	15JAN2021	121/38	3	No	O	NA/TCN	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871239	GENRL	Pyrexia/ FEVER	2	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1087 10871241	IMMUN	Rubber sensitivity/ Latex Allergy#	2	11FEB2021	149/C	1	No	O	NA	N	N/N
	SKIN	Rash/ Arm Rash - Left#	2	11FEB2021	149/6	1	No	O	NA	R (16FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10MAR2021	2/1	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001 1087 10871252	EAR	Vertigo/ VERTIGO	2	22SEP2020	5/71	2	No	O	NA/TC	R (01DEC2020)	N/N
	GASTR	Vomiting/ Vomiting#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1087 10871299	GENRL	Chills/ chills	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever	2	24SEP2020	2/8	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1087 10871308	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871310	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1087 10871343	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1087 10871348	RESP	Asthma/ ASTHMA EXACERBATION	1	30SEP2020	23/2	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1087 10871349	GENRL	Chills/ Chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1087 10871354	GENRL	Vaccination site pain/ Soreness in Vaccine Arm	1	08SEP2020	1/C	1	Yes		NA	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	1	11SEP2020	4/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ Myalgia	1	11SEP2020	4/C	1	Yes		P/W	N	N/N
16-55/ C4591001 1087 10871355	BLOOD	Lymphadenopathy/ Swollen Right Cervical Lymph Node	2	05OCT2020	1/5	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1087 10871360	GENRL	Injection site pain/ Injection Site Pain - Left Deltoid#	4	09JAN2021	2/4	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1087 10871361	GASTR	Nausea/ Nausea	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ Body Ache	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1087 10871372	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Soreness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	IMMUN	Seasonal allergy/ Seasonal Allergies#	2	09FEB2021	131/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1087 10871420 16-55/ C4591001	GENRL	Injection site pain/ Deltoid Injection Site Pain - Left#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
1087 10871457	NERV	Headache/ Headache#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
1087 10871471		Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle Pain - Shoulder, Left#	4	06JAN2021	2/4	2	Yes		NA	R (09JAN2021)	N/N
1087 10871486	GENRL	Chills/ Chills	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
1087 10871487		Fatigue/ Fatigue	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001	PSYCH	Insomnia/ Worsening of Insomnia	2	26OCT2020	20/C	2	No	O	NA/TC	N	N/N
1087 10871491											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871493	MUSC	Myalgia/ Generalized Muscle Pain*		18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Left Deltoid Injection Site Pain	1	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body Aches	2	07OCT2020	1/8	1	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ Fever	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1087 10871510	GENRL	Chills/ Chills	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
		Fatigue/ Fatigue	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
		Pyrexia/ low grade fever	2	12OCT2020	1/3	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1087 10871530	VASC	Hypertension/ Hypertension	2	31OCT2020	10/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1087 10871545	NERV	Headache/ Headache	1	17OCT2020	5/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1087 10871546	GENRL	Pyrexia/ Fever	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1087 10871550	MUSC	Rotator cuff syndrome/ Worsening of torn rotator cuff - shoulder, right	1	22OCT2020	10/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871554	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
		Vomiting/ Vomiting	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1087 10871555	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
		Vomiting/ Vomiting	1	16OCT2020	3/5	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1087 10871557	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		No	O	P	UNK	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871584	GASTR	Gastrooesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	1	09NOV2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1087 10871586	CARD	Tachycardia/ Tachycardia	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1087 10871593	PSYCH	Depression/ Depression	1	08NOV2020	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1088 10881059	SURG	Chondroplasty/ Cartilage repaired with surgery	2	18DEC2020	102/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1088 10881107	GASTR	Oedema mouth/ Angioedema of the oral cavity#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/Y
		Tongue oedema/ Angioedema of the tongue#	4	01FEB2021	1/1	1	Yes		NA/TC	R (01FEB2021)	N/Y
16-55/ C4591001 1088 10881201	SKIN	Dermatitis contact/ ALLERGY TO POISON SUMAC	2	05DEC2020	62/C	2	No	O	NA	N	N/N
16-55/ C4591001 1088 10881213	MUSC	Myalgia/ MUSCLE PAIN/ACHE	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1088 10881220	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1088 10881259	INV	Mammogram abnormal/ Abnormal mammogram	2	NOV2020	1/C	2	No	CND	NA	N	N/N
16-55/ C4591001 1089 10891015	INFEC	Tonsillitis/ Tonsillitis	2	14SEP2020	28/1	2	No	O	NA/TCN	R (14SEP2020)	N/N
	PSYCH	Depression/ worsening depression	2	02NOV2020	77/30	2	No	O	NA/TC	R (01DEC2020)	N/N
16-55/ C4591001 1089 10891025	GENRL	Chills/ chills	2	29SEP2020	41/C	1	No	O	NA	N	N/N
		Pyrexia/ fever	2	29SEP2020	41/C	1	No	O	NA	N	N/N
16-55/ C4591001 1089 10891065	INFEC	Diabetic foot infection/ Infection right pinky toe (secondary to diabetes)	2	17JAN2021	144/33	3	No	O	NA/TC/TCN	R (18FEB2021)	Y/N
	VASC	Hypertension/ Hypertension#	2	14FEB2021	172/C	2	No	CD	NA/TC	N	N/N
16-55/ C4591001 1089 10891067	MUSC	Muscle spasms/ back spasms	1	15AUG2020	10/10	2	No	O	NA/TC	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1089 10891103	INFEC	Skin infection/ right knee superficial infection of the skin	1	28AUG2020	18/14	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1089 10891105	INJ&P	Overdose/ unknown drug Overdose	2	05FEB2021	159/5	3	No	O	NA	R (09FEB2021)	N/N
16-55/ C4591001 1089 10891107	RESP	Upper-airway cough syndrome/ post nasal drip	2	08JAN2021	129/2	1	No	O	NA	R (09JAN2021)	N/N
16-55/ C4591001 1089 10891173	MUSC	Osteoarthritis/ Worsening of OA left knee#	3	03MAR2021	20/1	2	No	O	NA/TC/TCN	R (03MAR2021)	N/N
16-55/ C4591001 1089 10891181	INJ&P	Exposure during pregnancy/ Exposure During Partner Pregnancy	2	25DEC2020	102/C		No	O	NA	N	N/N
16-55/ C4591001 1089 10891182	RESP	Chronic obstructive pulmonary disease/ worsening of COPD	1	26AUG2020	2/2	2	No	O	NA/TC	R (27AUG2020)	N/N
	INJ&P	Fall/ Fall	1	09SEP2020	16/1	2	No	O	NA	R (09SEP2020)	N/N
		Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N
	GASTR	Nausea/ nausea	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N	
		Substance abuse/ worsening of polysubstance abuse	1	27SEP2020	34/2	2	No	O	NA	R (28SEP2020)	N/N	
16-55/ C4591001 1089 10891193	IMMUN	Hypersensitivity/ worsening of allergies	1	08SEP2020	14/3	1	No	O	NA	R (10SEP2020)	N/N	
16-55/ C4591001 1089 10891205	SURG	Hysterectomy/ complete hysterectomy#	3	23DEC2020	6/1	2	No	O	NA	R (23DEC2020)	N/N	
16-55/ C4591001 1089 10891207	GENRL	Oedema peripheral/ bilateral edema legs	2	05NOV2020	49/3	1	No	O	NA	R (07NOV2020)	N/N	
16-55/ C4591001 1089 10891253	INFEC	Cellulitis/ left side facial cellulitis	1	11SEP2020	8/13	2	No	O	NA/TC	R (23SEP2020)	N/N	
	GASTR	Swollen tongue/ swollen tounge	1	12SEP2020	9/4	1	No	O	NA	R (15SEP2020)	N/N	
16-55/ C4591001 1089 10891261	INFEC	Herpes zoster/ worsening shingles right bottom	1	19SEP2020	12/4	1	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1089 10891273	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	25DEC2020	85/C		No	O	NA	UNK	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1089 10891289	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N
16-55/ C4591001 1090 10901015	GASTR	Diarrhoea/ diarrhea, single episode	2	04OCT2020	42/1	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C4591001 1090 10901020	RESP	Oropharyngeal pain/ sore throat, intermittent	1	14AUG2020	12/5	1	No	O	NA	R (18AUG2020)	N/N
	GASTR	Nausea/ Nausea#	3	20FEB2021	2/3	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	20FEB2021	2/4	2	Yes		NA	R (23FEB2021)	N/N
	MUSC	Pain in extremity/ Left arm pain#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	3	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1090 10901024	GENRL	Chills/ chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1090 10901029	GENRL	Fatigue/ Fatigue#	3	02MAR2021	2/4	1	Yes		NA	R (05MAR2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901038	RESP	Oropharyngeal pain/ sore throat	1	20AUG2020	17/4	2	No	O	NA	R (23AUG2020)	N/N	
16-55/ C4591001 1090 10901044	GENRL	Fatigue/ Fatigue#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N	
		Injection site pain/ Injection site pain-right arm#	3	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1090 10901046	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
		Pyrexia/ Fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N	
16-55/ C4591001 1090 10901058	GASTR	Dry mouth/ Xerostomia#	4	12MAR2021	2/C	1	Yes		NA	N	N/N	
16-55/ C4591001 1090 10901065	NERV	Headache/ headaches, daily in afternoon	2	28AUG2020	1/47	2	Yes		NA/TC	R (13OCT2020)	N/N	
16-55/ C4591001 1090 10901076	GENRL	Pyrexia/ Fever#	4	05MAR2021	2/3	2	Yes		NA	R (07MAR2021)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901094	NERV	Burning sensation/ burning sensations, legs	1	18AUG2020	12/18	2	Yes		NA	R (04SEP2020)	N/N
	MUSC	Tendonitis/ tendonitis, right wrist	2	30SEP2020	34/63	2	No	O	NA/TC	R (01DEC2020)	N/N
16-55/ C4591001 1090 10901099	GENRL	Injection site pain/ Injection site pain-severe#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Arthralgia/ Generalized arthralgia#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Cervical lymphadenopathy- bilateral#	4	30JAN2021	2/5	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1090 10901140	INFEC	Appendicitis perforated/ acute appendicitis with perforation#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
		Focal peritonitis/ localized peritonitis#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
		Pelvic abscess/ pelvic abscess#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
	GENRL	Injection site pain/ Injection site pain-right arm#	4	18FEB2021	1/3	2	Yes		NA/TC/W	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/3	2	Yes		NA/TC	R (20FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1090 10901147	INFEC	Ear infection/ ear infection, both ears	2	01OCT2020	32/11	2	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 1090 10901154	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	
		Fatigue/ Fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
	NERV	Headache/ Headache#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1090 10901172	INV	Body temperature increased/ elevated temperature	2	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	2	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1090 10901174	MUSC	Muscle spasms/ muscle spasms, injection arm	2	04SEP2020	2/3	2	Yes		NA	R (06SEP2020)	N/N	
16-55/ C4591001 1090 10901187	NERV	Facial paralysis/ Bell's Palsy right face	2	10SEP2020	3/3	1	Yes		NA/TC	R (12SEP2020)	N/N	
16-55/ C4591001 1090 10901201	GENRL	Chills/ Chills#	3	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901220	MUSC	Myalgia/ Myalgia#	3	03MAR2021	1/3	2	Yes		NA/TC	R (05MAR2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1090 10901226	MUSC	Myalgia/ Myalgia#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1090 10901251		Pain/ Body aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	1	24AUG2020	6/5	2	No	O	NA	R (28AUG2020)	N/N
16-55/ C4591001 1090 10901253	GENRL	Chills/ Chills	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	VASC	Hypertension/ High Blood pressure	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901277	EAR	Ear pain/ Otalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	3/3	3	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1090 10901291	EAR	Ear pain/ otalgia, left ear	1	06SEP2020	5/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1090 10901294	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/2	3	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1090 10901295	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pain/ Body aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/1	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1090 10901316	MUSC	Spinal stenosis/ Spinal Stenosis	2	29SEP2020	6/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901325	GENRL	Chills/ Chills	1	23SEP2020	21/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1090 10901326	GENRL	Injection site pain/ Left arm injection site pain	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1090 10901329	GENRL	Injection site pain/ Injection site pain-left arm#	3	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1090 10901336	INFEC	Diverticulitis/ worsening diverticulitis#	2	04JAN2021	98/15	2	No	O	NA/TC	R (18JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	3/1	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	29JAN2021	3/1	2	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901355	PSYCH	Anxiety/ worsening anxiety	1	23SEP2020	15/33	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1090 10901360	GENRL	Chills/ Chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1090 10901366	GENRL	Chills/ Chills	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N
	MUSC	Arthralgia/ Generalized joint pains	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
		Myalgia/ Generalized muscle aches	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	1/4	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1090 10901369	MUSC	Arthralgia/ left shoulder pain	1	17SEP2020	8/8	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1090 10901373	GENRL	Chills/ Chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection site pain-Left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901375	NERV	Pain/ Generalized body aches	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
		Headache/ Headache	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1090 10901380	NERV	Headache/ Headache#	4	24FEB2021	2/2	2	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1090 10901383	INJ&P	Fall/ Fall	2	12OCT2020	12/1	1	No	O	NA/TCN	R (12OCT2020)	N/N
	GENRL	Skin laceration/ Forehead laceration	2	12OCT2020	12/1	2	No	O	NA/TCN	R (12OCT2020)	N/N
		Chills/ chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/Y
		Injection site pain/ Injection site pain	2	07OCT2020	1/4	2	Yes		NA/TC	R (10OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	08OCT2020	2/6	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1090 10901384	REPRO	Adnexal torsion/ Right ovarian torsion	2	07DEC2020	63/6	4	No	O	NA/TCN	R (12DEC2020)	Y/N
16-55/ C4591001 1090 10901391	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1090 10901392	GASTR	Nausea/ Nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Left arm injection site pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901394	BLOOD	Lymphadenopathy/ Swollen lymph nodes-left axilla	2	07OCT2020	2/28	3	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1090 10901397	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/5	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	3/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1090 10901398	MUSC	Exostosis/ Bone spur-right knee	2	06NOV2020	31/C	1	No	O	NA	N	N/N
16-55/ C4591001 1090 10901407	GENRL	Injection site pain/ injection side pain, left arm	1	17SEP2020	2/8	2	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ left arm injection pain	1	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1090 10901408	NERV	Headache/ Headache#	3	24FEB2021	1/2	2	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901410	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1090 10901417	GENRL	Injection site pain/ Injection site pain-left arm	1	18SEP2020	2/8	2	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain-Left arm	2	08OCT2020	2/7	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1090 10901418	GENRL	Fatigue/ Tiredness#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1090 10901422	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901424	GENRL	Fatigue/ Fatigue#	3	04MAR2021	3/4	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1090 10901429	GENRL	Injection site pain/ Injection site pain-left arm	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1090 10901432	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/4	2	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	13OCT2020	2/3	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1090 10901441	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901443	GENRL	Pain/ Body aches	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1090 10901452	INJ&P	Arthropod sting/ Hornet sting, R thigh, with localized inflammatory response	1	29SEP2020	7/10	1	No	O	NA/TC	R (08OCT2020)	N/N
	GENRL	Chills/ Chills#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain-left arm#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
		Malaise/ Malaise#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	MUSC	Arthralgia/ Arthralgia-generalized#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
		Myalgia/ Myalgia#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1090 10901457	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ Injection site pain-left arm	2	15OCT2020	2/5	2	Yes		NA/TC	R (19OCT2020)	N/N
		Pyrexia/ Fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain-left arm	2	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901461	GENRL	Pain/ Body aches	2	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1090 10901465	GENRL	Injection site pain/ Injection site pain-left arm	2	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
1090 10901465	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1090 10901474	GENRL	Injection site pain/ Injection site pain-left arm	2	17OCT2020	2/4	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1090 10901477	GENRL	Chills/ chills	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	1	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
		Pain/ Body aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1090 10901480	GENRL	Pain/ Body aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	14OCT2020	1/4	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001	INJ&P	Fall/ Fall#	3	11MAR2021	16/1	2	No	O	NA	R (11MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901481		Radius fracture/ Right radial head fracture#	3	11MAR2021	16/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1090 10901482	MUSC	Myalgia/ Cervical myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1090 10901484	GENRL	Chills/ Chills	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Injection site pain-left arm	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pyrexia/ Fever	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	2	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1090 10901489	GENRL	Chills/ Chills	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
		Fatigue/ Tiredness	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1090 10901498	GENRL	Chills/ Chills#	4	14JAN2021	2/2	1	Yes	NA	R	(15JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	2/3	2	Yes	NA	R	(16JAN2021)	N/N
		Injection site swelling/ Swelling at injection site-left arm#	4	14JAN2021	2/3	2	Yes	NA	R	(16JAN2021)	N/N
		Pyrexia/ Fever#	4	14JAN2021	2/2	2	Yes	NA/TC	R	(15JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	14JAN2021	2/2	2	Yes	NA/TC	R	(15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/3	2	Yes	NA/TC	R	(16JAN2021)	N/N
16-55/ C4591001 1090 10901502	GENRL	Chills/ Chills	2	06NOV2020	2/2	2	Yes	NA	R	(07NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes	NA/TC	R	(07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/3	1	Yes	NA/TC	R	(08NOV2020)	N/N
16-55/ C4591001 1090 10901503	GENRL	Injection site pain/ Injection site pain-Left arm	1	16OCT2020	2/1	1	Yes	NA	R	(16OCT2020)	N/N
16-55/ C4591001 1090 10901507	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes	P/TC	R	(22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901508	GENRL	Injection site pain/ Injection site pain-left arm	1	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1090 10901509	GENRL	Pyrexia/ Fever	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Chest discomfort/ chest tightness	1	24OCT2020	6/5	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1090 10901510	GENRL	Fatigue/ Fatigue	2	07NOV2020	2/2	2	Yes		NA	R (08NOV2020)	N/N
		Pyrexia/ Fever	2	07NOV2020	2/1	2	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1090 10901513	GENRL	Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
	SKIN	Urticaria/ Hives on face, neck and arms#	4	25JAN2021	15/1	2	No	O	NA/TC	R (25JAN2021)	N/N
16-55/ C4591001 1090 10901516	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/5	2	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901517	GENRL	Injection site pain/ Injection site pain-left arm#	4	23FEB2021	1/5	2	Yes		NA/TC	R (27FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	1/5	2	Yes		NA/TC	R (27FEB2021)	N/N
	NERV	Fatigue/ Fatigue	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pain/ Bodyaches	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1090 10901518	NERV	Headache/ Headache	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Injection site pain/ Injection site pain-left arm	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Arthralgia/ Joint pains- generalized	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1090 10901526	GENRL	Injection site pain/ Injection site pain-left arm	1	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain- left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901530	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Injection site pain-right arm	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	23OCT2020	2/5	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain-Left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
		Pyrexia/ Fever	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	SKIN	Rash/ Body rash-all over	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1090 10901536	GENRL	Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	24OCT2020	2/2	2	Yes		NA/TC	R (25OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	INFEC	Pyelonephritis/ pyelonephritis	2	11FEB2021	91/2	2	No	O	NA/TC	R (12FEB2021)	Y/N
16-55/ C4591001 1090 10901537	GENRL	Chills/ Chills#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901538	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Injection site pain/ Injection site pain-left arm	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection site pain-left RM	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1090 10901544	GASTR	Diarrhoea/ Worsening diarrhea	1	24OCT2020	2/3	3	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N
		Pyrexia/ Fever	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/4	2	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain- left arm	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
		Pain/ Bodyaches	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain-left arm#	3	04MAR2021	2/2	2	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1090 10901548	GENRL	Injection site pain/ Injection site pain- left arm	2	16NOV2020	1/4	2	Yes		NA/TC	R (19NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901551	GENRL	Chills/ Chills	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N
		Pain/ Body aches	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1090 10901557	GENRL	Chills/ Chills	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N
		Fatigue/ Fatigue	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1090 10901557	GENRL	Pyrexia/ fever	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1090 10901558	NERV	Headache/ headache	2	17NOV2020	1/2	2	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain-	1	27OCT2020	1/4	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1090 10901559	GENRL	Chills/ Chills	2	19NOV2020	1/2	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	20NOV2020	2/1	1	Yes		NA/TC	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain-left arm	1	27OCT2020	1/5	2	Yes		NA/TC	R (31OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901565	GENRL	Injection site pain/ Injection site pain-left arm	2	17NOV2020	1/5	1	Yes		NA	R (21NOV2020)	N/N
	GASTR	Vomiting/ Vomiting	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Chills/ Chills	2	18NOV2020	2/1	3	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	18NOV2020	2/1	2	Yes		NA/TC	R (18NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/2	2	Yes		NA/TC	R (19NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N
	RESP	Nasal congestion/ Stuffy nose	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N
	INFEC	Hordeolum/ External hordeolum-right eye	1	14NOV2020	17/8	1	No	O	NA/TC	R (21NOV2020)	N/N
	NERV	Headache/ Headache#	3	21JAN2021	1/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	1/3	2	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	1/2	2	Yes		NA/TC	R (12FEB2021)	N/N
MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911008	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	02SEP2020	14/C	1	No	O	NA	N	N/N	
	VASC	Hypertension/ hypertension	2	02SEP2020	14/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1091 10911011	MUSC	Arthralgia/ generalized joint aches#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1091 10911014	GENRL	Chest pain/ chest pain	2	11NOV2020	84/1	2	No	O	NA	R (11NOV2020)	N/N	
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal Reflux	2	25NOV2020	98/1	2	No	O	NA/TC	R (25NOV2020)	N/N	
	GASTR	Haematemesis/ hematemesis	2	27NOV2020	100/1	2	No	O	NA	R (27NOV2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
		Myalgia/ generalized myalgia#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N	
	16-55/ C4591001 1091 10911022	NERV	Headache/ headache	1	22AUG2020	20/1	1	No	O	NA	R (22AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911032	INFEC	Otitis media/ otitis media	2	07SEP2020	15/9	2	No	O	NA/TC	R (15SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/Y
16-55/ C4591001 1091 10911052	GENRL	Injection site pain/ injection site pain#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1091 10911061	GENRL	Injection site pain/ injection site pain#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1091 10911062	GENRL	Pyrexia/ fever#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1091 10911067	GENRL	Injection site pain/ injection pain#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1091 10911070	GENRL	Chills/ chills#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	
		Fatigue/ fatigue#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Arthralgia/ generalized arthralgia#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N	
		Myalgia/ Myalgia#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N	
	MUSC	Myalgia/ generalized myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N	
	16-55/ C4591001 1091 10911072	GENRL	Chills/ chills#	4	11FEB2021	2/5	1	Yes		NA	R (15FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	2/5	2	Yes		NA	R (15FEB2021)	N/N	
	NERV	Headache/ Headache#	4	11FEB2021	2/5	1	Yes		NA	R (15FEB2021)	N/N	
	16-55/ C4591001 1091 10911079	GASTR	Nausea/ nausea#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
		NERV	Headache/ headache#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N	
		Vomiting/ vomiting#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ fever#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
	PSYCH	Insomnia/ insomnia#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	09JAN2021	3/2	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1091 10911088	GASTR	Crohn's disease/ Crohn's Disease	2	NOV2020	62/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1091 10911095	MUSC	Myalgia/ myalgia#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1091 10911113	NERV	Paraesthesia/ paresthesia in left finger tips	1	13AUG2020	1/1	1	No	O	NA	R (13AUG2020)	N/N
16-55/ C4591001 1091 10911116	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	METAB	Decreased appetite/ Loss of appetite#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease#	4	19FEB2021	3/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1091 10911121	GASTR	Diarrhoea/ diarrhea	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N
		Vomiting/ vomitting	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ chills	1	20AUG2020	8/1	1	Yes		NA	R (20AUG2020)	N/N
		Fatigue/ fatigue	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	20AUG2020	8/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1091 10911123	GENRL	Injection site pain/ injection site tenderness	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1091 10911133	GENRL	Injection site pain/ injection site pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/Y
	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint aches#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911134	GENRL	Fatigue/ fatigue	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
		Injection site pain/ injection site soreness	1	18AUG2020	1/4	1	Yes		NA/TC	R (21AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site bruising/ injection site bruising	1	19AUG2020	2/4	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site bruising/ injection site bruising	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ injection site soreness	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1091 10911140	GENRL	Injection site pain/ injection arm pain (whole limb)#	4	08JAN2021	1/2	2	Yes		NA/TCN	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1091 10911143	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ myalgia	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911144 16-55/ C4591001 1091 10911146	NERV	Headache/ intermittent headaches	1	20AUG2020	2/11	1	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Malaise/ malaise	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Pain/ body aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1091 10911149	GENRL	Injection site pain/ Injection site pain#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1091 10911152	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1091 10911156	GENRL	Pain/ body aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911157	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1091 10911162	GENRL	Injection site pain/ soreness at injection site	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
		Pain/ body aches	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	INJ&P	Muscle strain/ Right bicep muscle strain	2	16OCT2020	33/34	1	No	O	NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1091 10911164	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ fatigue#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1091 10911169	PSYCH	Anxiety/ anxiety	2	26SEP2020	12/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911174	GENRL	Injection site pain/ soreness at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ body aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1091 10911175	GENRL	Fatigue/ fatigue	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ fever	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1091 10911179	GENRL	Chills/ chills#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ fatigue#	4	02FEB2021	2/2	2	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911182	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ injection site pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ worsening myalgias	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ worsening headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1091 10911189	MUSC	Tendonitis/ left bicep tendonitis	2	15SEP2020	1/	1	No	O	NA	RS	N/N
16-55/ C4591001 1091 10911192	GENRL	Fatigue/ fatigue#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ injection site pain#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1091 10911196	GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911197	MUSC	Myalgia/ generalized muscle pain	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headaches	2	08OCT2020	22/1	1	No	O	NA	R (08OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N
	INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
	RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
	RESP	Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N
16-55/ C4591001 1091 10911202	RESP	Nasal congestion/ nasal congestion	2	10OCT2020	24/8	1	No	O	NA	R (17OCT2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1091 10911207	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911208	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		Injection site pain/ Injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
	NERV	Headache/ Headache	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1091 10911219	GENRL	Injection site pain/ L arm injection site pain	2	21SEP2020	1/5	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1091 10911220	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1091 10911226	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1091 10911232	GENRL	Injection site pain/ left injection-site pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911237	GENRL	Injection site pain/ L injection site pain	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ L arm injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1091 10911239		Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1091 10911250	RESP	Epistaxis/ epistaxis	1	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1091 10911252	GENRL	Injection site pain/ Injection site pain	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	INJ&P	Muscle strain/ worsening back strain	1	09SEP2020	2/8	1	No	O	NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911256	GENRL	Injection site pain/ site injection pain	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1091 10911257	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N
		Pain in extremity/ left arm pain (whole limb)#	4	12JAN2021	2/2	2	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1091 10911260	GENRL	Chills/ Chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Malaise/ Malaise	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1091 10911261	GENRL	Injection site pain/ injection site pain#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1091 10911270	GENRL	Injection site pain/ injection site soreness	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911271	GENRL	Injection site pain/ Pain at injection site	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1091 10911277	GENRL	Chills/ chills (without fever)	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1091 10911279	MUSC	Pain in extremity/ left arm pain	1	10SEP2020	1/10	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Malaise/ Malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911281	GENRL	Chills/ Chills#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
		Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1091 10911283	GENRL	Injection site pain/ Injection Site Soreness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1091 10911284	GASTR	Nausea/ nausea#	4	13JAN2021	2/3	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	13JAN2021	2/3	2	Yes		NA	R (15JAN2021)	N/N
	METAB	Decreased appetite/ anorexia#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	13JAN2021	2/3	2	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1091 10911289	MUSC	Myalgia/ muscle aches	1	14SEP2020	4/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ chills	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/Y
		Fatigue/ fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911290	MUSC	Myalgia/ myalgia	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/Y
	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1091 10911291	MUSC	Metatarsalgia/ worsening of metatarsalgia	1	21SEP2020	11/16	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1091 10911293	INJ&P	Muscle rupture/ R Deltoid Tear	1	20SEP2020	7/105	2	No	O	NA/TCN	R (02JAN2021)	N/N
16-55/ C4591001 1091 10911297	NEOPL	Lipoma/ Right deltoid lipoma	1	20SEP2020	7/105	1	No	O	NA/TCN	R (02JAN2021)	N/N
	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	02OCT2020	19/4	1	No	O	NA/TC	R (05OCT2020)	N/N
	INFEC	Fungal infection/ yeast infection	2	13FEB2021	132/7	1	No	O	NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/5	2	Yes		NA/W	R (26FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911298	MUSC	Myalgia/ generalized myalgia#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1091 10911300	GENRL	Injection site pain/ soreness at injection site	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	INFEC	Appendicitis/ Appendicitis	2	21OCT2020	16/2	4	No	O	NA/TCN	R (22OCT2020)	Y/N
16-55/ C4591001 1091 10911301	GENRL	Chills/ Chills	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
		Malaise/ Maliase	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	08OCT2020	1/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1091 10911306	GENRL	Injection site pain/ pain at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911310	GENRL	Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1091 10911311	MUSC	Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1091 10911311	GENRL	Injection site pain/ Injection site pain#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1091 10911313	INFEC	Otitis media/ Serous Otitis Media, R ear	2	29OCT2020	23/4	1	No	O	NA	R (01NOV2020)	N/N
16-55/ C4591001 1091 10911315	INJ&P	Tendon rupture/ Tear of bicep tendon	1	23SEP2020	7/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1091 10911319	GENRL	Injection site pain/ left arm injection site pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/Y
16-55/ C4591001	GENRL	Chills/ chills	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911320		Fatigue/ fatigue	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ headache	2	11OCT2020	4/3	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1091 10911321	INJ&P	Spinal compression fracture/ worsening of compression fracture in spine	2	OCT2020	1/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Myalgia/ muscle pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1091 10911334	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1091 10911336	GASTR	Nausea/ Nausea	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	13OCT2020	2/3	1	Yes		NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911340	MUSC	Myalgia/ Myalgias	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/Y
	NERV	Nerve compression/ pinched nerve in back	2	08DEC2020	55/C	2	No	O	NA/TC	N	N/N
	MUSC	Myalgia/ myalgia#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Pain in extremity/ left arm pain (whole limb)#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1091 10911341	GENRL	Injection site pain/ left arm injection site pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/Y
16-55/ C4591001 1091 10911342	GENRL	Chills/ chills	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911343	MUSC	Myalgia/ Myalgias	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GASTR	Tooth impacted/ wisdom tooth impaction	2	OCT2020	1/	1	No	O	NA/TCN	R (05NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1091 10911344	INFEC	Oral infection/ wisdom socket infection	2	05NOV2020	23/12	2	No	O	NA/TC	R (16NOV2020)	N/N
	NERV	Headache/ Headache	1	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
	GASTR	Nausea/ nausea	1	17OCT2020	19/1	1	No	O	NA	R (17OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	21OCT2020	3/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ L arm injection site pain	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001	INFEC	Gastritis viral/ viral gastritis#	2	24FEB2021	128/C	2	No	O	NA	N	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1091 10911350		Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	MUSC	Arthralgia/ Joint aches#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1091 10911351	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1091 10911353	GENRL	Injection site pain/ injection site pain	1	07OCT2020	2/57	1	Yes		NA	R (02DEC2020)	N/N
16-55/ C4591001 1091 10911355	CARD	Palpitations/ worsening of heart palpitations	2	25NOV2020	28/1	1	No	O	NA	R (25NOV2020)	N/N
16-55/ C4591001 1091 10911356	NERV	Headache/ headache	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1091 10911357	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1091 10911360	GENRL	Fatigue/ fatigue	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1091 10911363	GASTR	Diarrhoea/ diarrhea	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ fever	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ myalgias	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Arthralgia/ worsening of right wrist triangular fibrocartilage complex pain	2	09NOV2020	6/1	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1091 10911372	GENRL	Injection site pain/ pain at injection site#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1091 10911375	MUSC	Fatigue/ fatigue#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
		Myalgia/ worsening of myalgias#	4	05JAN2021	2/2	2	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1091 10911376	GENRL	Fatigue/ fatigue	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1091 10911376	NERV	Headache/ headache	2	25NOV2020	1/3	1	Yes		NA	R (27NOV2020)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1091 10911381	MUSC	Myalgia/ myalgias	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Pyrexia/ fever	1	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Pyrexia/ Fever#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Generalized myalgia#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1091 10911382	REPRO	Breast mass/ left breast mass	1	11NOV2020	15/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1091 10911383	INFEC	Infectious mononucleosis/ mononucleosis	2	13JAN2021	57/26	2	No	O	NA/TC/TCN	R (07FEB2021)	N/N
	HEPAT	Hepatic steatosis/ fatty liver	2	27JAN2021	71/C	1	No	O	NA	N	N/N
16-55/ C4591001 1091 10911386	GENRL	Chills/ Chills	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Chills/ chills	2	23NOV2020	1/5	1	Yes		NA	R (27NOV2020)	N/N
	NERV	Headache/ headache	2	23NOV2020	1/5	1	Yes		NA	R (27NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	24NOV2020	2/4	1	Yes		NA	R (27NOV2020)	N/N
16-55/ C4591001 1091 10911387	RESP	Asthma exercise induced/ Exercise induced asthma	1	30JAN2021	87/C	2	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	2	15FEB2021	1/4	2	Yes		NA	R (18FEB2021)	N/N
		Injection site swelling/ injection site swelling#	2	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1091 10911392	GENRL	Oedema peripheral/ left foot edema	1	01DEC2020	2/37	2	No	O	NA/TC	R (06JAN2021)	N/N
	MUSC	Arthralgia/ right knee joint pain	2	24DEC2020	3/14	2	No	O	NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1091 10911398	RESP	Asthma/ asthma attack	1	14DEC2020	12/1	1	No	O	NA	R (14DEC2020)	N/N
16-55/ C4591001 1092 10921002	SKIN	Rash/ Rash on right hand	2	10SEP2020	1/112	1	No	O	NA	R (30DEC2020)	N/N
16-55/ C4591001 1092 10921020	EYE	Scleral discolouration/ Painless erythema of left sclera	1	05SEP2020	17/16	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1092 10921027	GASTR	Diarrhoea/ Diarrhea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Nausea/ Nausea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001	INJ&P	Muscle strain/ muscle strain lower back	2	03OCT2020	26/14	2	No	O	NA/TC	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921033	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
1092 10921035	GASTR	Dyspepsia/ Heartburn#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/Y
1092 10921036	INFEC	Herpes zoster/ Herpes Zoster (Shingles)#	3	17FEB2021	17/10	2	No	O	NA/TC	R (26FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	02MAR2021	1/3	2	Yes		NA	R (04MAR2021)	N/N
	MUSC	Pain in extremity/ Injection arm pain#	4	02MAR2021	1/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1092 10921045	INFEC	Otitis media/ left otitis media	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N
		Sinusitis/ sinus infection	1	01SEP2020	9/11	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1092 10921064	GENRL	Injection site pain/ Injection arm soreness#	3	09FEB2021	1/2	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	02MAR2021	1/2	2	Yes		NA/TC	R (03MAR2021)	N/N
	GENRL	Chills/ Chills#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921065	GENRL	Pain/ Body Aches#	4	03MAR2021	2/2	2	Yes		NA/TC	R (04MAR2021)	N/N
		Injection site erythema/ Injection site redness	1	25AUG2020	1/5	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Pyrexia/ fever	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1092 10921081	EAR	Myalgia/ myalgia	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Ear pain/ Earache	2	18SEP2020	3/10	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1092 10921083	GENRL	Pyrexia/ Fever#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1092 10921084	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	METAB	Dyslipidaemia/ Dyslipidemia	2	09DEC2020	85/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921085	VASC	Hypertension/ hypertension	2	09DEC2020	85/C	1	No	O	NA	N	N/N
16-55/ C4591001 1092 10921098	INFEC	Rhinitis/ Coryza	2	20SEP2020	4/12	1	No	O	NA/TC	R (01OCT2020)	N/N
	VASC	Flushing/ Facial flushing#	4	09MAR2021	16/1	1	No	O	NA	R (09MAR2021)	N/N
	VASC	Flushing/ Facial Flushing#	4	10MAR2021	17/1	1	No	O	NA	R (10MAR2021)	N/N
16-55/ C4591001 1092 10921099	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ Body Aches	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1092 10921106	INFEC	Urinary tract infection/ urinary tract infection	2	08OCT2020	18/9	1	No	O	NA/TC	R (16OCT2020)	N/N
	SKIN	Rash/ scattered Rash	2	15OCT2020	25/3	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C4591001 1092 10921112	GENRL	Chills/ Chills#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1092 10921122	NERV	Fatigue/ Fatigue#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N	
		Injection site pain/ Injection site soreness#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N	
		Pyrexia/ Fever#	4	02MAR2021	1/C	1	Yes		NA	RG	N/N	
		Headache/ Headache#	4	02MAR2021	1/C	2	Yes		NA	RG	N/N	
	RESP	Epistaxis/ Nose bleed#	4	02MAR2021	1/1	2	Yes		NA	R (02MAR2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N	
	16-55/ C4591001 1092 10921130	RESP	Injection site pain/ Injection site soreness	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
			Pyrexia/ fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
			Epistaxis/ intermittent bilateral nose bleed	2	12OCT2020	21/29	1	No	O	NA	R (09NOV2020)	N/N
	16-55/ C4591001 1092 10921132	GENRL	Fatigue/ fatigue	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/Y
16-55/ C4591001 1092 10921139	NERV	Sciatica/ Sciatica	2	28SEP2020	6/C	1	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921142	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	INV	Blood pressure increased/ Elevated Blood Pressure	2	24SEP2020	1/2	1	No	O	NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Lethargy/ Lethargy	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1092 10921143	GENRL	Injection site pain/ injection site soreness	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
		Injection site papule/ Injection site papule	1	03SEP2020	2/C	1	Yes		NA	RG	N/N
		Pyrexia/ fever	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1092 10921146	GENRL	Injection site pain/ injection site pain	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
		Pyrexia/ fever	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
	MUSC	Back pain/ back ache	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
		Myalgia/ myalgia	1	03SEP2020	2/3	1	Yes		NA/TC	R (05SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1092 10921153		Pyrexia/ Fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1092 10921162	GENRL	Injection site pain/ Injection site soreness#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1092 10921168	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site tenderness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Malaise/ Malaise	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/1	1	Yes		NA	R (29SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1092 10921177	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N	
	INFEC	Localised infection/ Infection on finger	2	15DEC2020	78/11	1	No	O	NA/TC	R (25DEC2020)	N/N	
	GENRL		Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
			Chills/ Rigors#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
			Pyrexia/ Fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N	
	SKIN	Acne/ Pimple on vaginal area#	4	08JAN2021	1/3	2	No	O	NA/TC	R (10JAN2021)	N/N	
INFEC	Urinary tract infection/ Urinary Tract Infction#	4	29JAN2021	22/10	2	No	O	NA/TC	R (07FEB2021)	N/N		
16-55/ C4591001 1092 10921184	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	
		Chills/ Rigors#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N	
	MUSC	Back pain/ Back Pain#	4	07JAN2021	1/2	2	Yes		NA/TC	R (08JAN2021)	N/N	
	NERV	Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1092 10921186	MUSC	Osteoarthritis/ worsening osteoarthritis	2	02NOV2020	29/57	2	No	O	NA	R (28DEC2020)	N/N
16-55/ C4591001 1092 10921201	GENRL	Chills/ Chills#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1092 10921208	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	16JAN2021	81/C		No	O	NA	UNK	N/N
16-55/ C4591001 1092 10921211	GENRL	Chills/ Chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Fatigue/ Tiredness#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body Aches#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1092 10921218	GENRL	Injection site pain/ Injection Site Soreness#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Gastrointestinal sounds abnormal/ Borborygmus#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Nausea/ Nausea#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		Pain/ Body aches#	4	01MAR2021	1/2	2	Yes		NA/TC	R (02MAR2021)	N/N
	NERV	Headache/ Headache#	4	01MAR2021	1/2	2	Yes		NA/TC	R (02MAR2021)	N/N
16-55/ C4591001 1092 10921223	GENRL	Injection site pain/ Injection Site pain	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ Headache	1	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1092 10921248	GENRL	Injection site pain/ injection site soreness#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1092 10921272	GENRL	Pyrexia/ Fever	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	17NOV2020	1/5	1	Yes		NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1093 10931033	MUSC	Bursitis/ BURSITIS LEFT ELBOW	1	28AUG2020	8/11	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1093 10931039	GASTR	Constipation/ IDIOPATHIC CONSTIPATION	2	01DEC2020	68/C	1	No	O	NA/TC	RG	N/N	
		Gastroesophageal reflux disease/ GASTROESOPHAGEAL REFLUX DISEASE	2	01DEC2020	68/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1093 10931042	INFEC	Diverticulitis/ DIVERTICULITIS	2	15JAN2021	106/5	1	No	O	NA/TC	R (19JAN2021)	N/N	
16-55/ C4591001 1093 10931053	REPRO	Endometriosis/ ENDOMETRIOSIS	2	26SEP2020	12/47	1	No	O	NA/TC	R (11NOV2020)	N/N	
	INFEC	Bacterial vaginosis/ BACTERIAL VAGINOSIS	2	15NOV2020	62/8	1	No	O	NA/TC	R (22NOV2020)	N/N	
16-55/ C4591001 1093 10931058	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		25AUG2020	1/C		No	O	P	UNK	N/N	
16-55/ C4591001 1093 10931066	GENRL	Chills/ CHILLS	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
		Pain/ BODY ACHES	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1093 10931067	INFEC	Subcutaneous abscess/ Cutaneous abscess of left upper extremity#	2	20FEB2021	158/17	1	No	O	NA/TC	R (08MAR2021)	Y/N	
16-55/ C4591001 1093 10931070	MUSC	Osteoarthritis/ WORSENING OF GENERALIZED OSTEOARTHRITIS#	4	08MAR2021	28/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1093 10931078	GASTR	Nausea/ NAUSEA	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N	
	MUSC	Myalgia/ GENERALIZED MILD MUSCLE ACHES	2	15SEP2020	1/5	1	Yes		NA/TC	R (19SEP2020)	N/N	
	INFEC	Gastroenteritis/ GASTROENTERITIS#	2	19FEB2021	158/8	1	No	O	NA	R (26FEB2021)	N/N	
16-55/ C4591001 1093 10931084	MUSC	Arthralgia/ LEFT SHOULDER PAIN#	4	29JAN2021	1/3	1	No	O	NA	R (31JAN2021)	N/N	
16-55/ C4591001 1093 10931095	GASTR	Diarrhoea/ DIARRHEA	1	03SEP2020	4/1	1	Yes		NA	R (03SEP2020)	N/N	
	GENRL	Pain/ MILD BODY ACHES	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1093 10931111	RESP	Rhinorrhoea/ RUNNY NOSE	1	16SEP2020	9/5	1	No	O	NA/TC	R (20SEP2020)	N/N
	MUSC	Psoriatic arthropathy/ PSORIATIC ARTHRITIS	2	DEC2020	65/C				NA/TC	RG	N/N
16-55/ C4591001 1093 10931121	NERV	Headache/ HEADACHE	1	25SEP2020	15/1	1	No	O	NA/TC	R (25SEP2020)	N/N
	PSYCH	Anxiety/ ANXIETY	2	01FEB2021	120/C	1	No	O	NA/TC	RG	N/N
		Attention deficit hyperactivity disorder/ EXASERBATION OF ATTENTION DEFICIT DISORDER	2	01FEB2021	120/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1093 10931124	GENRL	Pyrexia/ FEVER	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ FEVER 101.5#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	INJ&P	Tendon injury/ RIGHT THIGH TENDON STRAIN	2	26OCT2020	18/113	1	No	O	NA/TC	R (15FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1093 10931133 16-55/ C4591001	METAB	Glucose tolerance impaired/ PRE-DIABETES	2	30OCT2020	17/C	1	No	O	NA/TC	RG	N/N
1093 10931134 16-55/ C4591001	GENRL	Chills/ CHILLS	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
1093 10931135		Pyrexia/ FEVER	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ MILD MUSCLE ACHES	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ MILD HEADACHE	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1093 10931158	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ FEVER#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1093 10931185	INFEC	Oral candidiasis/ ORAL CANDIDIASIS#	4	09MAR2021	7/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Vulvovaginal candidiasis/ CANDIDAL VULVOVAGINITIS#	4	09MAR2021	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1093 10931186	VASC	Hypertension/ WORSENING HYPERTENSION	1	10NOV2020	22/15	1	No	O	NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1093 10931195	GENRL	Pyrexia/ LOW-GRADE FEVER	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1093 10931203	GENRL	Chills/ CHILLS	2	15NOV2020	3/4	2	Yes		NA	R (18NOV2020)	N/N
		Fatigue/ FATIGUE	2	15NOV2020	3/4	2	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1093 10931205	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ HEADACHE	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1093 10931209	GENRL	Injection site pain/ LEFT ARM PAIN AT INJECTION SITE	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ BODY ACHES	2	17NOV2020	2/4	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001	PSYCH	Insomnia/ WORSENING INSOMNIA	2	11DEC2020	26/C	1	No	O	NA/TC	RG	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1093 10931218 16-55/ C4591001 1093 10931226	INJ&P	Foot fracture/ LEFT FOOT FRACTOR-5TH METATARSAL#	3	30DEC2020	3/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1094 10941010	MUSC	Arthralgia/ left wrist pain	2	30OCT2020	60/C	1	No	O	NA	RG	N/N
		Pain in extremity/ bilateral heel pain	2	30OCT2020	60/C	1	No	O	NA	RG	N/N
	REPRO	Erectile dysfunction/ erectile dysfunction	2	30OCT2020	60/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1094 10941016	INV	SARS-CoV-2 antibody test positive/ Positive COVID-19 serology test	2	13NOV2020	73/C	1	No	O	NA	N	N/N
16-55/ C4591001 1094 10941025	NERV	Restless legs syndrome/ restless leg syndrome	2	24NOV2020	76/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1094 10941070	MUSC	Back pain/ Back pain	1	21SEP2020	25/5	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1094 10941077	MUSC	Pain in extremity/ Left arm pain	2	30SEP2020	7/C	1	No	O	NA/TC	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1094 10941095	VASC	Peripheral arterial occlusive disease/ Atherosclerosis of native artery of both lower extremities	2	30DEC2020	99/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1094 10941098	MUSC	Back pain/ Back Pain	2	30SEP2020	3/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1094 10941129	GENRL	Pyrexia/ fever#	3	25FEB2021	2/5	1	Yes		NA	R (01MAR2021)	N/N	
	NERV	Headache/ intermittent headache#	3	25FEB2021	2/5	1	Yes		NA	R (01MAR2021)	N/N	
16-55/ C4591001 1094 10941132	SKIN	Hyperhidrosis/ sweat	1	19SEP2020	5/3	2	No	O	NA	R (21SEP2020)	N/N	
16-55/ C4591001 1094 10941155	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N	
		Road traffic accident/ motor vehicle accident	1	16OCT2020	22/1	3	No	O	NA	R (16OCT2020)	N/N	
16-55/ C4591001 1094 10941179	GENRL	Pyrexia/ fever#	4	18FEB2021	1/1	1	Yes		NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001	MUSC	Arthralgia/ left knee pain	1	17AUG2020	19/1	1	No	O	NA/TC	R (17AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1095 10951001	MUSC	Arthralgia/ polyarthralgias	1	06AUG2020	8/C	1	No	O	NA	N	N/N
16-55/ C4591001 1095 10951005	INFEC	Gastroenteritis viral/ viral gastroenteritis	2	01SEP2020	15/1	1	No	O	NA	R (01SEP2020)	N/N
16-55/ C4591001 1095 10951009	REPRO	Adnexal torsion/ torsion of right ovary	2	23DEC2020	125/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
16-55/ C4591001 1095 10951022	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ left arm injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1095 10951023	INFEC	Diverticulitis/ Diverticulitis flare	1	20AUG2020	18/5	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C4591001 1095 10951026	METAB	Decreased appetite/ Loss of appetite	1	13AUG2020	11/C	1	No	O	NA	RG	N/N
	INJ&P	Fall/ Fall	1	23AUG2020	21/1	1	No	O	NA	R (23AUG2020)	N/N
		Skin abrasion/ Left arm abrasions	1	23AUG2020	21/8	1	No	O	NA	R (30AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951029	RESP	Rhinitis allergic/ allergic rhinitis	2	03SEP2020	11/2	1	No	O	NA	R (04SEP2020)	N/N	
	GASTR	Diarrhoea/ diarrhea	2	04SEP2020	12/2	1	No	O	NA	R (05SEP2020)	N/N	
16-55/ C4591001 1095 10951047	INJ&P	Rib fracture/ Rib fracture	2	30AUG2020	6/33	1	No	O	NA/TC	R (01OCT2020)	N/N	
	GENRL	Malaise/ idiopathic malaise	2	31AUG2020	7/2	1	No	O	NA	R (01SEP2020)	N/N	
16-55/ C4591001 1095 10951055	REPRO	Cervical dysplasia/ ASCUS of cervix	1	10AUG2020	7/18	1	No	O	NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1095 10951058	VASC	Hypertension/ Worsening of Hypertension	2	22JAN2021	150/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1095 10951062	INJ&P	Arthropod bite/ nonvenomous insect bite of right elbow	1	17AUG2020	13/1	1	No	O	NA/TC	R (17AUG2020)	N/N	
	IMMUN	Seasonal allergy/ seasonal allergies	2	14SEP2020	20/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1095 10951066	PSYCH	Insomnia/ Worsening insomnia#	2	15JAN2021	143/C	2	No	O	NA	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951087	GENRL	Fatigue/ Fatigue	1	12AUG2020	7/2	1	No	O	NA	R (13AUG2020)	N/N
16-55/ C4591001 1095 10951095	RESP	Rhinitis allergic/ allergic rhinitis	1	17AUG2020	11/5	1	No	O	NA	R (21AUG2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N
		Injection site pain/ left arm pain at injection site#	4	04MAR2021	1/C	1	Yes		NA	RG	N/N
	MUSC	Myalgia/ generalized myalgias#	4	04MAR2021	1/1	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1095 10951106	MUSC	Arthralgia/ polyarthralgia	2	03SEP2020	7/2	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C4591001 1095 10951112	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Tenderness	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	VASC	Hot flush/ Hot Flashes	2	17SEP2020	2/C	1	Yes		NA	N	N/N
	NERV	Sinus headache/ Sinus Headache	2	25SEP2020	10/2	1	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1095 10951116	GENRL	Fatigue/ fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1095 10951119	MUSC	Back pain/ mechanical back pain	2	02JAN2021	109/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951124	SKIN	Dermatitis contact/ Dermatitis-poison ivy	1	12SEP2020	20/5	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1095 10951129	MUSC	Myalgia/ Myalgia post vaccine	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001	INV	Body temperature increased/ Elevated Body Temperature	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1095 10951132	MUSC	Myalgia/ Myalgia post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache post vaccination	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1095 10951137	GENRL	Vaccination site pain/ Left arm injection site pain post vaccine #1.#	3	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N
	GENRL	Chills/ Chills#	3	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1095 10951138	GENRL	Injection site pain/ left arm (deltoid) injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1095 10951141	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	P/TCN/W	N	N/N
16-55/ C4591001 1095 10951143	GASTR	Nausea/ nausea#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/Y
	GENRL	Injection site pain/ Pain at Injection Site 30 mins after dose#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/Y
	NERV	Dizziness/ dizziness#	3	13JAN2021	1/1	1	No	O	NA	R (13JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951144	GENRL	Injection site pain/ pain right shoulder injection site (serapin)	1	09SEP2020	15/5	1	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1095 10951148	GENRL	Chills/ Chills post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	PSYCH	Anxiety disorder/ Anxiety Disorder	2	NOV2020	46/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1095 10951149	INV	Body temperature increased/ elevated temperature	1	13SEP2020	18/2	1	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1095 10951150	INFEC	Soft tissue infection/ soft tissue infection left leg*		JUN2020		1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1095 10951153	GENRL	Injection site pain/ injection site pain left arm	2	22SEP2020	1/6	1	Yes		NA/TC	R (27SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951154	MUSC	Pyrexia/ fever post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
		Myalgia/ myalgia post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
	NERV	Headache/ headache post vaccination	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N	
	GASTR	Nausea/ nausea post vaccination	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain left arm	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/Y	
	16-55/ C4591001 1095 10951156	GENRL	Injection site pain/ Injection site pain left arm	1	29AUG2020	2/4	1	Yes		NA	R (01SEP2020)	N/N
		GENRL	Chills/ Post vaccine chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
			Fatigue/ Post vaccine fatigue	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		NERV	Pyrexia/ Post vaccine fever	2	16SEP2020	1/2	3	Yes		NA/TC	R (17SEP2020)	N/N
	Headache/ Post vaccine headache		2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001 1095 10951159	GENRL	Injection site pain/ Injection site pain right arm	1	29AUG2020	1/4	1	Yes		NA	R (01SEP2020)	N/Y	
	GENRL	Chills/ Chills	2	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951160	GENRL	Fatigue/ fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site post vaccination	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site warmth/ Warmth at injection site	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1095 10951161	GENRL	Fatigue/ Fatigue post vaccination	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ injection site reaction left arm myalgia	1	29AUG2020	1/3	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1095 10951168	MUSC	Arthralgia/ Arthralgia post vaccine	1	29AUG2020	1/3	2	Yes		NA/TC	R (31AUG2020)	N/N
	SOCCI	Menopause/ Perimenopausal	1	14SEP2020	17/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951169	CONG	Developmental hip dysplasia/ Right Hip dysplasia	2	20FEB2021	153/C	2	No	O	NA	N	N/N
16-55/ C4591001 1095 10951170	NERV	Headache/ Headache	1	29AUG2020	1/3	1	Yes		NA/TC	R (31AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain left arm	1	30AUG2020	2/3	1	Yes		NA/TC	R (01SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1095 10951171	SKIN	Dermatitis contact/ Contact Dermatitis Left Arm	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1095 10951172	GENRL	Injection site pain/ Left arm injection site pain#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1095 10951173	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
		Coronary artery disease/ Coronary Artery Disease	1	05SEP2020	8/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951174	MUSC	Myalgia/ Myalgia	1	09SEP2020	10/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1095 10951176	GENRL	Injection site pain/ right side injection site pain	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951177	GENRL	Injection site pain/ injection site pain right arm	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ post vaccination myalgia	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ post vaccination headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ injection site myalgia left arm	1	03SEP2020	1/7	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site left arm	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ Generalized Rigors	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	16-55/ C4591001 1095 10951183	GENRL	Chills/ chills without fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)
		Fatigue/ fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1095 10951186	INJ&P	Tendon injury/ left finger tendon injury	2	26SEP2020	6/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1095 10951188	GENRL	Pyrexia/ fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Myalgia/ myalgia post vaccination	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1095 10951194	GENRL	Injection site pain/ injection site pain left arm	1	02SEP2020	2/5	1	Yes		NA/TC	R (06SEP2020)	N/N
	RESP	Rhinitis allergic/ allergic rhinitis	1	02SEP2020	2/5	1	No	O	NA/TC	R (06SEP2020)	N/N
	MUSC	Back pain/ Back Pain	2	15OCT2020	23/2	1	No	O	NA/TC	R (16OCT2020)	N/N
		Pain in extremity/ Bilateral leg pain	2	15OCT2020	23/2	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1095 10951196	INJ&P	Ligament sprain/ Right wrist sprain	1	08SEP2020	8/29	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1095 10951197	SKIN	Drug eruption/ Fixed drug eruption on feet bilaterally	2	26OCT2020	8/C	2	Yes		NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Intervertebral disc degeneration/ exacerbation of Degenerative Disc Disease	2	14JAN2021	88/2	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
16-55/ C4591001 1095 10951198	MUSC	Myalgia/ post vaccination myalgia	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site pain Left Arm	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/Y
	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1095 10951199	GENRL	Injection site pain/ injection site reaction myalgia	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1095 10951208	GENRL	Injection site pain/ myalgia due to intramuscular injection into deltoid muscle	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	INFEC	Tooth infection/ tooth infection	1	23SEP2020	22/16	1	No	O	NA/TC	R (08OCT2020)	N/N
	ENDO	Hypothyroidism/ worsening of hypothyroidism	1	08OCT2020	37/C	1	No	O	NA/TC	UNK	N/N
16-55/ C4591001 1095 10951218	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1095 10951225	MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Diaphoresis	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Injection site pain/ injection site left deltoid muscle pain	1	04SEP2020	1/4	1	Yes		NA	R (07SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N	
	INV	Body temperature increased/ elevated temperature	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N	
	16-55/ C4591001 1095 10951233	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N
	16-55/ C4591001 1095 10951241	GENRL	Injection site pain/ Injection site myalgia left arm	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ generalized fatigue	1	20OCT2020	21/2	1	No	O	NA	R (21OCT2020)	N/N	
	GENRL	Fatigue/ generalized fatigue	1	30OCT2020	31/2	2	No	O	NA	R (31OCT2020)	N/N	
	16-55/ C4591001 1095 10951250	GENRL	Injection site pain/ injection site pain	2	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/Y
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1095 10951251	MUSC	Myalgia/ Myalgia post vaccination	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
		Injection site pain/ pain at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
		Injection site swelling/ swelling at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
		Injection site warmth/ warmth at injection site left arm	2	20OCT2020	1/6	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ worsening headache	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1095 10951255	GENRL	Injection site pain/ pain at injection site left arm post vaccine	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1095 10951257	GENRL	Fatigue/ fatigue	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site pain left arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951259	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ worsening Headache	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Pain/ body aches#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1095 10951262	GASTR	Umbilical hernia/ Umbilical Hernia#	4	01FEB2021	22/C	1	No	O	NA/TC	N	N/N
	MUSC	Myalgia/ myalgia left arm	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Fatigue/ Generalized fatigue	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Malaise/ generalized malaise	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1095 10951266	GENRL	Injection site pain/ left arm pain at injection site	1	08OCT2020	1/5	1	Yes		NA/TC	R (12OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	29OCT2020	2/2	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951267	MUSC	Myalgia/ myalgia	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Chills/ chills	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
		Pyrexia/ Fever	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1095 10951274	MUSC	Myalgia/ myalgias	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	NERV	Headache/ mild headache	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	NERV	Headache/ headache	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1095 10951277	INJ&P	Ligament rupture/ Right ACL tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N
		Meniscus injury/ right meniscus tear	1	19OCT2020	8/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951278	GASTR	Nausea/ Nausea	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	INFEC	Abscess limb/ Right leg anterior abscess	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951280		Infected bite/ Cellulitis due to spider bite right anterior leg	1	19OCT2020	8/11	3	No	O	NA/TC	R (29OCT2020)	N/N
	PSYCH	Anxiety/ Worsening anxiety	2	03DEC2020	31/C	2	No	O	NA/TC	RG	N/N
	NERV	Headache/ Headache	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/Y
	MUSC	Pain in extremity/ Left Hand Pain	2	20NOV2020	17/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Injection site pain left arm	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
	METAB	Hyperlipidaemia/ Hyperlipidemia	1	19OCT2020	8/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ injection site pain right arm	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	INJ&P	Ligament sprain/ left fifth toe sprain	1	21OCT2020	10/11	1	No	O	NA	R (31OCT2020)	N/N
	MUSC	Myalgia/ left deltoid myalgia	1	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ headache	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1095 10951285	GENRL	Injection site pain/ injection site pain left arm	1	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Chills/ chills	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ injection site pain left arm	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1095 10951286	GENRL	Injection site pain/ injection site pain left arm	1	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/Y
	GENRL	Chills/ chills	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		Injection site pain/ injection site pain right arm	2	03NOV2020	1/3	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1095 10951288	MUSC	Myalgia/ Myalgias	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951290	GENRL	Asthenia/ Weakness	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
		Chills/ Chills	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
	INV	Heart rate increased/ Elevated Heart Rate	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
	GASTR	Aphthous ulcer/ aphthous ulcers to soft palate	2	25NOV2020	22/C	1	Yes		NA	N	N/N
16-55/ C4591001 1095 10951291	GENRL	Injection site pain/ Pain at injection site L arm#	3	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1095 10951293	GENRL	Chills/ Chills Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
		Fatigue/ Fatigue Post Vaccine	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1095 10951294	GASTR	Diarrhoea/ diarrhea	1	16OCT2020	1/1	1	Yes		NA	R (16OCT2020)	N/N
	INJ&P	Fall/ Fall	2	28NOV2020	25/15	1	No	O	NA/TC	R (12DEC2020)	N/N
	MUSC	Pain in extremity/ left leg pain	2	28NOV2020	25/15	1	No	O	NA/TC	R (12DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1095 10951295	GENRL	Injection site pain/ Pain at injection site left arm*		16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Synovial cyst/ Ganglion cyst right wrist	1	02NOV2020	18/4	1	No	O	NA	R (05NOV2020)	N/N
16-55/ C4591001 1095 10951304	GENRL	Injection site pain/ injection site pain left arm	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ pain at injection site left arm	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Systemic lupus erythematosus/ lupus	2	27NOV2020	17/C	2	No	O	NA	N	N/N
16-55/ C4591001 1095 10951306	GASTR	Diarrhoea/ Diarrhea	2	18NOV2020	2/4	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18NOV2020	2/4	1	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	18NOV2020	2/4	1	Yes		NA/TC	R (21NOV2020)	N/N
16-55/ C4591001 1095 10951307	GENRL	Chills/ chills	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ elevated temperature	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1095 10951308	PSYCH	Depression/ worsening of depression	2	DEC2020	1/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951310	PSYCH	Attention deficit hyperactivity disorder/ ADHD diagnosed by Psychiatrist	2	25JAN2021	42/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1095 10951317	GENRL	Fatigue/ Fatigue	2	15DEC2020	1/1	1	Yes		NA	R (15DEC2020)	N/Y
16-55/ C4591001 1095 10951319	INJ&P	Joint dislocation/ L Patellar Dislocation	2	02JAN2021	6/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore throat	1	05OCT2020	53/3	1	No	O	NA	R (07OCT2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	1	22JAN2021	162/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection pain	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961035 16-55/ C4591001 1096 10961036	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N	
16-55/ C4591001 1096 10961042	GENRL	Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1096 10961059	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	7/4	2	Yes		NA/TC	R (28AUG2020)	N/N	
16-55/ C4591001 1096 10961062	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N	
	VASC	Hypertension/ worsening of hypertension	2	14SEP2020	6/C	1	No	O	NA/TC	N	N/N	
	MUSC	Muscular weakness/ bilateral lower extremity weakness	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N	
16-55/ C4591001 1096 10961063	MUSC	Muscle spasms/ left upper arm Muscle spasms	1	22AUG2020	4/2	1	Yes		NA	R (23AUG2020)	N/N	
16-55/ C4591001 1096 10961078	RESP	Cough/ Cough	1	01SEP2020	13/4	1	No	O	NA	R (04SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961083	MUSC	Osteoarthritis/ osteoarthritis	2	NOV2020	52/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1096 10961088	GASTR	Dyspepsia/ Indigestion	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain in both elbows and knees	2	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1096 10961090	INJ&P	Limb injury/ Right arm injury	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N
		Road traffic accident/ motor vehicle accident	2	19SEP2020	9/1	2	No	O	NA/TC	R (19SEP2020)	N/N
	MUSC	Pain in extremity/ Right arm pain	2	19SEP2020	9/78	2	No	O	NA	R (05DEC2020)	N/N
16-55/ C4591001 1096 10961093	GASTR	Flatulence/ Gassiness	2	18FEB2021	161/14	2	No	O	NA	R (03MAR2021)	N/N
16-55/ C4591001 1096 10961097	NERV	Headache/ Intermittent headaches	2	13SEP2020	2/3	1	Yes		NA/TC	R (15SEP2020)	N/N
	SKIN	Rash/ generalized rash on body	2	13SEP2020	2/6	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961098	PSYCH	Insomnia/ Insomnia	2	06OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1096 10961115	RESP	Oropharyngeal pain/ Sore throat	1	12SEP2020	20/8	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C4591001 1096 10961130	NERV	Tension headache/ stress headaches	1	26AUG2020	2/23	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1096 10961137	INJ&P	Concussion/ concussion	1	13SEP2020	19/5	2	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1096 10961138	METAB	Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	06OCT2020	21/C	1	No	O	NA/TC	N	N/N
	PSYCH	Anxiety/ worsening of anxiety	2	06OCT2020	21/133	1	No	O	NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1096 10961141	GENRL	Fatigue/ Fatigue	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1096 10961150	INFEC	Ear infection/ Right ear infection	1	13SEP2020	18/5	1	No	O	NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961168	NERV	Tension headache/ stress headache	2	22FEB2021	159/16	1	No	O	NA/TC	R (09MAR2021)	N/N
16-55/ C4591001 1096 10961169	GASTR	Flatulence/ gassiness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ chills	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Fatigue/ fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ injection site tenderness	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ fever	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	GASTR	Abdominal pain upper/ upper abdominal pain	2	15FEB2021	152/1	2	No	O	NA	R (15FEB2021)	N/N
	GASTR	Abdominal pain upper/ Upper abdominal pain	2	20FEB2021	157/1	2	No	O	NA	R (20FEB2021)	N/N
16-55/ C4591001 1096 10961170	SKIN	Rash/ rash around right elbow#	3	19JAN2021	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1096 10961186	GENRL	Injection site pain/ injection site soreness*		29AUG2020	1/3	2	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961206	NERV	Headache/ Intermittent Headaches	1	02SEP2020	2/38	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1096 10961207	INJ&P	Epicondylitis/ lateral epicondylitis of the left elbow	1	09SEP2020	9/C	1	No	O	NA	N	N/N
	SKIN	Dermatitis contact/ Contact dermatitis on left arm	1	19SEP2020	19/17	1	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1096 10961208	SKIN	Hyperhidrosis/ Sweating	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1096 10961209	RESP	Nasal congestion/ Nasal congestion	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N
		Oropharyngeal pain/ Sore throat	1	16SEP2020	16/3	1	No	O	NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/Y
16-55/ C4591001 1096 10961213	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
		Injection site pain/ Injection site soreness	1	02SEP2020	1/3	2	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961215	GENRL	Injection site pain/ Injection site soreness	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	1/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	07SEP2020	6/9	1	No	O	NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
		Pain/ BODY ACHES	1	03SEP2020	2/2	1	Yes		NA/TC	R (04SEP2020)	N/N
		Pyrexia/ FEVER	1	03SEP2020	2/1	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	04SEP2020	3/3	1	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness*		03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1096 10961226	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961236	GENRL	Chills/ Chills	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever (102F max)	2	26SEP2020	1/2	2	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	2	26SEP2020	1/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	27SEP2020	2/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1096 10961240	NERV	Presyncope/ presyncope	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/Y
	GASTR	Nausea/ Nausea	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
		Vomiting/ Vomiting	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	8/3	1	No	O	NA	R (02OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	09DEC2020	78/1	2	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1096 10961244	INFEC	Conjunctivitis/ left eye conjunctivitis	2	17OCT2020	25/8	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1096 10961255	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	20/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Anxiety/ Worsening of anxiety	2	08OCT2020	16/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1096 10961256	NERV	Dizziness/ Lightheaded*		04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C4591001 1096 10961262	GENRL	Injection site erythema/ Injection site redness on left arm (3 units on sponsor's caliper)	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
		Injection site pain/ Injection site pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1096 10961264	INJ&P	Road traffic accident/ motor vehicle accident	2	24OCT2020	30/1	1	No	O	NA	R (24OCT2020)	N/N
	MUSC	Back pain/ Lower Back Pain	2	24OCT2020	30/61	2	No	O	NA/TC	R (23DEC2020)	N/N
	GENRL	Pain/ generalized body aches	2	26OCT2020	32/6	1	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1096 10961265	GENRL	Injection site erythema/ injection site redness left upper arm	2	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection site pain left upper arm	2	24SEP2020	1/5	2	Yes		NA	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961267	MUSC	Myalgia/ General muscle aches	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness (left arm)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1096 10961271	GASTR	Nausea/ NAUSEA	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1096 10961275	GENRL	Chills/ CHILLS	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ BODY ACHE	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	VASC	Hot flush/ INTERMITTENT HOT FLAHERS	2	25SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1096 10961275	GENRL	Injection site pain/ Injection site soreness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1096 10961277	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1096 10961278	BLOOD	Lymphadenopathy/ Right swollen lymph node under jaw	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1096 10961280	INFEC	Sialoadenitis/ Sialadenitis	1	13SEP2020	9/4	1	No	O	NA	R (16SEP2020)	N/N	
	RESP	Oropharyngeal pain/ Sore throat	1	13SEP2020	9/2	1	No	O	NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Generalized muscle aches due to exercise	1	22SEP2020	18/C	1	No	O	NA	N	N/N	
	GENRL	Chills/ Chills	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N	
		Injection site pain/ Injection site soreness	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N	
	GENRL	Injection site swelling/ Injection site swelling	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/Y	
		Tooth infection/ Canine Tooth Infection#	3	29JAN2021	17/C	2	No	O	NA/TC	N	N/N	
	INFEC	Tooth infection/ tooth infection	1	15SEP2020	8/16	1	No	O	NA/TC	R (30SEP2020)	N/N	
		Epicondylitis/ right tennis elbow	2	15DEC2020	78/C	2	No	O	NA/TC	N	N/N	
	INFEC	Ear infection/ left ear infection	2	03JAN2021	97/8	1	No	O	NA/TC	R (10JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961307	GENRL	Fatigue/ fatigue	2	07OCT2020	6/4	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1096 10961331	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	4/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	20SEP2020	6/2	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20SEP2020	6/2	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	6/3	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1096 10961336	GENRL	Fatigue/ Fatigue	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Injection Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache*		15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	3/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	19SEP2020	5/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	5/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20SEP2020	6/2	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1096 10961343	GENRL	Injection site pain/ Injection Site pain left arm#	3	31DEC2020	2/4	1	Yes		NA	R (03JAN2021)	N/N
16-55/ C4591001 1096 10961348	GENRL	Injection site pain/ Injection site soreness	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1096 10961350	INFEC	Sinusitis/ sinus infection	1	01OCT2020	15/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1096 10961362	INJ&P	Meniscus injury/ left meniscus tear	1	19SEP2020	3/137	2	No	O	NA	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961375	GENRL	Injection site pain/ Site injection pain	1	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1096 10961376	GENRL	Injection site pain/ Injection site soreness	1	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Injection site pruritus/ Injection site pruritus	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Injection site swelling/ Injection site swelling	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1096 10961378	GENRL	Injection site pain/ Injection site soreness	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN IN LEFT ARM	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
	GENRL	Pyrexia/ FEVER	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE ACHES	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	01NOV2020	3/3	1	Yes		NA	R (03NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1096 10961382	GENRL	Injection site pain/ Injection site soreness	1	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/Y
16-55/ C4591001 1096 10961385	GENRL	Chills/ CHILLS	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ FATIGUE	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ BODY ACHES	1	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ FEVER	1	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	31OCT2020	2/4	2	Yes		NA	R (03NOV2020)	N/N
		Pyrexia/ FEVER	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1098 10981009	CARD	Coronary artery disease/ Coronary Artery Disease#	2	01JAN2021	115/C	1	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ Hypertension#	2	01JAN2021	115/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1098 10981025	RESP	Dry throat/ Dry Throat	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1098 10981054	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1098 10981091	METAB	Obesity/ Obesity	2	21OCT2020	29/C	1	No	O	NA	RG	N/N
		Type 2 diabetes mellitus/ Type 2 Diabetes	2	21OCT2020	29/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1098 10981101	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1098 10981137	GENRL	Chills/ Chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Asthenia/ Weakness	1	12SEP2020	3/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1098 10981140	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1098 10981141	GENRL	Pain/ Bodyache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1098 10981152		Pain/ Bodyache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1098 10981161	MUSC	Back pain/ BackPain	1	20SEP2020	7/1	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1098 10981163	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1098 10981176	GASTR	Nausea/ Nausea	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	30SEP2020	15/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1098 10981177	INV	Body temperature increased/ Elevated Temperature	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1098 10981180	GENRL	Chills/ Chills	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1098 10981183	GENRL	Pyrexia/ Fever	1	16SEP2020	1/4	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1098 10981188	GENRL	Pyrexia/ Fever	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1098 10981196	GENRL	Peripheral swelling/ Swelling of Right and left arms	1	28SEP2020	8/1	1	No	O	NA	R (28SEP2020)	N/N
	SKIN	Erythema/ Redness of right arms and left arms	1	28SEP2020	8/1	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1098 10981207	GENRL	Injection site pain/ Left injection site pain	1	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
		Injection site pain/ Left arm injection site pain	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	INV	Body temperature increased/ Elevated Temperature	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1098 10981217	GENRL	Pain/ Bodyache	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1098 10981229	GENRL	Chills/ Chills	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Injection site pain/ Injection site Pain	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pain/ Bodyaches	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1098 10981243	GENRL	Chills/ Chills	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle Ache	1	03OCT2020	2/4	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1101 11011004	GENRL	Injection site erythema/ injection site redness	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ arm soreness in injection arm	1	02SEP2020	2/2	2	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ pain at the injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	2/2	2	Yes		NA/TC	R (03SEP2020)	N/N
	GASTR	Nausea/ nausea	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1101 11011005	GENRL	Pyrexia/ fever#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ headache#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1101 11011007	GENRL	Chills/ chills#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1101 11011010	MUSC	Myalgia/ muscle aches#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011012	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1101 11011013	GENRL	Injection site warmth/ injection site warmth	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ headache	1	04SEP2020	2/1	1	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1101 11011016	GENRL	Injection site pain/ injection site pain#	3	05MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1101 11011029	GENRL	Injection site pain/ injection site pain#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/Y
		Pain/ generalized body aches#	4	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011030	GENRL	Pyrexia/ fever#	4	18JAN2021	1/2	2	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ fever	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	RESP	Cough/ cough	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Upper respiratory tract congestion/ head congestion	1	11SEP2020	2/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1101 11011033	GENRL	Chills/ chills	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ fever	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1101 11011034	GENRL	Chills/ chills	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ pain at injection site	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	METAB	Decreased appetite/ decreased appetite	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ nausea	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011038	GENRL	Chills/ chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pain/ generalized body aches#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1101 11011039	NERV	Headache/ headache#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1101 11011040	GENRL	Injection site pain/ injection site pain	2	02OCT2020	2/1	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	3	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	02MAR2021	1/C	1	Yes		NA/TC	RG	N/N
	GENRL	Pyrexia/ fever#	4	03MAR2021	2/C	1	Yes		NA	RG	N/N
	NERV	Headache/ headache#	4	03MAR2021	2/C	1	Yes		NA/TC	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011041	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	1/C	1	Yes		NA	RG	N/N
		Pyrexia/ fever#	3	19FEB2021	1/2	2	Yes		NA	R (20FEB2021)	N/Y
	GENRL	Pain/ generalized body aches#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1101 11011045	GENRL	Injection site pain/ injection site pain	1	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1101 11011048	GENRL	Pyrexia/ fever	2	05OCT2020	1/3	2	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Muscle fatigue/ muscle fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
		Sinus congestion/ sinus congestion	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1101 11011052	GENRL	Pyrexia/ fever	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1101 11011056	GENRL	Injection site pain/ injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	3/1	1	Yes		NA	R (17SEP2020)	N/N
1101 11011059	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pyrexia/ low grade fever#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	INFEC	Gastroenteritis/ GASTROENTERITIS	1	18SEP2020	4/1	1	No	O	NA	R (18SEP2020)	N/N
1101 11011060	REPRO	Adenomyosis/ adenomyosis	2	16OCT2020	11/81	2	No	O	NA	R (04JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	2	Yes		NA	R (21JAN2021)	N/N
		Pain/ general body aches#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	CARD	Tachycardia/ tachycardia#	4	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
	GENRL	Pain/ body aches#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011061	GASTR	Nausea/ nausea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1101 11011062	EYE	Eye pain/ bilateral eye soreness	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	08OCT2020	2/8	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/3	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1101 11011065	GENRL	Chills/ chills#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1101 11011067	GASTR	Diarrhoea/ diarrhea	2	14OCT2020	8/1	1	No	O	NA	R (14OCT2020)	N/N
	GENRL	Chills/ chills#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N
		Pyrexia/ fever#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	11MAR2021	2/1	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1101 11011069	INJ&P	Road traffic accident/ motor vehicle accident/subject was the driver	2	19OCT2020	11/1	2	No	O	NA	R (19OCT2020)	N/N
	MUSC	Myalgia/ muscle pain post-traumatic	2	19OCT2020	11/7	2	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1101 11011070	GENRL	Injection site pain/ injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1101 11011072	GENRL	Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1101 11011073	GENRL	Injection site pain/ injection site pain#	3	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1101 11011075	GENRL	Effusion/ fluid near spine	1	26SEP2020	10/C	2	No	O	NA/TC	RG	N/N
	INJ&P	Contusion/ left thigh bruise	1	26SEP2020	10/11	1	No	O	NA	R (06OCT2020)	N/N
		Road traffic accident/ motor vehicle accident	1	26SEP2020	10/1	2	No	O	NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1101 11011079	GENRL	Injection site erythema/ injection site redness	1	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1101 11011080	GENRL	Injection site pain/ injection site pain#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ fever#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1101 11011085	GENRL	Chills/ chills#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ fatigue#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ injection site pain#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1101 11011094 16-55/ C4591001 1101 11011097	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/4	1	Yes		NA/TC	R (30JAN2021)	N/N
	GASTR	Abdominal pain upper/ stomach pain#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ injection site pain#	4	19FEB2021	1/5	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ fever#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Non-cardiac chest pain/ non-cardiac chest pain#	4	21FEB2021	3/4	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	21FEB2021	3/2	1	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ worsening headache#	4	21FEB2021	3/2	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1101 11011107	GENRL	Injection site pain/ injection site pain	1	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1101 11011115	NERV	Headache/ headache	1	21OCT2020	2/3	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Sinus congestion/ sinus congestion	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
	INFEC	Genital herpes/ genital herpes	1	09NOV2020	21/C	2	No	O	NA/TC	N	N/N
	INFEC	Coxsackie viral infection/ infection of coxsackievirus	2	06DEC2020	25/10	2	No	O	NA	R (15DEC2020)	N/N
	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	19DEC2020	38/C		No	O	NA	UNK	N/N
	PREG	Abortion spontaneous/ spontaneous abortion#	2	20FEB2021	101/1	3	No	O	NA	R (20FEB2021)	Y/N
16-55/ C4591001 1107 11071003	GASTR	Tongue discomfort/ BURNT SENSATION ON TONGUE	1	11AUG2020	14/35	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1107 11071010	INFEC	Vulvovaginal mycotic infection/ YEAST INFECTION VAGINAL	1	11AUG2020	13/7	1	No	O	NA/TC	R (17AUG2020)	N/N
	GENRL	Pain/ BODYACHES#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ FEVER#	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Dizziness/ DIZZINESS#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/Y
		Headache/ HEADACHE#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1107 11071015	MUSC	Pain in extremity/ LEFT ARM PAIN	1	16AUG2020	14/8	1	Yes		NA	R (23AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Haematochezia/ POSSIBLE BLOOD STREAKED STOOL	2	22SEP2020	28/C	1	No	O	NA	N	N/N
16-55/ C4591001 1107 11071020	INV	Blood testosterone decreased/ LOW TESTOSTERONE#	4	24FEB2021	17/C	1	No	O	NA/TC	N	N/N
	VASC	Hypertension/ HYPERTENSION#	4	24FEB2021	17/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1107 11071031	GASTR	Colitis/ ASCENDING COLITIS	2	25NOV2020	73/19	3	No	O	NA/TC	R (13DEC2020)	Y/N
16-55/ C4591001 1107 11071054	MUSC	Muscle twitching/ LEFT LOWER LIP TWITCH	1	06AUG2020	1/5	1	Yes		NA	R (10AUG2020)	N/N
	PSYCH	Anxiety/ ANXIETY	2	SEP2020	6/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1107 11071059	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1107 11071065	BLOOD	Microcytic anaemia/ MICROCYTIC ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N
	INV	Red blood cell morphology abnormal/ ABNORMAL RBC	2	09NOV2020	75/C	3	No	O	NA	N	Y/N

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## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		MORPHOLOGY INCLUDING SICKLE CELLS									
16-55/ C4591001 1107 11071102	INFEC	Tooth abscess/ TOOTH ABSCESS#	4	07FEB2021	21/8	1	No	O	NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1107 11071112	MUSC	Neck pain/ CERVICALGIA	1	29AUG2020	17/32	1	No	O	NA/TC	R (29SEP2020)	N/N
	GENRL	Chills/ CHILLS#	4	25FEB2021	4/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ FEVER#	4	25FEB2021	4/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1107 11071114	INFEC	Otitis media/ SEROUS OTITIS MEDIA#	4	03MAR2021	24/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1107 11071118	RENAL	Renal atrophy/ RIGHT KIDNEY ATROPHY	2	OCT2020	24/C	1	No	O	NA	N	N/N
16-55/ C4591001 1107 11071122	INFEC	Abscess oral/ ORAL ABSCESS	2	17DEC2020	101/11	1	No	O	NA/TC	R (27DEC2020)	N/N
16-55/ C4591001 1107 11071123	GENRL	Chills/ CHILLS	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1107 11071129	MUSC	Fatigue/ FATIGUE	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ FEVER	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Myalgia/ MUSCLE PAIN	2	14SEP2020	1/4	2	Yes		NA	R (17SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	RESP	Dyspnoea/ SHORTNESS OF BREATH	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1107 11071134	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	1	31AUG2020	14/23	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1107 11071146	GENRL	Injection site pain/ LEFT ARM INJECTION SITE PAIN	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1107 11071151	METAB	Vitamin D deficiency/ VITAMIN D DEFICIENCY	2	11JAN2021	124/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1107 11071156	VASC	Hypertension/ HYPERTENSION	2	11JAN2021	124/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE LEFT ARM	1	20AUG2020	1/3	1	Yes		NA/TC	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ FATIGUE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1107 11071171	REPRO	Prostatitis/ ACUTE PROSTATITIS	1	11SEP2020	18/104	1	No	O	NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ CHILLS#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ FEVER#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT THE INJECTION SITE#	3	12JAN2021	1/6	2	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Chills/ CHILLS#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ FATIGUE#	3	13JAN2021	2/5	1	Yes		NA	R (17JAN2021)	N/N
		Pain/ BODYACHES#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	RESP	Nasal congestion/ NASAL CONGESTION	1	15SEP2020	14/11	1	No	O	NA/TC	R (25SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1107 11071193 16-55/ C4591001	INJ&P	Muscle rupture/ PARTIAL TEAR-LEFT CALF MUSCLE	1	16SEP2020	14/38	1	No	O	NA/TC	R (23OCT2020)	N/N
1107 11071195 16-55/ C4591001	GENRL	Chills/ CHILLS	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
1107 11071200		Injection site pain/ LEFT ARM PAIN (INJECTION PAIN)	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1107 11071204	GENRL	Chills/ CHILLS	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ PAIN AT THE INJECTION SITE (LEFT ARM)	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1109 11091001	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1109 11091002	GENRL	Injection site pain/ Injection site tenderness	1	29JUL2020	1/1	1	Yes		NA	R (29JUL2020)	N/N
16-55/ C4591001 1109 11091010	GENRL	Injection site pain/ injection site tenderness	1	29JUL2020	1/3	2	Yes		NA/TC	R (31JUL2020)	N/N
16-55/ C4591001 1109 11091011	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	11MAR2021	2/3	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1109 11091016	INJ&P	Contusion/ contusion of right hip	1	13AUG2020	15/C	1	No	O	NA	N	N/N
		Contusion/ contusion to pelvis	1	13AUG2020	15/C	1	No	O	NA	N	N/N
		Fall/ FALL FROM STEP	1	13AUG2020	15/1	1	No	O	NA	RS (13AUG2020)	N/N
	INFEC	Tooth abscess/ DENTAL ABSCESS#	3	23FEB2021	2/9	2	No	O	NA/TC	R (03MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091021	GASTR	Vomiting/ EMESIS#	4	05MAR2021	1/1	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1109 11091028	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	05MAR2021	1/3	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1109 11091030	GENRL	Injection site erythema/ Injection Site Redness	1	30JUL2020	1/2	1	Yes		NA	R (31JUL2020)	N/N
16-55/ C4591001 1109 11091043	GENRL	Pyrexia/ FEVER#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1109 11091060	PSYCH	Bipolar disorder/ WORSENNING OF BIPOLAR DISORDER	2	04SEP2020	16/77	1	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1109 11091080	GENRL	Chills/ CHILLS	1	02AUG2020	2/1	1	Yes		NA	R (02AUG2020)	N/N
16-55/ C4591001 1109 11091110	GENRL	Chills/ CHILLS#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Fatigue/ FATIGUE#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ FEVER 101.0 F#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	INJ&P	Tooth fracture/ FRACTURE TOOTH#	3	27JAN2021	9/7	2	No	O	NA/TC/TCN	R (02FEB2021)	N/N
	GENRL	Chills/ CHILLS#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ MYALGIA#	4	09FEB2021	1/30	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001 1109 11091122	GENRL	Injection site pain/ INJECTION SITE PAIN#	4	13FEB2021	1/4	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1109 11091159	MUSC	Myalgia/ LEFT ARM MYALGIA	1	04AUG2020	1/5	1	Yes		NA	R (08AUG2020)	N/N
16-55/ C4591001 1109 11091180	GENRL	Fatigue/ FATIGUE#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ FEVER#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1109 11091204	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
		Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091223	GENRL  NERV	Pyrexia/ FEVER#	4	15FEB2021	1/C	1	Yes		NA	N	N/N
		Headache/ HEADACHE#	4	15FEB2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1109 11091242	GENRL  NERV	Fatigue/ FATIGUE#	4	14FEB2021	2/C	1	Yes		NA	N	N/N
		Headache/ HEADACHE#	4	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1109 11091246	SKIN	URTICARIA CHEST/STOMACH Urticaria/	2	12SEP2020	5/24	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1109 11091258	SKIN	Dermatitis contact/ allergic contact dermatitis on all extremities and trunk	1	25AUG2020	10/16	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1109 11091266	GENRL	Chills/ CHILLS#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1109 11091287	SKIN	Rash/ Rash on both hands	1	05SEP2020	16/4	1	No	O	NA/TC	R (08SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091304	GENRL	Pyrexia/ Fever 101#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1109 11091309	GENRL	Fatigue/ FATIGUE#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ INJECTION SITE PAIN#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1109 11091320	INV	Body temperature increased/ ELEVATED TEMPERATURE 102.0	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
16-55/ C4591001 1109 11091331	GENRL	Injection site pain/ INJECTION SITE PAIN LEFT ARM*		26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1109 11091343	GENRL	Fatigue/ FATIGUE	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	29AUG2020	2/2	1	Yes		NA/TC/TCN	R (30AUG2020)	N/N
16-55/ C4591001 1109 11091361	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	2	02MAR2021	161/4	1	No	O	NA/TC	R (05MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091362	GENRL	Chills/ CHILLS#	4	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1109 11091397	EYE	Dry eye/ DRY EYES	1	09SEP2020	8/8	1	Yes		NA	R (16SEP2020)	N/N
	EYE	Dry eye/ DRY EYES	1	20SEP2020	19/18	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1109 11091415	NERV	Syncope/ Syncope episode	2	29DEC2020	95/C	3	No	O	NA/TC	RG	N/N
16-55/ C4591001 1109 11091425	INFEC	Sinusitis/ SINUSITIS#	3	08MAR2021	10/5	2	No	CD	NA	R (12MAR2021)	N/N
16-55/ C4591001 1109 11091444	GASTR	Diverticulum intestinal haemorrhagic/ BLOOD IN STOOL DIVERTICULOSIS	2	10OCT2020	12/11	2	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1109 11091448	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1109 11091453	MUSC	Pain in extremity/ right leg pain#	2	10MAR2021	164/C	1	No	O	NA/TCN	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1109 11091455	GENRL	Chills/ CHILLS#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ FEVER 101.3#	4	18FEB2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1109 11091466	MUSC	Muscle spasms/ muscle spasm upper right abdomen	2	19OCT2020	20/6	3	No	O	NA	R (24OCT2020)	N/N
16-55/ C4591001 1109 11091473	GENRL	Pyrexia/ FEVER 101F	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1109 11091488	EAR	Ear pain/ Earache(bilateral)	1	18SEP2020	9/11	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1109 11091492	MUSC	Back pain/ LOW BACK PAIN	2	16OCT2020	16/58	2	Yes		NA	R (12DEC2020)	N/N
16-55/ C4591001 1109 11091557	GENRL	Injection site pain/ Injection Site Pain	2	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1110 11101002	MUSC	Neck pain/ neck pain	1	06AUG2020	7/8	1	No	O	NA	R (13AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101013	HEPAT	Cholelithiasis/ Cholelithiasis	2	04DEC2020	107/2	1	No	O	NA	R (05DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Fatigue/ fatigue	1	07AUG2020	7/4	1	Yes		NA	R (10AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the site of injection.#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	INV	Body temperature increased/ Elevated temperature 98.5 F#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1110 11101019	NERV	Headache/ Headache.#	4	13JAN2021	2/1	1	Yes		NA/TC	R (13JAN2021)	N/N
	INFEC	Helicobacter infection/ Helicobacter Pylori Infection	2	11JAN2021	144/C	1	No	O	NA/TC	RG	N/N
	INFEC	Cellulitis/ Cellulitis Left hand	2	13JAN2021	146/16	1	No	O	NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1110 11101020	NERV	Headache/ Headache	1	07AUG2020	5/3	1	Yes		NA/TC	R (09AUG2020)	N/N
16-55/ C4591001 1110 11101021	GASTR	Diarrhoea/ diarrhea	1	25AUG2020	23/1	1	No	O	NA	R (25AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101022	GENRL	Injection site pain/ Pain at the Site of Injection Left Deltoid#	3	25JAN2021	1/C	1	Yes		NA/TC	N	N/N
	INV	Body temperature increased/ Elevated Temperature (99.9F)#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	21FEB2021	7/1	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Pain at site injection (Left Deltoid)#	4	03FEB2021	1/3	1	Yes		NA/TC	R (05FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1110 11101025	GENRL	Chills/ Chills#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea (1 episode)#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1110 11101027	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ FATIGUE	1	03AUG2020	1/10	2	Yes		NA	R (12AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ DIARRHEA	1	04AUG2020	2/9	2	Yes		NA	R (12AUG2020)	N/N
	NERV	Headache/ HEADACHE	1	04AUG2020	2/9	2	Yes		NA/TCN	R (12AUG2020)	N/N
16-55/ C4591001 1110 11101045	GENRL	Injection site pain/ PAIN AT SITE INJECTION	1	12AUG2020	7/4	1	No	O	NA	R (15AUG2020)	N/N
16-55/ C4591001 1110 11101050	VASC	Hypertension/ Hypertension	2	12NOV2020	78/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1110 11101057	GENRL	Injection site pain/ Pain at the site of injection.#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
16-55/ C4591001 1110 11101058	GENRL	Injection site pain/ pain at site injection (left deltoid)#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1110 11101059	METAB	Hypertriglyceridaemia/ HYPERTRIGLYCERIDEMIA	1	12AUG2020	6/C	1	No	O	NA	N	N/N
16-55/ C4591001 1110 11101064	RESP	Rhinorrhoea/ runny nose	1	19AUG2020	10/8	1	No	O	NA	R (26AUG2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea#	3	25JAN2021	1/6	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101072	GENRL	Injection site pain/ Pain at site of injection (Right deltoid)#	3	25JAN2021	1/6	1	Yes		NA	R (30JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	15FEB2021	1/6	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1110 11101076	GENRL	Fatigue/ fatigue#	3	02MAR2021	1/1	1	Yes		NA	R (02MAR2021)	N/N
		Injection site pain/ pain at the site of injection (left deltoid)#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N
	NERV	Headache/ headache#	3	02MAR2021	1/1	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1110 11101078	GASTR	Toothache/ toothache	2	28SEP2020	28/23	1	No	O	NA/TC	R (20OCT2020)	N/N
	GENRL	Chills/ chills#	4	08MAR2021	1/2	1	Yes		NA	R (09MAR2021)	N/N
	NERV	Headache/ Headache#	4	09MAR2021	2/C	1	Yes		NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101082	INJ&P	Joint injury/ right knee injury	2	29SEP2020	29/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1110 11101091	SKIN	Rash maculo-papular/ Maculopapular rash to abdomen, chest, back and upper arms	1	30AUG2020	18/3	1	No	O	NA/TC	R (01SEP2020)	N/N
	RESP	Rhinorrhoea/ Runny nose	2	08OCT2020	37/1	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1110 11101092	GENRL	Fatigue/ fatigue#	3	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at site of injection (left deltoid)#	3	24FEB2021	2/4	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1110 11101106	GENRL	Injection site pain/ pain at the site of injection (left deltoid)#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1110 11101117	MUSC	Bursitis/ Bursitis of Left Foot	2	30SEP2020	22/71	2	No	O	NA/TC	R (09DEC2020)	N/N
		Plantar fasciitis/ Left Plantar Fasciitis	2	30SEP2020	22/71	2	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1110 11101122	GENRL	Injection site pain/ pain at the injection site left arm#	3	26FEB2021	1/4	1	Yes		NA	R (01MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
	INV	Body temperature increased/ elevated temperature 100.0 degrees Fahrenheit#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
	NERV	Headache/ headache#	3	27FEB2021	2/4	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1110 11101131	INJ&P	Limb injury/ Right Shoulder Injury	2	03OCT2020	20/	2	No	O	NA/TC	R	N/N
	MUSC	Arthritis/ Arthritis on Right Shoulder	2	NOV2020	49/C	1	No	O	NA	N	N/N
16-55/ C4591001 1110 11101145	MUSC	Muscle spasms/ Cramp on right foot.	2	26JAN2021	133/3	1	No	O	NA	R (28JAN2021)	N/N
16-55/ C4591001 1110 11101151	MUSC	Myalgia/ mild muscle pain	1	08SEP2020	12/9	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	2/8	2	Yes		NA/TC	R (26SEP2020)	N/N
	EYE	Vitreous floaters/ Right eye visual floaters	2	14OCT2020	27/10	2	No	O	NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	27/13	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	22FEB2021	1/8	1	Yes		NA	R (01MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101158 16-55/ C4591001	MUSC	Rotator cuff syndrome/ right bicep tendon rotator cuff tear	2	20DEC2020	91/C	2	No	O	NA/TC/TCN	RG	N/N
1110 11101162 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy#	2	25FEB2021	161/C		No	O	NA	UNK	N/N
1110 11101164 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	25FEB2021	161/C		No	O	NA	UNK	N/N
1110 11101165 16-55/ C4591001	GASTR	Dental caries/ dental cavity	1	04SEP2020	7/1	2	No	O	NA/TC	R (04SEP2020)	N/N
1110 11101167	SKIN	Acne/ acne	2	14JAN2021	119/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site left arm#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
1110 11101168	MUSC	Myalgia/ muscle aches#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	VASC	Hypertension/ Hypertension	2	06JAN2021	107/C	1	No	O	NA/TC/TCN	N	N/N
1110 11101175											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101181	GENRL	Chills/ chills#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ pain at site of injection#	3	18FEB2021	1/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1110 11101186	GENRL	Chills/ chills#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N
		Fatigue/ fatigue#	4	12MAR2021	1/C	2	Yes		NA	N	N/N
		Pyrexia/ fever 101.0 degrees Fahrenheit#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N
		Swelling/ painful swelling on the left side of the neck#	4	12MAR2021	1/2	1	Yes		NA/TC	R (13MAR2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	12MAR2021	1/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1110 11101187	GASTR	Colitis ulcerative/ Ulcerative Colitis	2	07DEC2020	77/C	2	No	O	NA/TC	RG	N/N
		Gastritis/ Gastritis	2	07DEC2020	77/C	1	No	O	NA/TC/TCN	RG	N/N
	INFEC	Appendicitis/ Acute Appendicitis	2	07DEC2020	77/4	3	No	O	NA/TC/TCN	R (10DEC2020)	Y/N
	GENRL	Injection site pain/ Pain at site injection (left deltoid)#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101189	RESP	Oropharyngeal pain/ sore throat	1	15SEP2020	5/2	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1110 11101198	GENRL	Injection site pain/ pain at the injection site left arm#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1110 11101199	GENRL	Injection site pain/ Pain at the Site of Injection on left Arm#	3	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	3	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1110 11101203	GENRL	Chills/ chills#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ body aches#	3	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1110 11101211	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome	1	22SEP2020	19/C	1	No	O	NA/TC	N	N/N
	METAB	Hypocholesterolaemia/ hypocholesteremia	1	22SEP2020	19/C	1	No	O	NA/TC	RS	N/N
	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	3	17FEB2021	2/3	1	Yes		NA/TC	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	09MAR2021	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1110 11101212	INFEC	Helicobacter infection/ Helicobacter Pylori Infection	2	04FEB2021	134/18	1	No	O	NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1110 11101213	INFEC	Urinary tract infection/ urinary tract infection#	3	12MAR2021	16/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1110 11101219	GENRL	Pain/ Body Aches#	4	17FEB2021	1/C	1	Yes		NA	N	N/N
		Pyrexia/ Fever (100.2 degrees Fahrenheit)#	4	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1110 11101220	BLOOD	Lymphadenopathy/ Bilateral axillary adenopathy	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1110 11101227	GENRL	Injection site pain/ Pain at the site of injection (right deltoid)#	3	03MAR2021	2/3	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1110 11101229	REPRO	Vaginal haemorrhage/ Vaginal Bleeding (prolonged)	1	14DEC2020	96/31	2	No	O	NA/TCN	R (13JAN2021)	N/N
	GENRL	Swelling/ swelling left deltoid area#	3	24FEB2021	2/15	2	Yes		NA/TC	R (10MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101235	GENRL	Fatigue/ fatigue#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ pain at injection site (left deltoid)#	3	25FEB2021	1/4	1	Yes		NA	R (28FEB2021)	N/N
	INV	Body temperature increased/ elevated temperature#	3	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1110 11101236	SKIN	Rash/ rash to legs	2	08OCT2020	7/149	1	No	O	NA	R (05MAR2021)	N/N
	MUSC	Back pain/ back pain	2	31OCT2020	30/9	1	No	O	NA/TC	R (08NOV2020)	N/N
	EYE	Eye pruritus/ Bilateral Eye Itchiness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
		Ocular hyperaemia/ Bilateral Eye redness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
	GASTR	Abdominal discomfort/ Abdominal Discomfort	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	44/80	1	No	O	NA	R (01FEB2021)	N/N
	RESP	Throat irritation/ Throat Itchiness	2	14NOV2020	44/3	1	No	O	NA	R (16NOV2020)	N/N
	EYE	Visual impairment/ change in vision	2	06DEC2020	66/2	2	No	O	NA	R (07DEC2020)	Y/N
	SKIN	Rash/ Generalize Rash	2	05JAN2021	96/2	1	No	O	NA	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101237	GENRL	Injection site pain/ MILD INJECTION PAIN	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1110 11101246	GENRL	Injection site pain/ Pain at injection site left deltoid	1	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Malaise/ malaise	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1110 11101264	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ fever	2	07OCT2020	1/2	3	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1110 11101268	GASTR	Gastrooesophageal reflux disease/ Acid reflux	2	19FEB2021	137/2	1	No	O	NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1110 11101269	GENRL	Chills/ chills	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Arthralgia/ Left Shoulder pain	2	01JAN2021	87/C	1	No	O	NA	N	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101271		Pyrexia/ Fever#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/C	1	Yes		NA	N	N/N
	BLOOD	Lymphadenopathy/ Adenopathy (left armpit)#	4	08FEB2021	34/C	1	Yes		NA	N	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at site of injection#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
1110 11101274											
16-55/ C4591001	CONG	Factor II mutation/ prothrombin gene mutation#	3	MAR2021	1/C	1	No	O	NA	N	N/N
1110 11101275											
	GENRL	Injection site pain/ pain at site of injection (left deltoid)#	3	04MAR2021	2/C	1	Yes		NA	N	N/N
	GENRL	Injection site haemorrhage/ ecchymosis at site of injection 2 cm#	3	07MAR2021	5/C	1	Yes		NA	N	N/N
	INV	Body temperature increased/ elevated temperature 99.6 degrees Fahrenheit#	3	07MAR2021	5/C	1	Yes		NA/TC	N	N/N
	VASC	Haematoma/ hematoma at mid left arm 10 cm#	3	07MAR2021	5/C	2	Yes		NA	N	N/N
	INV	Blood pressure increased/ elevated blood pressure#	3	12MAR2021	10/C	2	No	O	NA	N	N/N
16-55/ C4591001	GASTR	Dental caries/ Left side molar cavity	2	10FEB2021	125/17	1	No	O	NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101278 16-55/ C4591001	BLOOD	Iron deficiency anaemia/ iron deficiency anemia	1	02OCT2020	12/C	1	No	O	NA/TC	N	N/N
1110 11101282 16-55/ C4591001	GENRL	Injection site pain/ Pain at the site of injection (Left Deltoid)#	4	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
1110 11101286	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Pain/ Body Aches#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1110 11101290	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at site injection (Left Deltoid)#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	INV	Body temperature increased/ Elevated temperature#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1110 11101293	GENRL	Injection site pain/ Pain at the site of injection (Right deltoid)#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site right arm#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101294	GASTR	Injection site swelling/ swelling of injection site right arm#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1110 11101294	GASTR	Dental caries/ Toothache (Dental Cavity)	1	01OCT2020	9/1	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1110 11101298	SKIN	Papule/ Papule left upper arm	1	24SEP2020	2/	1	Yes		NA	R	N/N
16-55/ C4591001 1110 11101308	GENRL	Injection site pain/ Pain at site injection	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1110 11101308	GENRL	Injection site pain/ Site injection pain#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
16-55/ C4591001 1110 11101311	PSYCH	Attention deficit hyperactivity disorder/ attention deficit hyperactivity disorder#	4	02MAR2021	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1110 11101313	GENRL	Injection site pain/ Pain at site injection	1	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1110 11101319	NERV	Headache/ headache	1	01OCT2020	4/2	2	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1110 11101319	RENAL	Dysuria/ Dysuria	2	28OCT2020	10/21	1	No	O	NA/TC	R (17NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1110 11101320	GENRL	Asthenia/ Generalized weakness#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Chills/ Chills#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Injection site pain/ Injection Site pain#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
16-55/ C4591001 1110 11101321	BLOOD	Lymphadenopathy/ Lymphadenopathy to left neck	2	21OCT2020	2/C	1	Yes		NA	RG	N/N
	BLOOD	Neutropenia/ Neutropenia	2	26OCT2020	7/C	3	Yes		NA	N	N/N
16-55/ C4591001 1110 11101323	METAB	Hypercholesterolaemia/ hypercholesterolemia	2	30OCT2020	11/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1110 11101325	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/23	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1110 11101337	GASTR	Irritable bowel syndrome/ Irritable Bowel Syndrome	2	02NOV2020	12/C	2	No	O	NA/TC	N	N/N
	GASTR	Gastritis/ Gastritis	2	03NOV2020	13/15	2	No	O	NA/TC	R (17NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101338 16-55/ C4591001 1110 11101343	GENRL	Chills/ Chills	2	27OCT2020	1/5	2	Yes		NA	R (31OCT2020)	N/N
		Pyrexia/ Fever	2	27OCT2020	1/5	2	Yes		NA/TC	R (31OCT2020)	N/N
	RESP	Cough/ Cough	2	27OCT2020	1/18	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C4591001 1110 11101346	GENRL	Fatigue/ Fatigue	2	04NOV2020	6/3	2	No	O	NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	6/3	1	No	O	NA/TC	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Pain at site injection#	3	31DEC2020	3/3	1	Yes		NA/TC	R (02JAN2021)	N/N
	MUSC	Back pain/ Back pain#	3	01JAN2021	4/2	1	No	O	NA/TC	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the site of injection.#	4	18JAN2021	1/8	1	Yes		NA/TC	R (25JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
		Paraesthesia/ Tingling Left forearm.#	4	18JAN2021	1/1	1	Yes		NA	R (18JAN2021)	N/Y
	GENRL	Chills/ Chills#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pain/ Body aches#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
		Pyrexia/ Fever (100.2)#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Injection site rash/ Rash Left Deltoid below injection site#	4	22JAN2021	5/6	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1110 11101349	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)	N/N
16-55/ C4591001 1110 11101354	RESP	Rhinorrhoea/ Rhinorrea	1	16OCT2020	2/8	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1110 11101356	GENRL	Pyrexia/ fever	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1110 11101361	GENRL	Injection site pain/ pain at injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ chills	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ headache	2	11NOV2020	2/1	2	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1110 11101372	MUSC	Myalgia/ Myalgia#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	GASTR	Gastritis/ Gastritis	1	03NOV2020	6/C	2	No	O	NA/TC	RG	N/N
1110 11101377	GENRL	Fatigue/ Fatigue	1	14NOV2020	2/1	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001	GENRL	Arthralgia/ Joint Pain (Generalized)	1	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	01SEP2020	2/2	2	Yes		NA/TCN	R (02SEP2020)	N/N
1111 11111072	GENRL	Pain/ Body aches	2	01SEP2020	2/2	3	Yes		NA/TCN	R (02SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness#	3	29JAN2021	1/4	2	Yes		NA	RS (01FEB2021)	N/N
1111 11111081	MUSC	Pain in extremity/ Left sore arm#	3	30JAN2021	2/4	1	Yes		NA	R (02FEB2021)	N/N
1111 11111082	SKIN	Angioedema/ ANGIO-EDEMA BOTH EYES	1	23AUG2020	13/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1111 11111099 16-55/ C4591001	GENRL	Injection site pain/ Soreness (pain) at injection site#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
1111 11111101 16-55/ C4591001	NERV	Headache/ headache	2	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
1111 11111115 16-55/ C4591001	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N
1111 11111130 16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary lymph node swelling#	4	13JAN2021	3/4	1	Yes		NA	R (16JAN2021)	N/N
1111 11111139 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
1111 11111143		Injection site pain/ Left sore arm at injection site#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Dizziness/ Lightheadedness#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1111 11111155	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body aches	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1111 11111159	MUSC	Neck pain/ Neck pain#	4	04FEB2021	25/5	2	No	O	NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1111 11111169	RESP	Dyspnoea/ Air Huunger	1	02SEP2020	1/2	2	No	CD	NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Left sore arm at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1111 11111172	GENRL	Injection site pain/ Injection site soreness#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1111 11111176	SKIN	Rash/ Rash on right side of neck	1	14SEP2020	7/21	2	No	CD	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1111 11111200	MUSC	Pain in extremity/ Right sore arm#	3	22JAN2021	1/2	1	Yes		NA/TCN	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121012	GENRL	Injection site erythema/ Redness at injection site#	4	12FEB2021	1/C	1	Yes		NA	RG	N/N
		Injection site swelling/ Swelling at injection site#	4	12FEB2021	1/C	1	Yes		NA	RG	N/N
		Pyrexia/ Low grade fever#	4	12FEB2021	1/2	1	Yes		NA/TCN	R (13FEB2021)	N/N
	MUSC	Pain in extremity/ Right sore arm#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	2	18DEC2020	120/2	2	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
	PSYCH	Anxiety/ Worsening of anxiety	1	20AUG2020	21/35	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1112 11121026	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121047	INJ&P	Hand fracture/ Broken finger, left middle finger	1	12AUG2020	10/21	3	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C4591001 1112 11121064	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/5	2	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/5	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/5	2	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	1/5	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1112 11121069	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121071	INFEC	Urinary tract infection/ Urinary tract infection	1	10AUG2020	6/13	1	No	O	NA/TC	R (22AUG2020)	N/N
16-55/ C4591001	INFEC	Pharyngitis streptococcal/ Strep Throat	1	24AUG2020	20/12	1	No	O	NA/TC	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121078 16-55/ C4591001	NERV	Headache/ Headache, mild#	2	16DEC2020	86/2	2	Yes		NA/TC	R (17DEC2020)	N/N
1112 11121081 16-55/ C4591001	VASC	Haematoma/ Hematoma	1	12AUG2020	3/12	1	No	O	NA/TC	R (23AUG2020)	N/N
1112 11121087 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
1112 11121090		Injection site pain/ Injection site pain#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	VASC	Hypertension/ Worsening of Hypertension#	4	25JAN2021	22/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Leg pain	2	06SEP2020	7/1	1	No	O	NA/TC	R (06SEP2020)	N/N
1112 11121091 16-55/ C4591001	NEOPL	Transitional cell carcinoma/ Urothelial Carcinoma	2	14OCT2020	45/C	3	No	O	NA/TC	RG	N/N
1112 11121100 16-55/ C4591001	SKIN	Dermatitis contact/ Allergic reaction to poison ivy	1	25AUG2020	16/10	2	No	O	NA/TC	R (03SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121101	MUSC	Bursitis/ Bursitis, left shoulder	2	22OCT2020	21/19	2	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	07JAN2021	1/4	2	Yes		NA/TC	R (10JAN2021)	N/N
1112 11121102	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/4	2	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	2/3	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
1112 11121105	MUSC	Myalgia/ Muscle Aches#	4	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
1112 11121110	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	06JAN2021	1/2	2	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121117	GENRL	Chills/ Chills#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
		Fatigue/ Fatigue#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	23JAN2021	2/2	2	Yes		NA/TC/TCN	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1112 11121122	NEOPL	Uterine leiomyoma/ Worsening INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	Y/N
	REPRO	Uterine haemorrhage/ Worsening of Abnormal Uterine Bleeding	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	N/N
16-55/ C4591001 1112 11121123	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1112 11121125	INFEC	Tinea infection/ Ringworm	1	19AUG2020	3/31	2	No	O	NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121128	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
16-55/ C4591001 1112 11121138	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/6	2	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
16-55/ C4591001 1112 11121151	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)	N/N
		Pyrexia/ Fever#	3	22DEC2020	1/2	2	Yes		NA/TC	R (23DEC2020)	N/N
	NERV	Headache/ Headache#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site paraesthesia/ Paresthesia, injection site, left arm	2	14SEP2020	4/2	2	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121156 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
1112 11121158		Injection site pain/ Injection site pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
1112 11121160		Pyrexia/ Fever#	4	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	2	Yes		NA	R (24DEC2020)	N/N
1112 11121171											
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	09OCT2020	25/6	3	No	O	NA/TC	R (14OCT2020)	N/N
1112 11121173											
16-55/ C4591001	GENRL	Injection site pain/ Injection site Pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
1112 11121183											
16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	29SEP2020	15/38	3	No	O	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121184	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/1	2	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary tract infection	1	13SEP2020	18/4	1	No	O	NA/TC	R (16SEP2020)	N/N
1112 11121188	GENRL	Chills/ Chills#	4	08JAN2021	2/2	3	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC/TCN	R (18SEP2020)	N/N
1112 11121190		Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	29AUG2020	2/4	2	Yes		NA	R (01SEP2020)	N/N
1112 11121191	MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/4	2	Yes		NA/TC	R (01SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	30AUG2020	3/2	1	Yes		NA	R (31AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121192 16-55/ C4591001	BLOOD	Lymph node pain/ Lymph node pain, under left arm	2	18SEP2020	2/5	3	Yes		NA/TC	R (22SEP2020)	N/N
1112 11121193		Lymphadenopathy/ Lymph node swelling (under left arm)	2	18SEP2020	2/6	3	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/5	3	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
1112 11121194 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain, post vaccine	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
1112 11121197 16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
1112 11121198	GENRL	Injection site pain/ Injection site pain, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches, post vaccination	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121199	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1112 11121200	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		Injection site erythema/ Redness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ Injection site pain	1	01SEP2020	2/3	1	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
		Pyrexia/ Fever#	4	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	09JAN2021	2/3	2	Yes		NA/TC	R (11JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness, left arm, post vaccine	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121204	NERV	Headache/ Headache	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pain/ Pain, left side neck and upper arm	2	30SEP2020	8/13	2	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/3	2	Yes		NA/TC	R (24DEC2020)	N/N
1112 11121207	MUSC	Myalgia/ Muscle aches(all over)	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	GENRL	Peripheral swelling/ Arm swelling, left arm	2	28SEP2020	5/3	2	Yes		NA/TC	R (30SEP2020)	N/N
1112 11121214	MUSC	Myalgia/ Muscle aches, post vaccine	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain, post vaccination	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
1112 11121216	MUSC	Myalgia/ Muscle Ache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121226	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1112 11121234	GENRL	Fatigue/ Fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1112 11121237	GENRL	Injection site pain/ Injection site pain (post vaccination)	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1112 11121242	MUSC	Myalgia/ Muscle aches	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1112 11121249	GENRL	Injection site pain/ Injection site pain, post vaccination	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121253	MUSC	Myalgia/ Myalgia#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	3	18DEC2020	2/2	1	Yes		NA/TC	RS (19DEC2020)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	1/2	2	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	07JAN2021	2/2	2	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1112 11121254	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	NERV	Headache/ Headache	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1112 11121256	GASTR	Diarrhoea/ Mild Diarrhea	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	2/8	2	Yes		NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121261	GENRL	Injection site swelling/ Injection site swelling	1	07OCT2020	2/22	2	Yes		NA/TC	R (28OCT2020)	N/N
		Injection site pain/ Injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain, generalized	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1112 11121266	MUSC	Myalgia/ Muscle Aches	2	28OCT2020	1/2	1	Yes		NA/TC	R (29OCT2020)	N/N
		Myalgia/ Muscle Ache	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1112 11121268	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	16DEC2020	1/4	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1112 11121269	GENRL	Injection site pain/ Injection site pain#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		MUSC	Myalgia/ Muscle Aches	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)
16-55/ C4591001 1112 11121282	GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121284	MUSC	Myalgia/ Muscle Aches	1	09OCT2020	1/2	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain, post injection	2	28OCT2020	1/2	2	Yes		NA	R (29OCT2020)	N/N
	GENRL		Fatigue/ Fatigue	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)
	MUSC	Myalgia/ Muscle Aches	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	2/3	1	Yes		NA	RS (19DEC2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/2	1	Yes		NA/TC	R (18DEC2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	20JAN2021	1/3	2	Yes		NA/TC	R (22JAN2021)	N/N
GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
16-55/ C4591001	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121296 16-55/ C4591001 1112 11121297	MUSC	Myalgia/ Muscle Aches	1	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	03NOV2020	2/1	2	Yes		NA/TC	R (03NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	2/2	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1112 11121298	GENRL	Injection site pain/ Injection Site Pain, left arm	1	12OCT2020	1/1	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1112 11121299	GENRL	Pyrexia/ Fever	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1112 11121305	GENRL	Fatigue/ Fatigue	2	03NOV2020	1/3	2	Yes	NA	R	(05NOV2020)	N/N
		Injection site pain/ Injection site Pain	2	03NOV2020	1/3	2	Yes	NA	R	(05NOV2020)	N/N
		Pyrexia/ Fever	2	03NOV2020	1/3	1	Yes	NA	R	(05NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03NOV2020	1/3	2	Yes	NA/TC	R	(05NOV2020)	N/N
16-55/ C4591001 1112 11121308	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/1	1	Yes	NA/TC	R	(04NOV2020)	N/N
16-55/ C4591001 1112 11121315	GENRL	Injection site pain/ Injection site pain, (post vaccination)	1	20OCT2020	2/2	1	Yes	NA/TC	R	(21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	2	Yes	NA	R	(12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11NOV2020	1/2	2	Yes	NA/TC	R	(12NOV2020)	N/N
16-55/ C4591001 1112 11121318†	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes	NA	R	(18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	05JAN2021	1/3	2	Yes	NA	R	(07JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	05JAN2021	1/3	2	Yes	NA	R	(07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1112 11121319	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1112 11121328	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04JAN2021	1/3	2	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1112 11121332	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1112 11121342	MUSC	Patellofemoral pain syndrome/ Chondromalacia Patallae	2	18JAN2021	68/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1114 11141008	GENRL	Chills/ CHILLS#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ ARM PAIN AT INJECTION SITE#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1114 11141009	GENRL	Fatigue/ FATIGUE#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1114 11141041	NERV	Headache/ exacerbation of headaches	1	25AUG2020	8/3	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C4591001 1114 11141053	GENRL	Pyrexia/ Fever	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1114 11141063	METAB	Glucose tolerance impaired/ Prediabetes	2	SEP2020	1/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1114 11141065	SKIN	Dermatitis contact/ Poison Ivy Rash Back	1	07SEP2020	19/8	1	No	O	NA	R (14SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	25FEB2021	1/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001	PSYCH	Anxiety/ Anxiety	2	01OCT2020	18/C	1	No	O	NA	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1114 11141076 16-55/ C4591001 1114 11141093	GASTR	Diarrhoea/ Diarrhea#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
		Nausea/ Nausea#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Soreness#	4	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1116 11161002	GENRL	Injection site pain/ arm pain at injection site#	3	22JAN2021	1/5	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1116 11161023	INFEC	Cellulitis/ Cellulitis Located On Lower Right Leg	2	18OCT2020	31/12	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1116 11161036	GENRL	Fatigue/ fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Pain/ generalized body aches#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ Headaches	1	01SEP2020	5/25	1	No	O	NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1116 11161047	GENRL	Pain/ generalized body aches#	3	05MAR2021	1/8	1	Yes		NA	R (12MAR2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	05MAR2021	1/8	1	Yes		NA	R (12MAR2021)	N/N
1116 11161049	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N
16-55/ C4591001	HEPAT	Bile duct stone/ Cholelithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
1116 11161059	INJ&P	Maternal exposure before pregnancy/ maternal exposure before pregnancy	2	09NOV2020	49/C	1	No	O	NA	UNK	N/N
	SOCCL	High risk sexual behaviour/ unprotected, heterosexual intercourse	2	23NOV2020	63/1	1	No	O	NA	RS (23NOV2020)	N/N
16-55/ C4591001	GASTR	Abdominal hernia/ Upper Abdominal Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N
1116 11161083		Umbilical hernia/ Umbilical Hernia	1	SEP2020	1/	1	No	O	NA/TCN	R (21OCT2020)	N/N
	GENRL	Chills/ chills#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N
		Fatigue/ fatigue#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	3	04MAR2021	2/5	1	Yes		NA	R (08MAR2021)	N/N
16-55/ C4591001 1116 11161099	INFEC	Urinary tract infection/ Urinary Tract Infection	2	18OCT2020	24/12	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1116 11161115	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1116 11161140	INFEC	Tooth infection/ Wisdom tooth infection#	2	12MAR2021	171/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1116 11161148	GENRL	Injection site pain/ Arm pain at injection site#	3	30JAN2021	2/4	1	Yes		NA	R (02FEB2021)	N/N
	GASTR	Abdominal pain/ abdominal cramps#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Injection site pain/ injection site pain#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Malaise/ malaise#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
		Pyrexia/ low grade temperature#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	METAB	Decreased appetite/ lack of appetite#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Back pain/ back pain#	4	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	21FEB2021	3/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1116 11161154	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection- unspecified type	2	17JAN2021	110/26	1	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1116 11161186	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
	INFEC	Herpes zoster/ shingles#	3	30JAN2021	2/28	2	No	O	NA	R (26FEB2021)	N/N
16-55/ C4591001 1116 11161200	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain/ Body Aches	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Pain @ Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161204	MUSC	Arthralgia/ Joint Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Myalgia/ Muscle Pains	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Tenosynovitis stenans/ DeQuervain's Tendinosis	1	24SEP2020	14/C	1	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ fatigue#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Presyncope/ Presyncope during blood draw	2	06NOV2020	30/1	1	No	O	NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site- left deltoid#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
GENRL	Injection site pruritus/ Itching at injection site- left deltoid muscle#	3	13JAN2021	6/1	1	Yes		NA	R (13JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161260	GENRL	Fatigue/ fatigue#	3	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ chills#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		Pyrexia/ fever#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1116 11161261	GENRL	Injection site pain/ Pain at injection site- left deltoid muscle#	3	16JAN2021	2/3	1	Yes		NA	R (18JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature 99.0 to 100.1#	4	05FEB2021	3/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1116 11161276	GENRL	Injection site mass/ Knot at Injection Site	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1116 11161305	GENRL	Chills/ Body Chills	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
		Fatigue/ Fatigue	2	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Pain @ Injection Site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1116 11161308	GENRL	Chills/ chills#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ generalized body aches#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
		Pyrexia/ fever#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1116 11161310	IMMUN	Drug hypersensitivity/ allergic reaction to concomitant medication	2	18OCT2020	3/2	1	No	CD	NA	R (19OCT2020)	N/N
16-55/ C4591001 1116 11161320	PSYCH	Anxiety/ Anxiety	1	01OCT2020	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1117 11171011	INJ&P	Fall/ FALL#	4	06FEB2021	25/1	2	No	O	NA/TCN	R (06FEB2021)	N/N
		Fibula fracture/ BROKEN BONE, FIBULA, RIGHT, DISTAL#	4	06FEB2021	25/C	2	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1117 11171015	MUSC	Arthralgia/ KNEE PAIN, LEFT, WORSENING	2	OCT2020	23/C	2	No	O	NA/TC/TCN	N	N/N
	INJ&P	Tooth fracture/ BROKEN TOOTH	2	NOV2020	54/	2	No	O	NA/TC/TCN	R	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171036	MUSC	Rhabdomyolysis/ RHABDOMYOLYSIS	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N
	NERV	Syncope/ Syncope Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N
	RENAL	Acute kidney injury/ ACUTE KIDNEY INJURY	1	26AUG2020	7/5	1	No	O	NA/TC	R (30AUG2020)	N/N
	PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N
	METAB	Hypocalcaemia/ HYPOCALCEMIA	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	PSYCH	Insomnia/ WORSENING INSOMNIA	2	SEP2020	1/C	2	No	O	NA	RG	N/N
	RESP	Snoring/ SNORING	2	SEP2020	1/C	2	No	O	NA	N	N/N
	VASC	Hypertension/ WORSENING HYPERTENSION	2	SEP2020	1/C	2	No	O	NA/TC	N	N/N
	MUSC	Musculoskeletal stiffness/ NECK STIFFNESS	2	21SEP2020	12/34	1	No	O	NA	R (24OCT2020)	N/N
	MUSC	Pain in extremity/ ARM SORENESS, LEFT	2	22SEP2020	13/11	2	No	O	NA	R (02OCT2020)	N/N
	METAB	Diabetes mellitus/ WORSENING DIABETES MELLITUS TYPE 2	2	10NOV2020	62/C	2	No	O	NA/TC	RG	N/N
	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	20NOV2020	72/6	4	No	O	NA/TC/TCN	R (25NOV2020)	Y/N
	PSYCH	Major depression/ MODERATE EPISODE OF	2	30DEC2020	112/3	3	No	O	NA/TC/TCN	R (01JAN2021)	Y/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171058	RENAL	MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS Chronic kidney disease/ CHRONIC KIDNEY DISEASE, STAGE 2, WORSENING	2	31DEC2020	113/C	2	No	O	NA	RG	N/N
	BLOOD	Lymphadenopathy/ SUPRACLAVICULAR LYMPHADENOPATHY, RIGHT*		25AUG2020	1/C	1	No	O	NA	N	N/N
	NERV	Headache/ Headache	1	27AUG2020	3/3	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1117 11171066	NERV	Dizziness/ LIGHT HEADEDNESS#	4	01FEB2021	1/1	1	Yes		NA/TCN	R (01FEB2021)	N/N
16-55/ C4591001 1117 11171070	SKIN	Rash maculo-papular/ Maculopapular Rash, Generalized	1	07SEP2020	13/19	2	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1117 11171091	INJ&P	Skin laceration/ Laceration, Left Thumb	1	09SEP2020	15/21	2	No	O	NA/TC/TCN	R (29SEP2020)	N/N
	INFEC	Localised infection/ INFECTION, LEFT THUMB	2	09DEC2020	76/14	2	No	O	NA/TC	R (22DEC2020)	N/N
	SKIN	Localised infection/ INFECTION, RIGHT GREAT TOE Ingrowing nail/ INGROWN TOE NAIL, RIGHT GREAT TOE	2	09DEC2020	76/42	2	No	O	NA/TC	R (19JAN2021)	N/N
	SKIN	Ingrowing nail/ INGROWN TOE NAIL, RIGHT GREAT TOE	2	12JAN2021	110/1	2	No	O	NA/TC/TCN	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171100	NERV	Headache/ HEADACHE	1	11SEP2020	8/4	2	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1117 11171102	PSYCH	Attention deficit hyperactivity disorder/ ADHD, WORSENING	1	17SEP2020	14/126	1	No	O	NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1117 11171121	SKIN	Angioedema/ ANGIOEDEMA	2	31OCT2020	26/4	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1117 11171156	VASC	Hypertension/ HYPERTENSION*		24SEP2020	1/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1117 11171174	INJ&P	Concussion/ CEREBRALCONCUSSION	2	01JAN2021	80/C	2	No	O	NA	RG	N/N
		Head injury/ HEAD TRAUMA	2	01JAN2021	80/C	2	No	O	NA	RG	N/N
	INFEC	Herpes zoster/ SHINGLES, SINGLE DERMATOME	2	03JAN2021	82/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1117 11171178	GENRL	Non-cardiac chest pain/ CHEST PAIN, NON CARDIAC#	2	27JAN2021	100/2	2	No	O	NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N
	GASTR	Gastritis/ ACUTE GASTRITIS W/O HEMMORRHAGE	1	23OCT2020	18/39	2	No	O	NA/TC/TCN	R (30NOV2020)	N/N
		Vomiting/ BILIOUS VOMITING	1	23OCT2020	18/5	3	No	O	NA/TC/TCN	R (27OCT2020)	N/N
	GASTR	Abdominal pain/ ABDOMINAL PAIN	1	26OCT2020	21/2	2	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1117 11171187	EAR	Tinnitus/ EAR RINGING, LEFT	2	27OCT2020	1/1	1	No	O	NA	R (27OCT2020)	N/Y
16-55/ C4591001 1117 11171192	INFEC	Ear infection/ EAR INFECTION#	4	02MAR2021	12/9	2	No	O	NA/TC	R (10MAR2021)	N/N
16-55/ C4591001 1117 11171197	MUSC	Exostosis/ BONE SPUR, LEFT HEEL, WORSENING	2	06DEC2020	24/1	2	No	O	NA/TC/TCN	R (06DEC2020)	N/N
16-55/ C4591001 1118 11181003	INJ&P	Concussion/ CONCUSSION	2	03DEC2020	95/16	2	No	O	NA/TC	R (18DEC2020)	N/N
		Fall/ fall	2	03DEC2020	95/1	2	No	O	NA	R (03DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1118 11181009	NERV	Rib fracture/ LEFT SIDE FRACTURE RIBS	2	03DEC2020	95/16	2	No	O	NA/TC	R (18DEC2020)	N/N
		Headache/ mild headache#	3	31JAN2021	2/5	1	Yes		NA	R (04FEB2021)	N/N
		Pain/ body aches#	3	02FEB2021	4/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1118 11181028	GENRL	Sinus congestion/ sinus congestion#	3	02FEB2021	4/3	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Back pain/ WORSENING OF CHRONIC LOWER BACK PAIN#	3	10FEB2021	12/10	2	No	O	NA/TCN	R (19FEB2021)	N/N
	MUSC	Muscle spasms/ back spasms	1	21AUG2020	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1118 11181040	INFEC	Vulvovaginal mycotic infection/ VAGINAL YEAST INFECTION	2	12OCT2020	34/3	1	No	CD	NA/TC	R (14OCT2020)	N/N
	INFEC	Sinusitis/ sinus infection	2	25JAN2021	139/10	1	No	O	NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1118 11181089	RESP	Epistaxis/ epistaxis#	4	17FEB2021	3/C	1	No	O	NA	RG	N/N
16-55/ C4591001	RENAL	Nephrolithiasis/ NEPHROLITHIASIS	2	25SEP2020	9/14	1	No	O	NA/TCN	R (08OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1118 11181100	INJ&P	Tooth fracture/ BROKEN RIGHT UPPER QUADRANT MOLAR#	3	31JAN2021	2/26	2	No	O	NA/TC	R (25FEB2021)	N/N	
16-55/ C4591001 1118 11181110	GENRL	Oedema peripheral/ left foot edema	1	08NOV2020	21/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1118 11181117	PSYCH	Anxiety/ worsening of anxiety	1	24OCT2020	4/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1118 11181121	INJ&P	Road traffic accident/ motor vehicle accident	1	31OCT2020	10/1	1	No	O	NA	R (31OCT2020)	N/N	
	MUSC	Musculoskeletal chest pain/ muscular chest pain	1	31OCT2020	10/10	1	No	O	NA	R (09NOV2020)	N/N	
16-55/ C4591001 1120 11201028	MUSC	Pain in extremity/ R hand pain	2	15DEC2020	114/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1120 11201044	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	15/1	1	No	O	NA/TC	R (09SEP2020)	N/N	
16-55/ C4591001	NERV	Hypersomnia/ HYPERMORPHOLOGY	2	28NOV2020	96/C	1	No	O	NA	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1120 11201082		Migraine/ MIGRAINES	2	28NOV2020	96/1	1	No	O	NA	R (28NOV2020)	N/N
	INFEC	Bacterial vulvovaginitis/ BACTERIAL VAGINITIS	2	14DEC2020	112/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1120 11201103	INFEC	Folliculitis/ folliculitis back of neck	2	26AUG2020	2/6	2	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1120 11201104	MUSC	Plantar fasciitis/ Worsening of plantar fasciitis	1	18AUG2020	13/6	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1120 11201148	GENRL	Fatigue/ Fatigue	1	15AUG2020	4/2	3	Yes		NA	R (16AUG2020)	N/N
16-55/ C4591001 1120 11201154	METAB	Vitamin D deficiency/ vitamin d deficiency	2	FEB2021	152/C	1	No	O	NA	N	N/N
16-55/ C4591001 1120 11201198	SKIN	Rash/ RASH TO LEFT FOREARM	2	02SEP2020	1/2	2	No	O	NA	R (03SEP2020)	N/N
	SKIN	Rash/ RASH TO RIGHT FOREARM	2	09SEP2020	8/1	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C4591001	METAB	Hyperlipidaemia/ hyperlipidemia#	2	25FEB2021	171/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1120 11201220 16-55/ C4591001 1120 11201250	SKIN	Rash/ Rash torso and legs	1	27AUG2020	7/16	1	No	O	NA/TC	R (11SEP2020)	N/N
1120 11201250	NERV	Burning sensation/ Burning sensation in palm of left hand	2	16SEP2020	6/1	2	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1120 11201266	EYE	Blindness unilateral/ LOSS OF VISION LEFT EYE	2	04DEC2020	67/C	4	No	O	NA	N	Y/N
1120 11201266	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N
16-55/ C4591001 1120 11201299	INFEC	Otitis media/ otitis media	1	06OCT2020	14/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1120 11201334	GASTR	Diarrhoea/ Diarrhea	1	28OCT2020	13/2	1	No	O	NA	R (29OCT2020)	N/N
1120 11201334	MUSC	Neck pain/ NECK PAIN	1	04NOV2020	20/C	2	No	CND	NA/TC	RG	N/N
16-55/ C4591001 1120 11201346	MUSC	Neck pain/ Neck Pain	2	12NOV2020	3/2	1	No	CND	NA/TC/TCN	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1121 11211085	NERV	Headache/ Headache	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1121 11211112	INFEC	COVID-19/ COVID-19	2	24OCT2020	26/C	3	No	O	NA/TC	RS	Y/N
16-55/ C4591001 1122 11221005	GENRL	Chest pain/ chest aches	1	06SEP2020	4/26	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	1	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Feeling hot/ sensation of hotness	2	26SEP2020	3/6	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1122 11221008	GENRL	Chills/ CHILLS#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ FATIGUE#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	MUSC	Myalgia/ GENERALIZED MUSCLE PAIN#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1122 11221009	NERV	Paraesthesia/ tingling of fingers in right hand	2	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/Y



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1122 11221012	GENRL	Fatigue/ fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	METAB	Decreased appetite/ loss of appetite	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ muscle pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	NERV	Headache/ headache	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N	
	GENRL	Chills/ Chills		2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Fatigue/ fatigue	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
			Injection site pain/ injection site arm pain	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
			Pyrexia/ Fever	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
MUSC	Myalgia/ myalgia	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N		
16-55/ C4591001 1122 11221014	GENRL	Fatigue/ fatigue, excessive	1	11SEP2020	3/4	1	Yes		NA	R (14SEP2020)	N/N	
	GASTR	Gingival bleeding/ bleeding gums	2	01OCT2020	2/89	1	Yes		NA	R (28DEC2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Loose tooth/ loose tooth	2	01OCT2020	2/89	1	Yes		NA	R (28DEC2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/128	1	Yes		NA	R (05FEB2021)	N/N
	SKIN	Alopecia/ hair loss	2	01OCT2020	2/128	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1122 11221016	GENRL	Injection site paraesthesia/ tingling at injection site	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1122 11221024	GASTR	Diarrhoea/ Diarrhea	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Pain in extremity/ right upper arm dull ache#	3	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Chills/ chills#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Fatigue/ fatigue#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ injection site pain#	4	23FEB2021	2/C	1	Yes		NA/TC	N	N/N
	MUSC	Myalgia/ muscle aches#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1122 11221025	INFEC	Oral herpes/ worsening of cold sore	1	15SEP2020	6/4	1	No	O	NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221026	GENRL	Fatigue/ fatigue#	3	22DEC2020	2/2	1	Yes		NA/TC	R (23DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	22DEC2020	2/3	1	Yes		NA/TC	R (24DEC2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	3	22DEC2020	2/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N
	NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N
16-55/ C4591001 1122 11221028	GENRL	Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ injection site pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ joint soreness at the shoulders	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1122 11221030	GENRL	Malaise/ Malaise	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001	NERV	Dizziness/ Dizziness (Loss of Balance)	1	28SEP2020	15/5	2	No	CD	NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1122 11221032	GASTR	Hypoaesthesia oral/ tongue numbness#	3	04FEB2021	1/1	1	Yes	NA	R	(04FEB2021)	N/Y
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	06JAN2021	1/3	1	Yes	NA/TC	R	(08JAN2021)	N/N
1122 11221033	GENRL	Chills/ chills#	4	07JAN2021	2/2	1	Yes	NA/TC	R	(08JAN2021)	N/N
		Injection site pain/ injection site pain#	4	07JAN2021	2/2	1	Yes	NA/TC	R	(08JAN2021)	N/N
		Pyrexia/ fever#	4	07JAN2021	2/2	1	Yes	NA/TC	R	(08JAN2021)	N/N
16-55/ C4591001	NERV	Headache/ headaches	1	12OCT2020	8/38	1	Yes	NA	R	(18NOV2020)	N/N
1122 11221040	GENRL	Chills/ chills#	3	18DEC2020	2/1	1	Yes	NA/TC	R	(18DEC2020)	N/N
		Malaise/ general malaise#	3	18DEC2020	2/1	1	Yes	NA/TC	R	(18DEC2020)	N/N
		Pyrexia/ Fever 100.3F#	3	18DEC2020	2/1	1	Yes	NA/TC	R	(18DEC2020)	N/N
	MUSC	Back pain/ body aches (back)#	3	18DEC2020	2/1	1	Yes	NA/TC	R	(18DEC2020)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	1/2	1	Yes	NA	R	(06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221042	CONG	Fatigue/ fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pain/ generalized body aches#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1122 11221042	CONG	Benign familial pemphigus/ exacerbation Haley-Haley disease#	2	24JAN2021	88/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1122 11221045	GENRL	Injection site pain/ pain at injection site	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
	NERV	Hypoaesthesia/ numbness in hand of injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
	NERV	Paraesthesia/ tingling sensation in injection arm	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/Y
16-55/ C4591001 1122 11221045	GENRL	Chills/ chills#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
	MUSC	Fatigue/ Fatigue#	3	23DEC2020	2/9	1	Yes		NA	R (31DEC2020)	N/N
		Pyrexia/ fever 100.4F#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
		Arthralgia/ Generalized joint pain (aches)#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
16-55/ C4591001 1122 11221045	MUSC	Myalgia/ muscle pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221047	NERV	Neck pain/ neck pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
		Pain in extremity/ injection arm pain#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
		Headache/ Headache#	3	23DEC2020	2/1	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ shaking chills#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Fatigue/ fatigue#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Injection site pain/ injection site pain#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Pain/ generalized body aches#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Pyrexia/ fever#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Neck pain/ neck pain#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N
	NERV	Pain in extremity/ bilateral calf pain#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N
		Headache/ headache behind eyes#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ chills#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221048	GENRL	Fatigue/ fatigue#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1122 11221051	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	25NOV2020	29/C		No	O	NA	UNK	N/N
16-55/ C4591001 1122 11221052	GENRL	Non-cardiac chest pain/ Acute Illness non cardiac chest pain	1	10OCT2020	2/3	2	Yes		NA	R (12OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	13JAN2021	1/5	1	Yes		NA	R (17JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Paraesthesia/ Paresthesia in bilateral nostrils#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Arthralgia/ Bilateral shoulder pain#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1122 11221053	SKIN	Eczema/ flare up of eczema	1	20OCT2020	8/24	1	No	O	NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	07NOV2020	4/6	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ very mild fatigue	2	08NOV2020	5/7	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1122 11221059	SKIN	Pruritus/ mild body itching-specific region: lateral aspect of right forearm and left side of neck	2	08NOV2020	5/7	1	No	O	NA	R (14NOV2020)	N/N
	INFEC	Cellulitis/ Cellulitis groin	2	15DEC2020	42/11	2	No	O	NA/TC/TCN	R (25DEC2020)	N/N
	BLOOD	Lymph node pain/ Tender lymph node right jaw#	2	31DEC2020	58/3	1	No	O	NA	R (02JAN2021)	N/N
		Lymphadenopathy/ Swollen lymph node right jaw#	2	31DEC2020	58/3	1	No	O	NA	R (02JAN2021)	N/N
	INFEC	Wound infection/ Infected laceration right thumb#	2	02JAN2021	60/3	1	No	O	NA/TC/TCN	R (04JAN2021)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Pain/ generalized body aches#	4	11JAN2021	1/4	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ rigors#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N
	REPRO	Dysmenorrhoea/ Worsening of dysmenorrhea	1	05AUG2020	7/13	1	No	O	NA/TC/TCN	R (17AUG2020)	N/N
		CONG	Congenital cystic kidney disease/ Polycystic kidney disease	1	17AUG2020	19/C	1	No	O	NA/TC	N
16-55/ C4591001 1123 11231019	PSYCH	Attention deficit hyperactivity disorder/ Attention deficit disorder	2	08SEP2020	16/C	2	No	O	NA/TC	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Chillblains/ Chilblains of fingers and toes	2	01NOV2020	70/C	2	No	O	NA	N	N/N
16-55/ C4591001 1123 11231041	GENRL	Fatigue/ FATIGUE	1	11AUG2020	7/2	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C4591001 1123 11231043	GENRL	Fatigue/ FATIGUE	1	12AUG2020	7/3	1	No	O	NA	R (14AUG2020)	N/N
	SKIN	Erythema/ Mild erythema bilateral nares	2	25AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C4591001 1123 11231046	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	2/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1123 11231064	GASTR	Hiatus hernia/ hiatal hernia	1	13AUG2020	4/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001	METAB	Hyperlipidaemia/ Hyperlipidemia	2	25JAN2021	145/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231067 16-55/ C4591001 1123 11231074	MUSC	Myalgia/ myalgia	1	16AUG2020	6/4	1	Yes		NA	R (19AUG2020)	N/N
1123 11231074	MUSC	Arthralgia/ knee pain	1	29AUG2020	19/9	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1123 11231094	GENRL	Fatigue/ FATIGUE	1	14AUG2020	2/8	1	No	O	NA	R (21AUG2020)	N/N
1123 11231094	MUSC	Arthralgia/ JOINT PAIN	1	19AUG2020	7/3	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C4591001 1123 11231102	MUSC	Myalgia/ myalgia#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
1123 11231102	NERV	Headache/ headache#	4	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1123 11231114	NEOPL	Lipoma/ Right axilla lipoma	2	23SEP2020	16/C	1	No	O	NA	N	N/N
1123 11231114	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1123 11231116	MUSC	Myalgia/ full body myalgias	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1123 11231117	MUSC	Periarthritis/ Worsening of right adhesive capsulitis shoulder	2	14SEP2020	7/23	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1123 11231124	GENRL	Chills/ CHILLS	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
		Pyrexia/ FEVER	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	MUSC	Myalgia/ FULL BODY MYALGIA	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1123 11231128	GENRL	Pyrexia/ Fever	2	09SEP2020	2/2	1	Yes		NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1123 11231143	MUSC	Myalgia/ Full body myalgia	2	12SEP2020	3/2	1	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1123 11231164	PSYCH	Anxiety/ Worsening of anxiety	2	03OCT2020	19/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1123 11231172	GENRL	Fatigue/ Fatigue	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231176	GENRL	Injection site pain/ Pain at injection site, left arm	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1123 11231183	RENAL	Nephrolithiasis/ Nephrolithiasis#	3	28JAN2021	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1123 11231187	GENRL	Pyrexia/ Fever	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1123 11231191	EAR	Cerumen impaction/ Right Cerumen impaction	2	11NOV2020	56/C	1	No	O	NA	N	N/N
16-55/ C4591001 1123 11231194	SKIN	Rash/ Rash on both feet	2	17SEP2020	2/36	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1123 11231197	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
		Injection site pain/ Pain at left injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231200	GENRL	Chills/ Chills	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	16SEP2020	1/5	1	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Full body myalgia	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	REPRO	Menometrorrhagia/ Worsening of menometrorrhagia	2	01OCT2020	16/21	1	No	O	NA	R (21OCT2020)	N/N
	HEPAT	Biliary colic/ Worsening of biliary colic	2	03OCT2020	18/1	2	No	O	NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Fatigue/ Fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	MUSC	Arthralgia/ Generalized arthralgia#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
NERV	Headache/ Headache#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1123 11231204	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	22OCT2020	38/C		No	O	NA	UNK	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231208	INJ&P	Fall/ Fall	1	18SEP2020	22/1	2	No	O	NA	R (18SEP2020)	N/N
		Foot fracture/ Left foot fracture	1	18SEP2020	22/12	1	No	O	NA/TC/TCN	R (29SEP2020)	N/N
16-55/ C4591001 1123 11231210	GENRL	Fatigue/ fatigue	2	26SEP2020	2/4	1	No	O	NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	26SEP2020	2/4	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1123 11231215	METAB	Vitamin D deficiency/ Vitamin D Deficiency	2	20OCT2020	22/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1123 11231216	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Full body myalgia	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	METAB	Type 2 diabetes mellitus/ type II diabetes#	2	06MAR2021	159/C				NA/TC	N	/N
16-55/ C4591001	GENRL	Chills/ Chills	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231217	MUSC	Arthralgia/ joint pain	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
		Myalgia/ Full body myalgia	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	PSYCH	Depression/ worsening of depression	2	12NOV2020	43/C	2	No	O	NA/TC	N	N/N
1123 11231220	GENRL	Chills/ chills	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
1123 11231221	MUSC	Myalgia/ myalgia	2	29SEP2020	1/4	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Arthralgia/ Joint pain	1	13SEP2020	4/3	1	Yes		NA/TC	R (15SEP2020)	N/N
1123 11231233	GENRL	Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	GASTR	Teething/ Wisdom tooth eruption with pain	1	30SEP2020	20/22	1	No	O	NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231237 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
1123 11231252 16-55/ C4591001	VASC	Hypertension/ Hypertension#	3	29JAN2021	2/C	1	No	CD	NA/TC	RG	N/N
1123 11231253 16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	3/3	1	Yes		NA	R (10OCT2020)	N/N
1123 11231264	GENRL	Chills/ Chills	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	3/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	3/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1123 11231289	GENRL	Chills/ Chills	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection site pain	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GASTR	Nausea/ nausea	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1123 11231294	GENRL	Chills/ Chills	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
		Malaise/ malaise	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ Headache	1	29SEP2020	7/2	1	No	O	NA/TC	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
		Fatigue/ Fatigue	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GASTR	Nausea/ nausea	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
NERV	Headache/ headache	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 1123 11231307	GENRL	Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1123 11231309	GENRL	Pyrexia/ Fever	2	15OCT2020	2/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1123 11231313	NERV	Headache/ Headache	1	06OCT2020	13/2	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1123 11231317	PSYCH	Bruxism/ Bruxism	2	27OCT2020	14/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1123 11231322	GASTR	Haemorrhoids/ Hemorrhoids	1	04OCT2020	10/5	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1123 11231327	INFEC	Vulvovaginal candidiasis/ Vulvovaginal candidiasis	1	02OCT2020	8/4	1	No	O	NA/TC	R (05OCT2020)	N/N
	INFEC	Acute sinusitis/ Acute sinusitis	2	30OCT2020	17/7	1	No	O	NA/TC	R (05NOV2020)	N/N
	INJ&P	Cartilage injury/ left labral tear#	2	11FEB2021	121/1	1	No	O	NA/TC/TCN	R (11FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ FULL BODY MYALGIA	1	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231328	GENRL	Chills/ Chills	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1123 11231334	INFEC	Cystitis/ Acute cystitis	1	01OCT2020	7/5	1	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1123 11231338	GENRL	Chills/ Chills	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1123 11231350	MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/4	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1123 11231359	MUSC	Neck pain/ Worsening of chronic neck pain	1	30OCT2020	19/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1123 11231360	SKIN	Pruritus/ Pruritus generalized	1	14OCT2020	3/7	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231365		Injection site pruritus/ Injection site pruritus	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/Y
16-55/ C4591001 1123 11231366	GASTR	Nausea/ Nausea	1	13OCT2020	2/4	1	Yes		NA/TC	R (16OCT2020)	N/N
	GASTR	Vomiting/ Vomiting	1	15OCT2020	4/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1123 11231375	GENRL	Chills/ Chills	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
		Pyrexia/ Fever	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	02NOV2020	1/3	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1123 11231381	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	BLOOD	Lymphadenopathy/ Left Axillary lymphadenopathy	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	07NOV2020	2/1	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001	INV	Blood pressure diastolic increased/ Increased diastolic blood pressure	2	09NOV2020	1/C	1	Yes		NA	N	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1123 11231392 16-55/ C4591001 1123 11231399	MUSC	Arthralgia/ Arthralgia of hips	2	12NOV2020	1/4	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Paraesthesia/ Paresthesia of lower extremities	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1123 11231405	GENRL	Chills/ Chills	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Arthralgia/ Arthralgia generalized	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
		Myalgia/ Myalgia	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Headache/ Headache	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1123 11231408	GENRL	Injection site erythema/ Redness at injection site	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N
		Injection site induration/ Induration at injection site	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241003	MUSC	Injection site swelling/ Swelling at injection site	2	18NOV2020	2/3	1	Yes		NA/TC	R (20NOV2020)	N/N
		Osteitis/ Inflamed first metatarsal	1	02SEP2020	24/36	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1124 11241012	NERV	Headache/ worsening headache#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N
		Injection site rash/ injection site rash#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1124 11241026	GENRL	Fatigue/ Fatigue	1	28AUG2020	17/2	1	Yes		NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1124 11241036	GENRL	Pain/ Body aches#	4	04MAR2021	1/2	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1124 11241042	INJ&P	Foot fracture/ Right foot fracture	1	01SEP2020	16/8	1	No	O	NA/TC	R (08SEP2020)	N/N
		Limb injury/ Left thumb injury	1	02SEP2020	17/1	1	No	O	NA/TCN	R (02SEP2020)	N/N
16-55/ C4591001 1124 11241047	GENRL	Injection site pain/ Muscle Soreness at injection site	2	13SEP2020	4/4	2	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241049	GENRL	Chills/ Chills	1	18AUG2020	2/C	2	Yes		NA	N	N/N
		Pyrexia/ Fever (101 degrees F)	1	18AUG2020	2/C	2	Yes		NA	N	N/N
	MUSC	Myalgia/ Muscle Pain	1	18AUG2020	2/C	2	Yes		NA	N	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/C	2	Yes		NA	N	N/N
16-55/ C4591001 1124 11241050	GENRL	Injection site pain/ injection site soreness#	4	05MAR2021	1/2	1	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1124 11241053	MUSC	Myalgia/ Myalgias	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1124 11241058	INFEC	Herpes zoster/ Shingles	2	04OCT2020	25/8	2	No	O	NA/TC	R (11OCT2020)	N/N
	MUSC	Rotator cuff syndrome/ Torn rotator cuff (right)	2	08OCT2020	29/25	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1124 11241066	INJ&P	Foot fracture/ Left foot fracture	1	07SEP2020	20/44	1	No	O	NA/TCN	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241071	GENRL	Injection site pain/ Injection site soreness	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1124 11241075	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Abdominal distension/ Bloating	2	28NOV2020	80/8	2	No	O	NA	R (05DEC2020)	N/N
		Abdominal pain/ Abdominal pain	2	28NOV2020	80/8	1	No	O	NA	R (05DEC2020)	N/N
	SKIN	Rash/ diffuse body rash	2	03DEC2020	85/3	1	No	O	NA	R (05DEC2020)	N/N
16-55/ C4591001 1124 11241081	GENRL	Pain/ Body Aches#	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1124 11241083	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/4	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1124 11241084	METAB	Hypokalaemia/ Hypokalemia (2.8)	1	01SEP2020	9/1	1	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241086	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1124 11241094	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1124 11241095	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1124 11241099	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1124 11241100	INJ&P	Head injury/ Mild trauma to central forehead	1	12SEP2020	18/7	2	No	O	NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site erythema	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001	REPRO	Dysmenorrhoea/ Menstrual cramps	1	11SEP2020	17/4	1	No	O	NA/TC	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241102	RESP	Nasal congestion/ Nasal Congestion	1	12SEP2020	18/6	1	No	O	NA/TC	R (17SEP2020)	N/N
		Oropharyngeal pain/ Sore Throat	1	12SEP2020	18/2	1	No	O	NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	12/4	2	No	O	NA/TC	R (28SEP2020)	N/N
		Lethargy/ Lethargy	2	25SEP2020	12/4	2	No	O	NA	R (28SEP2020)	N/N
	GASTR	Nausea/ NAUSEA#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1124 11241106	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N
	INJ&P	Fall/ Fall from Bicycle	2	27SEP2020	12/1	2	No	O	NA	R (27SEP2020)	N/N
16-55/ C4591001 1124 11241108	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	1/5	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1124 11241113	MUSC	Myalgia/ Myalgias	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ Worsening Headache	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241118	GENRL	Malaise/ Malaise	1	28AUG2020	2/3	2	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1124 11241125	INJ&P	Ligament sprain/ Right Ankle Sprain	2	07OCT2020	16/8	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1124 11241127	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1124 11241142	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1124 11241149	GENRL	Pyrexia/ Fever	2	25SEP2020	2/4	1	Yes		NA	R (28SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	25SEP2020	2/4	2	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241152		Injection site pain/ Injection site pain	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1124 11241167	INFEC	Urinary tract infection/ Suspected Urinary Tract Infection	1	20SEP2020	18/2	1	No	O	NA/TC	R (21SEP2020)	N/N
	NERV	Sciatic nerve neuropathy/ Left sided sciatic neuropathy	2	16OCT2020	25/78	2	No	O	NA	R (01JAN2021)	N/N
16-55/ C4591001 1124 11241168	GENRL	Pain/ body aches#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1124 11241170	GENRL	Chills/ Chills	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection site soreness	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Malaise/ General Malaise	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1124 11241174	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1124 11241179	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1124 11241184	NERV	Headache/ Headache	2	02OCT2020	4/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1124 11241196	SKIN	Rash/ Diffuse body rash#	4	02MAR2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1124 11241198	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1124 11241200	GENRL	Chills/ Chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	1/4	2	Yes		NA	R (05OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241202	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axilla adenopathy	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
1124 11241207	GENRL	Pyrexia/ Fever	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Bilateral hand soreness	1	13SEP2020	3/2	1	Yes		NA	R (14SEP2020)	N/N
1124 11241213	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Joint stiffness/ Joint stiffness	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
1124 11241216	MUSC	Myalgia/ Myalgias	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241218	NERV	Headache/ Headache	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1124 11241219	GENRL	Fatigue/ Fatigue	2	02OCT2020	3/8	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1124 11241222	METAB	Decreased appetite/ Loss of appetite	2	02OCT2020	3/15	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1124 11241222	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1124 11241223	SKIN	Night sweats/ Increased diaphoresis during sleep	2	25OCT2020	19/C	1	No	O	NA	N	N/N
16-55/ C4591001 1124 11241225	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	NOV2020	26/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1124 11241225	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/5	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1124 11241226	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/5	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1124 11241234	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1124 11241235	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1125 11251014	MUSC	Pain in extremity/ Pain in 3rd digit of Right hand	2	26NOV2020	86/1	1	No	O	NA/TC	R (26NOV2020)	N/N
16-55/ C4591001 1125 11251020	INJ&P	Cervical vertebral fracture/ Cervical Spine fracture	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N
		Craniocerebral injury/ traumatic brain injury	2	23DEC2020	111/30	3	No	O	NA/TC	R (21JAN2021)	Y/N
		Fall/ Fall from Stairs	2	23DEC2020	111/1	3	No	O	NA	R (23DEC2020)	N/N
		Rib fracture/ Rib Fractures	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251021	GENRL	Skull fracture/ Skull Fracture	2	23DEC2020	111/30	2	No	O	NA	R (21JAN2021)	N/N
16-55/ C4591001 1125 11251021	GENRL	Swelling/ under arm swelling left arm	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1125 11251028	INFEC	Sinusitis/ Sinus Infection	1	26AUG2020	14/5	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1125 11251029	INFEC	Sinusitis/ Sinus Infection	1	26AUG2020	14/5	1	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1125 11251044	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	23/4	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1125 11251053	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	03DEC2020	86/75	1	No	O	NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1125 11251062	VASC	Deep vein thrombosis/ Deep vein thrombosis of left leg	2	03DEC2020	86/1	1	No	O	NA/TC	R (03DEC2020)	N/N
16-55/ C4591001 1125 11251062	GENRL	Injection site pain/ INJECTION SITE PAIN	1	21AUG2020	1/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1125 11251062	MUSC	Arthralgia/ JOINT PAIN	1	26AUG2020	6/2	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251067	GENRL	Injection site pain/ injection site pain	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	24AUG2020	4/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
		Myalgia/ MUSCLE PAIN	1	25AUG2020	5/1	2	Yes		NA	R (25AUG2020)	N/N
	NERV	Headache/ headache	1	04SEP2020	15/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1125 11251075	INFEC	Sinusitis/ Sinus infection	2	05OCT2020	22/16	1	No	O	NA/TC	R (20OCT2020)	N/N
	MUSC	Osteoarthritis/ generalized Osteoarthritis	2	FEB2021	141/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1125 11251087	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	13OCT2020	30/8	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1125 11251091	GENRL	Injection site pain/ injection site pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26AUG2020	2/1	1	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251097	NERV	Headache/ headache	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	4/1	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1125 11251098	INJ&P	Fall/ fall	2	08FEB2021	146/1	1	No	O	NA	R (08FEB2021)	N/N
		Ligament rupture/ Ligament tear in right wrist	2	08FEB2021	146/1	1	No	O	NA	R (08FEB2021)	N/N
16-55/ C4591001 1125 11251106	RESP	Oropharyngeal pain/ Sore throat	2	28SEP2020	15/1	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1125 11251109	IMMUN	Seasonal allergy/ Acute exacerbation of seasonal allergies	2	18SEP2020	4/62	1	No	O	NA/TC	R (18NOV2020)	N/N
	METAB	Insulin resistance/ Insulin Resistance#	3	21DEC2020	4/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1125 11251126	GENRL	Pain/ Body Aches	1	08SEP2020	12/8	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1125 11251127	INFEC	Vulvovaginal candidiasis/ Vaginal Candidiasis#	3	04MAR2021	13/8	1	No	O	NA/TC	R (11MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251131	GASTR	Gastrooesophageal reflux disease/ Acid Reflux#	3	28JAN2021	7/C	1	No	O	NA/TC	RG	N/N
	PSYCH	Anxiety/ Anxiety#	3	28JAN2021	7/C	2	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ Hypertension#	3	05FEB2021	15/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1125 11251134	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity disorder#	2	23FEB2021	156/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1125 11251144	INFEC	Urinary tract infection/ Urinary tract infection	1	23SEP2020	22/5	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1125 11251174	METAB	Hypocholesterolaemia/ Hypocholesterolemia	2	28SEP2020	6/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1125 11251180	GENRL	Fatigue/ fatigue	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
		Pain/ bodyaches	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/5	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001	REPRO	Ovarian cyst/ Right Ovarian Cyst	2	22OCT2020	24/C	2	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1125 11251181	GASTR	Appendix disorder/ Appendicoliths	2	27OCT2020	29/93	2	No	O	NA	R (27JAN2021)	N/N
16-55/ C4591001 1125 11251182	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	8/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1125 11251183	GENRL	Pain/ bodyaches	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1125 11251193	GENRL	Injection site pain/ injection site pain	2	01OCT2020	4/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1125 11251201	RESP	Nasal congestion/ Stuffy nose	2	15OCT2020	14/4	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1125 11251202	GASTR	Oropharyngeal pain/ Sore throat	2	15OCT2020	14/3	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C4591001 1125 11251207	GENRL	Peptic ulcer/ Peptic Ulcer	1	20SEP2020	11/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1125 11251207	GENRL	Injection site pain/ Injection Site pain	1	14SEP2020	5/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1125 11251212	NERV	Syncope/ syncopal episode during vasovagal response during venous puncture	2	03NOV2020	35/1	1	No	O	NA	R (03NOV2020)	N/N
16-55/ C4591001 1125 11251219	PSYCH	Depression/ Worsening of Depression	2	26OCT2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N
	NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N
16-55/ C4591001 1126 11261005	INFEC	Herpes zoster/ Shingles	2	11NOV2020	73/11	1	No	O	NA/TC	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05JAN2021	2/5	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/7	2	Yes		NA/TC	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N
	NERV	Disturbance in attention/ Mental concentration difficulty#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N
		Dizziness/ Dizziness#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261006	INFEC	Dizziness/ Light headed#	4	26JAN2021	2/7	1	Yes		NA/TC	R (01FEB2021)	N/N
		Otitis media/ Left otitis media	1	16AUG2020	6/12	1	No	O	NA/TC	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1126 11261012	GENRL	Malaise/ Malaise#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain, injection site#	3	11JAN2021	1/2	2	Yes		NA	R (12JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	3	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	INFEC	Sinusitis/ Sinus Infection#	4	26FEB2021	25/5	2	No	O	NA/TC	R (02MAR2021)	N/N
16-55/ C4591001 1126 11261013	GENRL	Injection site pain/ Injection site pain#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261014	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Pain/ Body aches#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N
	NERV	Paraesthesia/ Generalized Body Tingling	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N
	SKIN	Urticaria/ Hives	1	12AUG2020	1/1	1	No	O	NA	R (12AUG2020)	N/N
	INFEC	Vulvovaginal candidiasis/ Candida of vagina	2	03SEP2020	2/4	1	No	O	NA/TC	R (06SEP2020)	N/N
	INFEC	Acute sinusitis/ Acute sinusitis	1	15AUG2020	3/6	1	No	O	NA/TC	R (20AUG2020)	N/N
	GASTR	Nausea/ Nausea#	3	07JAN2021	1/1	1	Yes		NA/TC/TCN	R (07JAN2021)	N/N
	GENRL	Swelling face/ Facial swelling#	3	07JAN2021	1/2	2	Yes		NA/TC/TCN	R (08JAN2021)	N/Y
	IMMUN	Allergy to vaccine/ VACCINE ALLERGIC REACTION#	3	07JAN2021	1/2	2	Yes		P/TC/TCN	R (08JAN2021)	N/Y
SKIN	Urticaria/ Hives, abdomen#	3	07JAN2021	1/2	1	Yes		NA/TC/TCN	R (08JAN2021)	N/N	
VASC	Flushing/ Facial Flushing#	3	07JAN2021	1/2	2	Yes		NA/TC/TCN	R (08JAN2021)	N/Y	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261018	MUSC	Myalgia/ Muscle aches#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	INFEC	Diverticulitis/ Diverticulitis	1	28AUG2020	16/4	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1126 11261022	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1126 11261024	GENRL	Injection site pain/ Left upper arm injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	3	30DEC2020	2/3	1	Yes		NA/TC	R (01JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	30DEC2020	2/3	2	Yes		NA/TC	R (01JAN2021)	N/N
		Pyrexia/ Fever, 100.4F#	3	30DEC2020	2/3	1	Yes		NA/TC	R (01JAN2021)	N/N
	GASTR	Dry mouth/ Dry mouth#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Pain, injection site#	4	19JAN2021	1/4	1	Yes		NA/TC	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261028	GENRL	Paraesthesia/ Facial tingling#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N
		Chills/ Body Chills#	4	21JAN2021	3/1	2	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ Fever#	4	21JAN2021	3/1	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1126 11261028	INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone, 5.0 UIU/ML	2	02OCT2020	29/155	1	No	O	NA	R (05MAR2021)	N/N
	GENRL	SARS-CoV-2 antibody test positive/ SARS-COV2-IGG, QL, IA Positive	2	02OCT2020	29/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261029	GENRL	Injection site pain/ Pain, Injection site	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Pain/ Bodyaches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Headache/ Headache	1	09SEP2020	24/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1126 11261030	GENRL	Non-cardiac chest pain/ Chest Pain, non-cardiac	2	28SEP2020	20/6	2	No	O	NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1126 11261033	GENRL	Injection site pain/ Pain, injection site#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1126 11261034	GENRL	Malaise/ Malaise#	4	16FEB2021	1/1	2	Yes		NA	R (16FEB2021)	N/N	
	NERV	Headache/ Headache#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N	
		Pain in extremity/ Left upper arm pain	1	17AUG2020	1/2	1	Yes		NA	R (18AUG2020)	N/N	
	GENRL	Chills/ Body Chills	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
		Fatigue/ Fatigue	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N	
	16-55/ C4591001 1126 11261035	INJ&P	Ligament sprain/ Left ankle sprain	2	08NOV2020	61/13	1	No	O	NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/Y	
GENRL	Chills/ Chills#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N		
	Injection site pain/ Left upper arm injection site pain#	4	19JAN2021	1/4	2	Yes		NA	R (22JAN2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261037	MUSC	Myalgia/ Muscle aches#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N
	GASTR	Nausea/ Nausea#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle aches#	3	29DEC2020	1/4	2	Yes		NA/TC	R (01JAN2021)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	1/4	2	Yes		NA/TC	R (01JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
		Injection site swelling/ Swelling, injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Pain/ Body Aches#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	METAB	Decreased appetite/ Decreased appetite#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Chills/ Body Chills#	4	20JAN2021	2/2	2	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1126 11261040		Pyrexia/ Fever#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Pain/ Body aches#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261041	INFEC	Cellulitis/ Cellulitis, Right Thumb	2	10SEP2020	2/11	2	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1126 11261043	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1126 11261044	HEPAT	Cholelithiasis/ Cholelithiasis	1	30AUG2020	12/C	2	No	O	NA/TC	N	N/N
	MUSC	Arthralgia/ Shoulder pain, Right	1	30AUG2020	12/1	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1126 11261046	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1126 11261047	GENRL	Injection site pain/ Pain, injection site#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left arm injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1126 11261048	INFEC	Vulvovaginal candidiasis/ Candida of vagina	1	08SEP2020	20/31	1	No	O	NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
		Pain/ Body aches	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1126 11261053	EAR	Cerumen impaction/ Bilateral Cerumen Impaction	1	07SEP2020	19/2	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1126 11261055	INJ&P	Fall/ Mechanical Fall	2	29SEP2020	20/1	2	No	O	NA	R (29SEP2020)	N/N
	MUSC	Musculoskeletal chest pain/ Chest wall pain, left	2	29SEP2020	20/25	2	No	O	NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	18JAN2021	1/3	2	Yes		NA/TC	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Body chills#	4	19JAN2021	2/2	2	Yes		NA	R (20JAN2021)	N/N
		Pain/ Body Aches#	4	19JAN2021	2/2	2	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1126 11261056	GENRL	Injection site pain/ Pain, injection site	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261060	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1126 11261061	MUSC	Pain in extremity/ Left upper arm pain	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N
		Malaise/ Malaise	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1126 11261062	REPRO	Pelvic pain/ Pelvic pain	1	25AUG2020	5/4	2	No	O	NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	ENDO	Hypothyroidism/ Hypothyroidism	2	12SEP2020	3/C	2	No	O	NA	N	N/N
	INV	C-reactive protein/ C-reactive protein, 1.6mg/dl	2	12SEP2020	3/C	2	No	O	NA	N	N/N
	RESP	Sleep apnoea syndrome/ Sleep Apnea	2	14OCT2020	35/C	2	No	O	NA/TCN	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261063	GENRL	Injection site pain/ Left arm injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1126 11261064	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1126 11261068	PSYCH	Stress/ Stress	2	17SEP2020	3/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/3	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	18FEB2021	2/3	2	Yes		NA	R (20FEB2021)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	07MAR2021	19/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1126 11261075	GENRL	Injection site pain/ Left upper arm injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261076		Fatigue/ Fatigue	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
		Injection site pain/ Left upper arm injection site pain	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left upper arm pain	2	14SEP2020	1/3	2	Yes		NA/TC	R (16SEP2020)	N/N
1126 11261078		Injection site pain/ Left Arm Injection Site Pain#	3	30DEC2020	1/4	1	Yes		NA/TC	R (02JAN2021)	N/N
16-55/ C4591001	GENRL										
1126 11261081		Fatigue/ Fatigue#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	31DEC2020	2/4	2	Yes		NA	R (03JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	3	31DEC2020	2/2	1	Yes		NA/TC	R (01JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
1126 11261082		Urticaria/ Urticaria all over body#	2	28FEB2021	166/5	2	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001	GENRL	Pain/ Body aches	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261083		Pyrexia/ Fever, 101.2F	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1126 11261085	GENRL	Fatigue/ Fatigue	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
	MUSC	Pain in extremity/ Upper right arm pain	1	27AUG2020	1/4	1	Yes		NA/TC	R (30AUG2020)	N/N
	NERV	Headache/ Headache	1	27AUG2020	1/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/4	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	2/4	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1126 11261086	GENRL	Injection site pain/ Pain, Injection site#	4	18JAN2021	1/3	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1126 11261092	GENRL	Injection site pain/ Pain, injection site#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Somnolence/ Drowsiness#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261093	MUSC	Pain in extremity/ Left upper arm pain	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	29AUG2020	2/3	1	Yes		NA/TC	R (31AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
		Pain/ Body aches	2	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1126 11261099	INJ&P	Muscle strain/ LUMBAR MUSCLE STRAIN	2	07DEC2020	81/9	1	No	O	NA/TC	R (15DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
		Pyrexia/ Fever, 100.3F#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ Fever#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261101	NERV	Headache/ Headache#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/1	2	Yes		NA	R (12JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	13JAN2021	3/1	2	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Pain/ Body Aches	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain, injection site	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	INFEC	Conjunctivitis/ Left conjunctivitis#	4	22JAN2021	4/2	1	No	O	NA	R (23JAN2021)	N/N
16-55/ C4591001 1126 11261105	GENRL	Chills/ Chills#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261109	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Left upper arm injection site pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1126 11261111	INFEC	Pain/ Body Aches	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Urinary tract infection/ Urinary tract infection	2	18OCT2020	28/7	2	No	O	NA/TC	R (24OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	13NOV2020	54/3	1	No	O	NA/TCN	R (15NOV2020)	N/N
	INFEC	Herpes simplex/ Worsening Herpes Simples	2	25NOV2020	66/8	2	No	O	NA/TC	R (02DEC2020)	N/N
	MUSC	Pain in jaw/ Mandibular pain	2	25NOV2020	66/8	1	No	O	NA/TCN	R (02DEC2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	26NOV2020	67/6	2	No	O	NA/TC	R (01DEC2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection#	3	03JAN2021	5/9	1	No	O	NA/TC	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261113	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1126 11261114	GENRL	Chills/ Chills, generalized#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Pyrexia/ Fever, 100.4F#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	INJ&P	Ligament sprain/ Left wrist sprain#	4	03FEB2021	17/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1126 11261116	NERV	Headache/ Headache	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Arthralgia/ Right shoulder join pain	2	07JAN2021	108/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain injection site	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261121	GENRL	Injection site pain/ Pain, Injection site	2	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/1	2	Yes		NA	R (22SEP2020)	N/N
		Pain/ Generalized Body Aches	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1126 11261122	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Nausea/ Nausea	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/3	2	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261124	MUSC	Pain in extremity/ Left upper arm pain	1	03SEP2020	2/5	2	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		Malaise/ Malaise	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	20OCT2020	29/4	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1126 11261126	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ Body Aches	2	25SEP2020	2/3	2	Yes		NA	R (27SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1126 11261128	GENRL	Fatigue/ Fatigue*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
		Malaise/ Malaise*		03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Pain in extremity/ Left upper arm pain*		03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261131	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	2/3	2	Yes		NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/1	1	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Pain Injection Site#	3	25JAN2021	1/2	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/7	2	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	18FEB2021	2/4	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1126 11261134	GENRL	Pain/ Body aches, generalized	1	04SEP2020	2/2	1	Yes		NA/TC	R (05SEP2020)	N/N
16-55/ C4591001 1126 11261141	GENRL	Pain/ Body aches (generalized)	2	24SEP2020	2/1	2	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Pain in extremity/ Right Foot Pain	1	14SEP2020	11/12	1	No	O	NA/TCN	R (25SEP2020)	N/N
	INJ&P	Limb injury/ Left shoulder injury	2	05NOV2020	42/27	1	No	O	NA	R (01DEC2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261142	NERV	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/4	2	Yes		NA	R (01JAN2021)	N/N
		Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	GASTR	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
		Abdominal pain/ Abdominal pain#	4	19JAN2021	2/4	2	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Nausea/ Nausea#	4	19JAN2021	2/4	3	Yes		NA/TC	R (22JAN2021)	N/N
		Vomiting/ Vomiting#	4	19JAN2021	2/4	3	Yes		NA/TC	R (22JAN2021)	N/N
		Pain/ Body Aches#	4	19JAN2021	2/4	2	Yes		NA/TC	R (22JAN2021)	N/N
		Pyrexia/ Fever, 102F#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
	MUSC	Muscle fatigue/ Muscle Fatigue#	4	19JAN2021	2/3	3	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N	
	Pyrexia/ Fever, 102.1F	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261143	REPRO	Pelvic pain/ Acute Female Pelvic Pain	2	17OCT2020	20/8	2	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	31DEC2020	2/3	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
	MUSC	Arthralgia/ Joint Aches, Generalized#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Disturbance in attention/ Mental concentration difficulty#	4	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1126 11261144	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1126 11261148	GENRL	Injection site pain/ Injection site pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Body aches	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1126 11261149	GENRL	Injection site pain/ Pain, injection site#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1126 11261150	GENRL	Injection site pain/ Injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	MUSC	Myalgia/ Muscle aches#	4	22JAN2021	2/3	1	Yes		NA	R (24JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N	
		Injection site pain/ Injection site pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N	
	EAR	Tinnitus/ Left Tinnitus	1	14SEP2020	6/6	1	No	O	NA	R (19SEP2020)	N/N	
	GENRL	Chills/ Chills	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N	
		Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N	
	16-55/ C4591001 1126 11261151	EYE	Conjunctivitis allergic/ Bilateral Allergic Conjunctivitis	1	11SEP2020	3/6	1	No	O	NA/TC	R (16SEP2020)	N/N
	16-55/ C4591001 1126 11261157	MUSC	Pain in extremity/ Left upper arm pain	1	09SEP2020	1/3	2	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Malaise/ Malaise	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261158	MUSC	Myalgia/ Muscle aches	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain	2	29SEP2020	2/4	2	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ Body Aches	2	29SEP2020	2/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills#	3	25JAN2021	1/2	2	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Left upper arm injection site pain#	3	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N
		Malaise/ Malaise#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	16FEB2021	1/3	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	Pyrexia/ Fever#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261161	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1126 11261166	GENRL	Injection site pain/ Pain, Injection Site	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ Chills	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Fatigue/ Fatigue	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	1	01OCT2020	21/4	1	Yes		NA/TC	R (04OCT2020)	N/N
		Injection site pain/ Pain, Injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Pain/ Body aches	1	01OCT2020	21/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261170	GENRL	Injection site pain/ Left upper arm injection site pain#	3	30DEC2020	1/4	2	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
		Pain/ Body Aches#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection#	4	03FEB2021	13/4	1	No	O	NA/TC	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261171	INJ&P	Fall/ Fall#	4	16FEB2021	26/1	1	No	O	NA	R (16FEB2021)	N/N
		Head injury/ Head Trauma#	4	16FEB2021	26/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	3	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Body Chills	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	1	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Neck pain/ Neck Pain	1	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Pain/ Body aches	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261172	GENRL	Injection site pain/ Pain, injection site	1	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261173	GENRL	Pyrexia/ Fever, 101.6F	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Myalgia/ Muscle Pain, Generalized	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
NERV	Headache/ Headache	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N	
GENRL		Pyrexia/ Fever, 100F	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1126 11261177	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	30JAN2021	2/6	2	Yes		NA	R (04FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ Fever#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Arthralgia/ left side upper extremity joint pain#	4	30JAN2021	2/6	2	Yes		NA	R (04FEB2021)	N/N
		Joint swelling/ Left upper extremity joint swelling#	4	30JAN2021	2/6	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1126 11261178	MUSC	Pain in extremity/ Left upper arm pain	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1126 11261182	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1126 11261183	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	28DEC2020	1/4	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Left Upper Arm Injection Site Pain#	4	19JAN2021	1/2	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	2/1	2	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261184	MUSC	Myalgia/ Muscle Aches#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	31DEC2020	2/2	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1126 11261185	GENRL	Injection site pain/ Injection site pain#	4	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Dizziness/ Dizzy Spell	1	21SEP2020	5/1	2	No	O	NA	R (21SEP2020)	N/N
GENRL	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/5	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Pain/ Body aches	2	09OCT2020	2/4	1	Yes		NA	R (12OCT2020)	N/N
	GENRL	Chills/ Chills#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	16FEB2021	1/4	2	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1126 11261186	GENRL	Injection site pain/ Pain, injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1126 11261187	GENRL	Fatigue/ Fatigue	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Pain, Injection site	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		Pain/ Body aches	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1126 11261189	INJ&P	Splinter/ Foreign body (splinter) in left hand#	2	24JAN2021	108/3	1	No	O	NA/TC/TCN	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Pain, Injection Site#	3	28JAN2021	1/4	2	Yes		NA	R (31JAN2021)	N/N
	INFEC	Vulvovaginal candidiasis/ Candida of Vagina#	3	06FEB2021	10/5	1	No	O	NA/TC	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261190	INJ&P	Frostbite/ Frostbite, Toes#	3	06FEB2021	10/8	1	No	O	NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Left Upper Arm Injection Site Pain#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain, injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/1	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1126 11261192	MUSC	Myalgia/ Muscle Aches#	4	12JAN2021	1/2	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/1	2	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1126 11261193	GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261194	NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain, Injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	EAR	Vertigo/ Vertigo	2	06NOV2020	29/15	1	No	O	NA	R (20NOV2020)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	3	30JAN2021	2/2	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain, injection site#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	PSYCH	Insomnia/ Insomnia#	4	05MAR2021	15/C	1	No	O	NA	N	N/N
16-55/ C4591001 1126 11261195	GENRL	Injection site pain/ Pain, injection site#	3	28JAN2021	1/4	2	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/1	1	Yes		NA/TC	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Skin ulcer/ Ulcer of left lower leg#	3	13FEB2021	17/C	1	No	O	NA/TC/TCN	RG	N/N
	GASTR	Abdominal pain upper/ Stomach cramps#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N
		Diarrhoea/ Diarrhea#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
		Nausea/ Nausea#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/4	2	Yes		NA	R (22FEB2021)	N/N
		Injection site warmth/ Injection site warmth#	4	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1126 11261196	MUSC	Myalgia/ Muscle Aches	2	13OCT2020	2/2	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1126 11261197	GENRL	Chills/ Chills	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		Malaise/ Malaise	1	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pain in extremity/ Left upper arm pain	1	21SEP2020	1/3	2	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261198	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Left injection site arm pain	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/2	2	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1126 11261199	GENRL	Injection site pain/ Left upper arm injection site pain#	3	29DEC2020	1/3	2	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Pain, Injection site	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1126 11261200		Pyrexia/ Fever	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	30OCT2020	2/3	2	Yes		NA	R (01NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	30OCT2020	1/8	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261201	GENRL	Fatigue/ FATIGUE	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ PAIN, INJECTION SITE	2	18NOV2020	1/3	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1126 11261202	GENRL	Injection site pain/ Injection site pain	1	31OCT2020	2/2	2	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1126 11261203	GENRL	Injection site pain/ Left upper arm injection site pain#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1126 11261204	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1126 11261205	METAB	Decreased appetite/ Decreased appetite	1	23NOV2020	13/C	1	No	O	NA	RG	N/N
	PSYCH	Depressed mood/ Depressed mood	1	23NOV2020	13/C	1	No	O	NA	RG	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261206	GENRL	Injection site pain/ Pain, injection site#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1126 11261207	GENRL	Injection site pain/ Pain Injection Site#	3	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1126 11261210	GENRL	Injection site pain/ Left upper arm injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1126 11261211	GENRL	Chills/ Chills#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1126 11261214	GENRL	Chills/ Chills#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Malaise/ Malaise#	3	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Left arm injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1126 11261215 16-55/ C4591001	GENRL	Injection site pain/ Left upper arm injection site pain#	3	17FEB2021	1/4	2	Yes		NA/TC	R (20FEB2021)	N/N
1126 11261220	NERV	Headache/ Headache#	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	3	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
1126 11261223 16-55/ C4591001	GENRL	Malaise/ Malaise#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
1126 11261224 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
1126 11261228	NERV	Headache/ Headache#	3	12FEB2021	1/3	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
1126 11261236											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1126 11261237	GENRL	Injection site pain/ Pain, injection site#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1126 11261237	GENRL	Injection site pain/ Injection Site Pain#	3	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1126 11261238	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1126 11261244	BLOOD	Lymphadenopathy/ Lymph node swelling left armpit#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1126 11261247	GENRL	Injection site pain/ Left upper arm injection site pain#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1126 11261248	GENRL	Injection site pain/ Left upper arm injection site pain#	3	11FEB2021	1/3	1	Yes		NA/TC	R (13FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1126 11261259	MUSC	Myalgia/ Muscle aches, generalized#	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	3	13FEB2021	3/1	2	Yes		NA/TC	R (13FEB2021)	N/N	
	GASTR	Irritable bowel syndrome/ Worsening irritable bowel syndrome#	2	14FEB2021	55/C	2	No	O	NA/TC/TCN	N	N/N	
	GENRL	Chills/ Chills#	3	12FEB2021	2/1	2	Yes		NA	R (12FEB2021)	N/N	
			Fatigue/ Fatigue#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches, generalized#	3	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N	
	INFEC	Vulvitis/ Vulvitis#	3	16FEB2021	6/7	2	No	O	NA/TC	R (22FEB2021)	N/N	
	RENAL	Dysuria/ Dysuria#	3	17FEB2021	7/6	2	No	O	NA	R (22FEB2021)	N/N	
	GENRL	Injection site pain/ Left upper arm injection site pain#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	
	16-55/ C4591001 1127 11271015	INFEC	Nasopharyngitis/ common cold	2	01OCT2020	45/4	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE#	3	06FEB2021	1/C	1	Yes		NA	N	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1127 11271017	MUSC	Arthralgia/ JOINT PAIN generalized#	3	06FEB2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1127 11271022	MUSC	Arthralgia/ joint pain	1	31JUL2020	2/C	2	Yes		NA/TC	N	N/N
	NERV	Headache/ headache	1	03AUG2020	5/14	3	Yes		NA/TC	R (16AUG2020)	N/N
	INFEC	Sinusitis/ Sinus infection	1	04AUG2020	6/C	2	No	O	NA/TC	N	N/N
	PSYCH	Insomnia/ Insomnia	1	22AUG2020	24/C	1	No	O	NA/TC	N	N/N
		Schizophrenia/ Schizophrenia	1	22AUG2020	24/C	1	No	O	NA/TC	N	N/N
	NERV	Headache/ Headache	1	15SEP2020	48/C	1	No	O	NA/TC	N	N/N
	GENRL	Influenza like illness/ Flu like symptoms	1	26SEP2020	59/C	1	No	O	NA	N	N/N
16-55/ C4591001 1127 11271026	SKIN	Dermatitis contact/ Contact dermatitis (poison ivy)	2	26AUG2020	8/9	1	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1127 11271028	MUSC	Myalgia/ muscle pain#	4	02MAR2021	2/C	2	Yes		NA	N	N/N
16-55/ C4591001	GENRL	Pain/ BODY ACHES#	4	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1127 11271072	RESP	Immune-mediated pneumonitis/ IMMUNE RESPONSE pneumonitis#	4	08FEB2021	4/5	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1127 11271073	PSYCH	Anxiety/ worsening of anxiety	2	02SEP2020	9/C	1	No	O	NA	N	N/N
		Depression/ worsening of depression	2	02SEP2020	9/C	1	No	O	NA	N	N/N
16-55/ C4591001 1127 11271086	GASTR	Dental caries/ Dental caries	2	04SEP2020	6/3	1	No	O	NA	R (06SEP2020)	N/N
		Toothache/ toothache	2	04SEP2020	6/3	1	No	O	NA/TC/TCN	R (06SEP2020)	N/N
16-55/ C4591001 1127 11271097	NERV	Sinus headache/ headache sinus	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N
16-55/ C4591001 1128 11281005	SKIN	Rash/ Rash upper torso	2	12SEP2020	25/C	2	No	O	NA/TC	N	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281017	INJ&P	Fall/ Fall	1	08AUG2020	8/1	2	No	O	NA	R (08AUG2020)	N/N	
		Lumbar vertebral fracture/ L2/L3 Fracture	1	08AUG2020	8/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1128 11281018	GASTR	Abdominal pain upper/ STOMACH PAIN	2	03SEP2020	15/22	2	No	O	NA/TC	R (24SEP2020)	N/N	
	GENRL	Chest discomfort/ CENTRAL CHEST DISCOMFORT	2	10OCT2020	52/1	2	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1128 11281045	GENRL	Injection site pain/ Injection site soreness, left arm#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N	
16-55/ C4591001 1128 11281057	INFEC	Tonsillitis/ tonsillitis	2	19SEP2020	25/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1128 11281061	INJ&P	Muscle strain/ intercostal muscle strain	1	07AUG2020	1/C	1	No	O	NA	N	N/N	
	GENRL	Injection site pain/ Left Deltoid Soreness, at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Chills/ Chills#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281064	MUSC	Fatigue/ Fatigue#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Injection site soreness, Left arm#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
		Myalgia/ Muscle aches#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	22/4	1	Yes		NA	R (31JAN2021)	N/N
	EAR	Vertigo/ Vertigo	2	31AUG2020	5/4	1	No	O	NA/TCN	R (03SEP2020)	N/N
	METAB	Dehydration/ dehydration	2	08OCT2020	43/3	1	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, Left Arm#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, right arm#	3	25FEB2021	1/5	1	Yes		NA	R (01MAR2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
MUSC	Fatigue/ Fatigue#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N	
	Arthralgia/ Joint Aches#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281077	GENRL	Injection site pain/ Injection Site Pain, Left arm#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Pain/ Body Aches#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever (102.0 F)#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1128 11281078	INFEC	Kidney infection/ Kidney Infection	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N
		Urinary tract infection/ URINARY TRACT INFECTION	1	15AUG2020	9/7	2	No	O	NA/TC	R (21AUG2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	38/6	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1128 11281095	GENRL	Injection site pain/ INJECTION SITE PAIN#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1128 11281098	SKIN	Macule/ Erythematous, Macule upper anterior thigh	2	13SEP2020	10/27	2	No	O	NA/TC	R (09OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ chest wall pain	2	08OCT2020	35/5	1	No	O	NA	R (12OCT2020)	N/N
	GENRL	Chills/ Chills#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection Site Soreness, Left Arm#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281101	MUSC	Tendonitis/ Bilateral Knee Pain (Patellar Tendonitis)	1	15AUG2020	4/C	1	No	O	NA/TC/TCN	N	N/N	
16-55/ C4591001 1128 11281103	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
	METAB	Hypokalaemia/ Severe Hypokalemia	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
	RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
16-55/ C4591001 1128 11281107	NERV	Presyncope/ presyncope (following blood draw)*		12AUG2020	1/1	2	Yes		NA	R (12AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N	
	MUSC	Pain in extremity/ Left Arm Soreness#	3	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	GENRL	Injection site erythema/ INJECTION SITE REDNESS#	4	26FEB2021	1/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1128 11281115	REPRO	Ovarian cyst/ RIGHT OVARIAN CYST	2	JAN2021	121/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1128 11281119	GASTR	Nausea/ nausea	1	27AUG2020	14/1	2	No	O	NA	R (27AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281123	REPRO	Vomiting/ vomiting	1	27AUG2020	14/4	2	No	O	NA	R (30AUG2020)	N/N
		Menorrhagia/ Menorrhagia#	2	28JAN2021	148/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1128 11281124	INFEC	Appendicitis/ APPENDICITIS#	2	15JAN2021	129/2	3	No	O	NA/TC/TCN	R (16JAN2021)	Y/N
	GENRL	Injection site pain/ Injection Site soreness, left arm#	3	13JAN2021	2/3	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1128 11281125	GENRL	Injection site pain/ INJECTION SITE SORENESS#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1128 11281128	INFEC	Urinary tract infection/ Urinary Tract Infection	1	06SEP2020	21/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1128 11281129	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever	2	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1128 11281132	MUSC	Myalgia/ MUSCLE ACHES	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281134	GENRL	Injection site pain/ Injection Site Soreness, right arm#	4	24FEB2021	1/2				NA	RS (25FEB2021)	N/N
16-55/ C4591001 1128 11281143	INJ&P	Muscle strain/ Bilateral LEG muscle strain	2	18SEP2020	9/32	2	No	O	NA/TC	R (19OCT2020)	N/N
	MUSC	Spondylitis/ unknown LUMBAR INFLAMATION	2	18SEP2020	9/32	2	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1128 11281147	GENRL	Pain/ Body aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	08SEP2020	1/3	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1128 11281152	GENRL	Injection site pain/ Injection Site Soreness, left arm#	4	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1128 11281153	HEPAT	Hepatocellular injury/ Hepatocellular injury	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N
	INFEC	Sepsis/ Sepsis	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281157	GENRL	Viral infection/ VIRAL SYNDROME	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Soreness, left arm#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Pain/ Body aches	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Pyrexia/ Fever	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N
		Headache/ Headache	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
		GENRL	Pain/ Body aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)
	NERV	Pyrexia/ Fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
Headache/ Headache		2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1128 11281170	GENRL	Pain/ Body Aches	1	25AUG2020	2/3	1	Yes		NA/TC	R (27AUG2020)	N/N
	RESP	Paranasal sinus discomfort/ Nasal Sinus Discomfort	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	12OCT2020	28/7	1	No	O	NA	R (18OCT2020)	N/N
	16-55/ C4591001 1128 11281171	MUSC	Myalgia/ left deltoid soreness#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281173	MUSC	Arthritis/ RIGHT SHOULDER INFLAMATION	1	17SEP2020	25/1	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1128 11281175	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Subjective Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1128 11281176	NERV	Syncope/ vasovagal syncope*		24AUG2020	1/1	3	No	O	NA	R (24AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ Body Aches	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Subject Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1128 11281178	GENRL	Injection site pain/ Injection Site Pain, left arm	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain, left arm	1	26AUG2020	3/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Periarthritis/ ADGESIVE CAPSULITITS (LEFT SHOULDER)	2	NOV2020	48/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1128 11281188	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1128 11281190	GENRL	Pain/ Body Aches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Subjective Fever	2	16SEP2020	2/1	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headaches	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1128 11281195	GASTR	Toothache/ Toothache, upper right side	1	27AUG2020	3/1	1	No	O	NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pain/ generalized body aches	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Axillary Adenopathy, left side	1	26AUG2020	1/4	1	Yes		NA/TCN	R (29AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281198	RENAL	Haematuria/ hematuria	2	15OCT2020	29/1	1	No	O	NA	R (15OCT2020)	N/N
1128 11281199	GENRL	Fatigue/ FATIGUE#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
1128 11281204		Pain/ body ache#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
		Pyrexia/ fever#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ left deltoid pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
1128 11281209	GENRL	Fatigue/ fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ fever#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001	GASTR	Nausea/ NAUSEA	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
1128 11281220	GENRL	Pyrexia/ FEVER (101)	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ HEADACHE	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1128 11281225	GENRL	Injection site pain/ Soreness at injection site, left arm	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ Body Aches	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1128 11281228	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN, RIGHT ARM	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1128 11281230	GENRL	Injection site pain/ Injection Site Soreness, left arm#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1128 11281231	GENRL	Injection site pain/ Soreness left arm, at injection site.*		31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Soreness left arm, at injection site.	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281232	NERV	Pyrexia/ Subjective fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1128 11281235	GENRL	Fatigue/ FATIGUE	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	INFEC	Bacterial vulvovaginitis/ Bacterial Vaginitis	2	15OCT2020	25/5	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1128 11281241	NEOPL	Breast cancer/ Breast Cancer	2	NOV2020	42/C	3	No	O	NA/TC/W	RG	N/N
16-55/ C4591001 1128 11281245	GENRL	Injection site pain/ INJECTION SITE SORENESS#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1128 11281247	NERV	Dizziness/ Dizziness*		01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	RESP	Cough/ COUGH	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N
		Nasal congestion/ NASAL CONGESTION	2	24SEP2020	2/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1128 11281255	INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection#	2	08JAN2021	110/5	2	No	O	NA/TC	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Left arm soreness, at injection site#	3	16JAN2021	5/11	2	Yes		NA	R (26JAN2021)	N/N
	GASTR	Abdominal pain upper/ Stomach pain#	3	18JAN2021	7/9	1	No	O	NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1128 11281257	GENRL	Injection site pain/ INJECTION SITE PAIN, LEFT ARM	1	01SEP2020	1/5	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281267		Fatigue/ FATIGUE	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	22SEP2020	2/2	1	Yes		NA/TCN	R (23SEP2020)	N/N
	MUSC	Myalgia/ SORE NECK MUSCLES	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Body Ache (muscle pain)	1	04SEP2020	3/1	2	Yes		NA	R (04SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	05SEP2020	4/2	2	Yes		NA	R (06SEP2020)	N/N
		Myalgia/ Body Aches (Muscle pain)	1	05SEP2020	4/2	3	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	07SEP2020	6/2	2	Yes		NA	R (08SEP2020)	N/N
	REPRO	Vaginal prolapse/ Vaginal Prolapse	2	01DEC2020	70/18	3	No	O	NA/TCN	R (18DEC2020)	Y/N
	REPRO	Rectocele/ Rectocele	2	17DEC2020	86/2	3	No	O	NA/TCN	R (18DEC2020)	Y/N
16-55/ C4591001 1128 11281268	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT ARM	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281269	MUSC	Myalgia/ MUSCLE PAIN	1	04SEP2020	3/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	05SEP2020	4/1	1	Yes		NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE, LEFT	1	07SEP2020	6/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1128 11281272	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ right deltoid soreness	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ right deltoid pain	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1128 11281274	GENRL	Chills/ Chills	1	06SEP2020	4/3	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1128 11281283	NERV	Headache/ Headache	1	08SEP2020	6/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001	INFEC	Vulvovaginal mycotic infection/ Vaginal Yeast Infection	1	04SEP2020	1/6	2	No	O	NA/TC	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281286 16-55/ C4591001 1128 11281287	MUSC	Myalgia/ left deltoid Soreness#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ Fever#	4	29JAN2021	1/3	1	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Soreness#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1128 11281288	INFEC	Ear infection/ Ear Infection	2	30SEP2020	6/10	2	No	O	NA	R (09OCT2020)	N/N
	RESP	Respiratory tract congestion/ Chest Congestion	2	30SEP2020	6/10	1	No	O	NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	2	10JAN2021	108/6	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Pyrexia/ Fever 102.5F#	4	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281289	GENRL	Injection site pain/ Injection site soreness, left arm#	4	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
	NERV	Headache/ Headache#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N	
	GENRL	Chills/ Chills	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
			Injection site pain/ left arm injection site pain/soreness	1	04SEP2020	1/5	1	Yes		NA	R (08SEP2020)	N/N
			Pyrexia/ Subjective Fever	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
			Injection site pain/ INJECTION SITE SORENESS, LEFT ARM	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1128 11281294		Pain/ BODY ACHES	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
		Pyrexia/ SUBJECTIVE FEVER	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Chills/ Chills	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Pain/ body aches	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	
		Pyrexia/ Subjective fever (99.7)	2	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281299	GENRL	Injection site pain/ Injection Site Soreness, left arm#	3	10MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1128 11281300	MUSC	Pain in extremity/ Left arm soreness#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1128 11281301	GENRL	Chills/ Chills	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	2/4	2	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ Subjective Fever	2	29SEP2020	2/1	1	Yes		NA/TC	R (29SEP2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	29SEP2020	2/4	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1128 11281305	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1128 11281306	GENRL	Chills/ CHILLS	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		Fatigue/ FATIGUE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1128 11281309	INFEC	Pain/ BODY ACHE	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		Urinary tract infection/ URINARY TRACT INFECTION	2	01OCT2020	3/29	2	No	O	NA/TC	R (29OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORNESS (RIGHT ARM)#	3	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1128 11281311	GENRL	Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1128 11281332	GENRL	Chills/ chills	2	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ INJECTION SITE SORENESS, LEFT ARM#	4	28JAN2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001	INV	Pain/ BODY ACHES#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Body temperature increased/ ELEVATED BODY TEMPERATURE (99.9)#	4	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281334		Pain/ Body Aches	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	23/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1128 11281337	GASTR	Vomiting/ VOMITTING#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
	GENRL	Chills/ CHILLS#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
		Pain/ BODY ACHES#	3	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
		Pyrexia/ FEVER (101.3F)#	3	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
	NERV	Headache/ HEADACHE#	3	02MAR2021	2/2	1	Yes		NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1128 11281345	GENRL	Pain/ Aches/Pain	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Subjective Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1128 11281357	GENRL	Injection site pain/ Injection Site Soreness, Left arm#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE SORENESS#	4	19JAN2021	1/1	1	Yes		NA	R (19JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1128 11281358 16-55/ C4591001	BLOOD	Lymphadenopathy/ Left Supraclavicular Adenopathy	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
1128 11281359	GENRL	Injection site pain/ Left Arm injection site Pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1128 11281384	GENRL	Chills/ CHILLS	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Body Chills	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1128 11281385	GENRL	Injection site pain/ Soreness left arm, at injection site.	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ subjective fever	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1129 11291001	GENRL	Fatigue/ fatigue#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N
		Injection site pain/ left deltoid injection site tenderness#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291005	GENRL	Chills/ chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
		Pyrexia/ fever#	4	11JAN2021	1/2	2	Yes		NA/TC	R (12JAN2021)	N/N
	GASTR	Internal hernia/ Internal Hernia	2	21JAN2021	157/2	3	No	O	NA/TCN	RS (22JAN2021)	N/N
		Intestinal obstruction/ bowel obstruction	2	21JAN2021	157/2	4	No	O	NA/TC/TCN	RS (22JAN2021)	Y/N
16-55/ C4591001 1129 11291017	MUSC	Musculoskeletal stiffness/ left deltoid muscle stiffness#	3	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Radiculopathy/ left arm radiculopathy#	3	22FEB2021	8/C	2	Yes		NA/TC	N	N/N
	GENRL	Pyrexia/ Fever#	4	09MAR2021	2/2	2	Yes		NA/TC	R (10MAR2021)	N/N
	SKIN	Pruritus/ Generalized Purities#	4	10MAR2021	3/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1129 11291019	NERV	Headache/ headache#	4	30JAN2021	6/8	2	No	O	NA	R (06FEB2021)	N/N
	VASC	Hypertension/ worsened hypertension#	4	30JAN2021	6/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1129 11291029	INFEC	Vulval abscess/ worsening furuncle vulva	2	30SEP2020	38/31	2	No	O	NA/TC	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Intervertebral disc protrusion/ herniated disk c-6	2	26NOV2020	95/C	2	No	O	NA/TC/TCN	N	N/N
	GASTR	Toothache/ right upper molar tooth pain	2	03JAN2021	133/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1129 11291042	GASTR	Dyspepsia/ Dyspepsia	1	08AUG2020	5/4	2	No	O	NA/TC	R (11AUG2020)	N/N
16-55/ C4591001 1129 11291045	INJ&P	Fall/ fall	2	31JAN2021	160/1	2	No	O	NA	RS (31JAN2021)	N/N
		Wrist fracture/ compound fracture left wrist	2	31JAN2021	160/C	2	No	O	NA/TCN	N	Y/N
16-55/ C4591001 1129 11291047	INFEC	Sinusitis/ sinusitis#	4	22FEB2021	1/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1129 11291061	INJ&P	Foot fracture/ fracture right great toe	2	10OCT2020	47/C	2	No	O	NA/TCN	RG	N/N
		Foot fracture/ fracture right second toe	2	10OCT2020	47/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1129 11291063	MUSC	Tendonitis/ sesamoiditis left big toe	2	15NOV2020	80/38	2	No	O	NA/TCN	R (22DEC2020)	N/N
16-55/ C4591001	MUSC	Back pain/ low back pain	2	31AUG2020	1/26	1	No	O	NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291072 16-55/ C4591001	NEOPL	Benign breast neoplasm/ benign breast nodules bilateral	1	17AUG2020	7/10	2	No	O	NA/TC/TCN	R (26AUG2020)	N/N
1129 11291092 16-55/ C4591001	IMMUN	Hypersensitivity/ allergic reaction bilateral hands, back, neck, left shoulder, right foot	2	12JAN2021	134/15	2	No	O	NA/TC	R (26JAN2021)	N/N
1129 11291096	INJ&P	Joint injury/ SI joint back injury#	2	23JAN2021	145/C	2	No	O	NA/TC	N	N/N
		Joint injury/ Sacroiliac Joint back injury#	2	23JAN2021	145/8	1	No	O	NA	R (30JAN2021)	N/N
	GENRL	Pain/ Body aches#	3	23FEB2021	1/1	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	3	23FEB2021	1/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1129 11291097	INFEC	Urinary tract infection/ urinary tract infection	2	19DEC2020	110/3	2	No	O	NA/TC	R (21DEC2020)	N/N
16-55/ C4591001 1129 11291120	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
		Injection site pain/ left deltoid injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left deltoid injection site tenderness#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1129 11291129	GENRL	Fatigue/ fatigue#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
		Pain/ body aches#	4	11JAN2021	1/3	2	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1129 11291142	NERV	Headache/ Headache	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N
	RESP	Sinus congestion/ sinus congestion	2	09OCT2020	26/3	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1129 11291145	NERV	Lethargy/ Lethargy#	4	14JAN2021	1/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1129 11291148	INJ&P	Muscle strain/ neck muscle strain	1	11SEP2020	18/4	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1129 11291153	MUSC	Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1129 11291157	MUSC	Myalgia/ Left deltoid tenderness	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	2	02JAN2021	104/5	2	No	O	NA/TC	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291163	GENRL	Pyrexia/ fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1129 11291165	GENRL	Chest pain/ Acute chest pain	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1129 11291187	GENRL	Pyrexia/ fever	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1129 11291189	MUSC	Arthralgia/ knee pain-right#	4	08FEB2021	28/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1129 11291196	INFEC	Ear infection/ ear infection-left	2	21NOV2020	41/12	2	No	O	NA/TC	R (02DEC2020)	N/N
	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactive Disorder	2	23JAN2021	104/C	2	No	O	NA/TC	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291197	GENRL	Injection site pain/ left arm injection site soreness#	3	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Back pain/ worsening low back pain#	3	03FEB2021	2/8	2	No	O	NA/TC	R (10FEB2021)	N/N
	GASTR	Nausea/ Nausea	1	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site soreness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Lip swelling/ Upper lip swelling	1	06OCT2020	15/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GASTR	Lip swelling/ lower lip swelling	1	11OCT2020	20/2	1	Yes		NA/TC	R (12OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
	GASTR	Lip swelling/ upper lip swelling	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N
	IMMUN	Drug hypersensitivity/ allergic reaction to study investigational product	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N
	SKIN	Urticaria/ Urticaria upper back	2	15OCT2020	3/C	1	Yes		NA/TC	RG	N/N
	GASTR	Lip swelling/ lower lip swelling	2	17OCT2020	5/C	1	Yes		NA/TC	RG	N/N
	EYE	Swelling of eyelid/ left lower eyelid swelling	2	18OCT2020	6/C	1	Yes		NA/TC	RG	N/N
	GENRL	Swelling face/ facial swelling	2	18OCT2020	6/C	1	Yes		NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1129 11291201	MUSC	Myalgia/ Left Deltoid tenderness	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ left deltoid tenderness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1129 11291202	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	1	26SEP2020	5/5	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1129 11291209	GENRL	Injection site pain/ left deltoid muscle injection site tenderness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle aches#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1129 11291210	GENRL	Fatigue/ fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ left deltoid tenderness	1	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1129 11291212	MUSC	Myalgia/ right deltoid muscle tenderness	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		Malaise/ malaise	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		Pain/ body aches	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1129 11291213	GENRL	Injection site pain/ left deltoid injection site tenderness#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1129 11291220	MUSC	Joint stiffness/ Joint Stiffness	1	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
	MUSC	Joint stiffness/ Joint Stiffness	2	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1129 11291224	GENRL	Malaise/ malaise#	4	20JAN2021	2/2	2	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1129 11291228	GENRL	Fatigue/ fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ injection site pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Myalgia/ Increased Muscle Pain	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Hypertension/ worsening hypertension	2	14NOV2020	12/C	2	No	O	NA/TC	N	N/N
	MUSC	Trigger finger/ worsening right 4th trigger finger	2	08DEC2020	36/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1129 11291238	GENRL	Chills/ chills	2	07NOV2020	2/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1129 11291244	GENRL	Injection site pain/ injection site tenderness-left deltoid	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1129 11291245	MUSC	Pain in extremity/ left arm soreness#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ headache#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ chills#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
		Injection site pain/ left deltoid muscle injection site soreness#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
	NERV	Headache/ headache#	4	19JAN2021	2/1	2	Yes		NA/TC	R (19JAN2021)	N/N
16-55/ C4591001 1129 11291256	EYE	Eye pain/ eye pain#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	3	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Back pain/ back pain muscular#	3	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10MAR2021	2/2	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1129 11291260	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
16-55/ C4591001 1129 11291262	GASTR	Lip swelling/ lip swelling	1	23NOV2020	1/12	1	No	O	NA/TC	R (04DEC2020)	N/N
	GASTR	Aphthous ulcer/ worsening canker sore episode of lips	1	27NOV2020	5/8	2	Yes		NA/TC	R (04DEC2020)	N/N
16-55/ C4591001 1129 11291263	GENRL	Injection site pain/ left deltoid injection site soreness#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1130 11301001	GENRL	Chills/ chills	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ muscle aches in bilateral legs	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1130 11301002	REPRO	Breast pain/ bilateral breast pain	1	25AUG2020	2/28	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1130 11301014	GENRL	Chills/ Chills#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
	MUSC	Myalgia/ Muscle aches#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1130 11301021	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ muscle pain whole body#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	INFEC	Genital herpes simplex/ Genital HSV1 outbreak#	4	18FEB2021	2/8	2	No	O	NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	4	18FEB2021	2/C	1	Yes		NA	RG	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/C	1	Yes		NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301032	GASTR	Vomiting/ emesis	1	02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
	NERV	Presyncope/ near syncope*		02SEP2020	1/1	1	No	O	NA	R (02SEP2020)	N/N
16-55/ C4591001 1130 11301033	RESP	Cough/ Cough	1	19SEP2020	18/4	1	No	O	NA	R (22SEP2020)	N/N
16-55/ C4591001 1130 11301044	GENRL	Injection site pain/ Injection Site Pain#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Lethargy/ Mild lethargy#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	INJ&P	Skin laceration/ Laceration to the Left 2nd finger#	4	06MAR2021	17/C	1	No	O	NA	N	N/N
16-55/ C4591001 1130 11301045	CARD	Palpitations/ Heart palpitations	2	21NOV2020	59/1	1	No	O	NA/TC	RS (21NOV2020)	N/N
16-55/ C4591001 1130 11301046	GENRL	Chills/ chills#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301051	MUSC	Myalgia/ Muscle pain#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/3	1	Yes		NA/TC	RS (20FEB2021)	N/N
	BLOOD	Lymph node pain/ Tender lymph nodes in armpits and neck#	4	19FEB2021	2/6	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Fatigue/ Significant fatigue#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pain/ Body Aches#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever 100.6-101F#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1130 11301056	REPRO	Breast discharge/ Right Nipple Discharge#	4	24FEB2021	7/9	1	No	O	NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache	2	28SEP2020	1/8	1	Yes		NA	R (05OCT2020)	N/N
	EAR	Vertigo positional/ Benign paroxysmal positional vertigo	1	19SEP2020	10/6	1	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C4591001 1130 11301064	GENRL	Chills/ chills#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1130 11301068		Pyrexia/ fever#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
	MUSC	Arthralgia/ joint pain/ache - generalized#	4	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		Back pain/ Low back pain#	4	27FEB2021	2/1	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1130 11301075	GENRL	Chills/ Chills#	3	07JAN2021	4/2	1	Yes		NA/TC	R (08JAN2021)	N/N
		Pain/ generalized aching#	3	07JAN2021	4/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1130 11301078	GENRL	Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	2/1	1	Yes		NA/TC	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301081	BLOOD	Lymphadenopathy/ swollen lymph node - right side of neck#	3	11FEB2021	15/2	1	No	O	NA	R (12FEB2021)	N/N
16-55/ C4591001 1130 11301082	GASTR	Diarrhoea/ Diarrhea#	4	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
		Pain/ Body Aches#	4	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever of 100.5F#	4	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Headache/ Massive headache#	4	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1130 11301087	INJ&P	Skin laceration/ Right foot laceration	2	06DEC2020	26/1	2	No	O	NA/TC/TCN	R (06DEC2020)	N/N
16-55/ C4591001 1130 11301088	GENRL	Chest discomfort/ chest tightness#	3	03JAN2021	13/2	1	No	O	NA	R (04JAN2021)	N/N
	MUSC	Back pain/ Back pain#	3	03JAN2021	13/5	1	No	O	NA/TC	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1130 11301090	GENRL	Chills/ chills#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1130 11301091	INFEC	Hordeolum/ LEFT LOWER HORDEOLUM INTERNUM	2	25NOV2020	9/10	1	No	O	NA/TC/TCN	R (04DEC2020)	N/N
16-55/ C4591001 1130 11301094	NERV	Radiculopathy/ worsening radiculopathy	2	24DEC2020	22/43	2	No	O	NA	R (04FEB2021)	N/N
16-55/ C4591001 1131 11311015	INJ&P	Eye contusion/ contusion of right eye	2	25SEP2020	18/5	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1131 11311020	MUSC	Coccydynia/ coccygeal pain	2	21OCT2020	50/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1131 11311024	IMMUN	Drug hypersensitivity/ allergic reaction, potentially related to study drug	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N
	SKIN	Urticaria/ allergic reaction, one hive appearing on right armpit	1	17AUG2020	1/1	2	Yes		NA/TC	R (17AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	1	18AUG2020	2/4	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1131 11311026	GASTR	Abdominal pain lower/ lower abdominal pain(near inguinal hernia removal site-2005)#	3	FEB2021	1/C	2	No	O	NA	N	N/N
16-55/ C4591001 1131 11311031	GENRL	Injection site pain/ injection site pain	2	08SEP2020	1/4	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	2/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1131 11311032	GENRL	Injection site pain/ pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1131 11311035	GENRL	Fatigue/ fatigue	2	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1131 11311038	GENRL	Fatigue/ fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Pain/ body aches#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Night sweats/ night sweats#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1131 11311042	INJ&P	Ligament sprain/ sprained left ankle	2	03OCT2020	26/39	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1131 11311046	GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Pyrexia/ fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1131 11311048	EAR	Vertigo/ vertigo	2	20OCT2020	43/C	3	No	O	NA	RG	N/N
16-55/ C4591001 1131 11311049	GENRL	Fatigue/ fatigue#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ injection site pain#	3	05FEB2021	1/4	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1131 11311051	GENRL	Injection site pain/ injection site soreness#	3	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1131 11311053	GENRL	Chills/ chills	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311062	INV	Pain/ body aches	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/Y
		Body temperature increased/ elevated temperature	2	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/Y
16-55/ C4591001 1131 11311062	NERV	Headache/ headache#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1131 11311069	NERV	Dizziness/ light headedness	2	11SEP2020	2/5	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1131 11311071	INJ&P	Procedural pain/ left arm pain post injection	1	22AUG2020	2/2	2	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1131 11311073	GENRL	Injection site pain/ left arm injection site pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	SKIN	Rash/ rash across chest	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1131 11311073	MUSC	Back pain/ left side low back pain	2	27SEP2020	14/10	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1131 11311076	MUSC	Arthralgia/ generalized joint pain	1	26AUG2020	3/16	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311080		Fatigue/ fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1131 11311081	NERV	Presyncope/ Near syncope*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N
	INFEC	Ear infection/ bilateral ear infection	2	14JAN2021	122/C	1	No	O	NA	RG	N/N
	EAR	Tinnitus/ tinnitus after exposure to loud sounds	2	10FEB2021	149/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1131 11311090	GENRL	Injection site haematoma/ injection site hematoma	2	18SEP2020	1/6	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1131 11311094	PSYCH	Anxiety/ Increased Anxiety#	3	02MAR2021	21/C	3	No	O	NA/TC	N	Y/N
	PSYCH	Major depression/ Major Depressive Disorder, single episode#	3	03MAR2021	22/C	3	No	O	NA/TC	N	Y/N
		Suicide attempt/ Suicidal Attempt#	3	03MAR2021	22/3	3	No	O	NA	R (05MAR2021)	Y/N
16-55/ C4591001 1131 11311097	SKIN	Pruritus/ generalized pruritus	1	28AUG2020	2/1	1	Yes		NA/TC	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311104	GENRL	Chills/ chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ fatigue	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1131 11311107	GENRL	Injection site pain/ injection site tenderness	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1131 11311111	GENRL	Injection site pain/ pain at injection site#	3	03MAR2021	1/1	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1131 11311117	NERV	Dizziness/ Worsening of dizziness	2	08NOV2020	48/2	3	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1131 11311124	GENRL	Injection site pain/ Injection site arm pain	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1131 11311129	GENRL	Injection site pain/ Injection site pain in arm	2	24SEP2020	1/4	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1131 11311132	INJ&P	Contusion/ right sided facial bruising	2	11OCT2020	20/8	1	No	O	NA	R (18OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311134	MUSC	Contusion/ right-sided shoulder bruising	2	11OCT2020	20/8	2	No	O	NA	R (18OCT2020)	N/N
		Fall/ mechanical fall	2	11OCT2020	20/1	2	No	O	NA	R (11OCT2020)	N/N
		Arthralgia/ shoulder pain, right	2	11OCT2020	20/C	2	No	O	NA/TC	N	N/N
	INJ&P	Contusion/ contusion on right thigh	1	17SEP2020	15/15	2	No	O	NA	R (01OCT2020)	N/N
16-55/ C4591001 1131 11311136	GENRL	Road traffic accident/ bicycle accident	1	17SEP2020	15/1	2	No	O	NA	R (17SEP2020)	N/N
		Skin abrasion/ abrasion right forearm	1	17SEP2020	15/15	2	No	O	NA/TCN	R (01OCT2020)	N/N
	INJ&P	Injection site pain/ injection site arm pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	METAB	Decreased appetite/ decreased appetite	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1131 11311147	SKIN	Night sweats/ night sweats	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain in left arm	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1131 11311148	GASTR	Nausea/ nausea	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311152	GENRL	Chills/ chills	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ arm pain at injection site	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ fever	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	INJ&P	Fall/ Fall	1	25SEP2020	17/1	1	No	O	NA	RS (25SEP2020)	N/N
		Skin abrasion/ bilateral knee abrasion	1	25SEP2020	17/21	1	No	O	NA/TC/TCN	RS (15OCT2020)	N/N
	INFEC	Carbuncle/ both axillary carbuncles	2	24OCT2020	25/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1131 11311157	GENRL	Pyrexia/ low grade temperature#	3	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	METAB	Decreased appetite/ decreased appetite#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GASTR	Vomiting/ vomiting#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1131 11311160	GENRL	Chills/ chills#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311161	MUSC	Fatigue/ fatigue#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
		Pyrexia/ low grade temperature elevation#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N
		Myalgia/ myalgia#	3	29DEC2020	1/2	2	Yes		NA/TC	R (30DEC2020)	N/N
	SURG	Chondroplasty/ arthroscopic labrum repair left shoulder#	4	03FEB2021	17/1	2	No	O	NA/TC/TCN	R (03FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	05JAN2021	1/4	2	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Pain/ body aches#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	INV	Body temperature increased/ low grade temperature elevation (99.9)#	4	25JAN2021	1/3	1	Yes		NA/TC/TCN	R (27JAN2021)	N/N
	NERV	Headache/ headache#	4	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	BLOOD	Lymphadenopathy/ lymph node swelling right axillary and supra-clavicular#	4	28JAN2021	4/5	2	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1131 11311162	MUSC	Myalgia/ muscle pain in back	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1131 11311172	MUSC	Joint swelling/ right knee swelling	2	02NOV2020	32/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	1/4	2	Yes		NA	R (14FEB2021)	N/N	
16-55/ C4591001 1131 11311173	GENRL	Injection site pain/ injection site pain	2	02OCT2020	2/7	1	Yes		NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1131 11311178	GENRL	Pyrexia/ fever, 100.7 degrees Fahrenheit	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N	
	MUSC	Myalgia/ muscle aches	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N	
16-55/ C4591001 1131 11311181	GENRL	Chills/ Chills	2	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N	
16-55/ C4591001 1131 11311183	NERV	Syncope/ vasovagal episode with syncope*		16SEP2020	1/1	1	No	O	NA	R (16SEP2020)	N/N	
16-55/ C4591001 1131 11311190	RESP	Sinus congestion/ Sinus congestion	1	06OCT2020	19/6	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001	GENRL	Pain/ generalized body pain	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311193	INJ&P	Rib fracture/ fracture of left rib	1	04OCT2020	17/C	2	No	O	NA/TC	RG	N/N
		Road traffic accident/ bicycle collision with motor vehicle	1	04OCT2020	17/1	2	No	O	NA/TC	RS (04OCT2020)	N/N
		Skin laceration/ laceration of left elbow	1	04OCT2020	17/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1131 11311201	GENRL	Fatigue/ fatigue	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Chills/ chills	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Fatigue/ fatigue	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
	INV	Body temperature increased/ elevated temperature, low grade	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	EYE	Angle closure glaucoma/ narrow angle glaucoma bilateral	2	22FEB2021	134/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1131 11311209	MUSC	Arthralgia/ right knee pain	2	19OCT2020	4/28	1	No	O	NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1131 11311221	GENRL	Injection site reaction/ injection site reaction#	3	13FEB2021	2/8	2	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311228	VASC	Hypertension/ worsening hypertension	1	01OCT2020	2/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1131 11311230	MUSC	Myalgia/ muscle pain in left arm#	3	15JAN2021	1/3	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1131 11311232	GENRL	Injection site pain/ injection site pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
	NERV	Migraine/ worsening of migraine headache, severe	2	30OCT2020	2/1	3	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1131 11311241	INFEC	Bacterial rhinitis/ bacterial infection in right nostril#	2	17FEB2021	108/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1131 11311243	INJ&P	Fall/ Fall	1	24OCT2020	12/1	2	No	O	NA	R (24OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ left rib pain	1	24OCT2020	12/C	2	No	O	NA/TC	RG	N/N
	CARD	Atrial fibrillation/ atrial fibrillation	2	01DEC2020	28/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1131 11311253	NERV	Somnolence/ somnolence	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1131 11311254	GENRL	Chills/ chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pain/ body aches	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1131 11311257	RESP	Epistaxis/ epistaxis in right nostril, post nasal swab collection	1	29OCT2020	1/5	2	No	CND	NA	R (02NOV2020)	N/N
16-55/ C4591001 1131 11311279	GENRL	Fatigue/ fatigue	2	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
		Injection site pain/ injection site pain	2	12JAN2021	2/3	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1133 11331059	GASTR	Vomiting/ vomiting	2	10OCT2020	25/2	2	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1133 11331113	NERV	Headache/ headache	2	27OCT2020	60/5	2	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1133 11331115	GASTR	Vomiting/ vomiting	2	19SEP2020	22/2	1	No	O	NA	R (20SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1133 11331117	INJ&P	Thermal burn/ right calf skin burn due to contact with very hot motorcycle pipe exhaust.	1	15AUG2020	8/45	2	No	O	NA/TC	R (28SEP2020)	N/N	
16-55/ C4591001 1133 11331119	NERV	Headache/ headache	1	04SEP2020	24/1	1	No	O	NA	R (04SEP2020)	N/N	
	RESP	Nasal congestion/ NASAL CONGESTION	1	04SEP2020	24/6	1	No	O	NA	R (09SEP2020)	N/N	
16-55/ C4591001 1133 11331120	INFEC	Upper respiratory tract infection/ Upper Respiratory INFECTION	2	01NOV2020	33/	2	No	O	NA	N	N/N	
16-55/ C4591001 1133 11331139	MUSC	Arthralgia/ Worsening left Hip Pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N	
		Arthralgia/ Worsening left elbow pain	2	06SEP2020	3/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1133 11331152	SKIN	Rash/ Intermittent Rash (arms, legs, and abdomen)	1	31AUG2020	18/9	2	Yes		NA/TC	R (08SEP2020)	N/N	
16-55/ C4591001 1133 11331170	VASC	Hypertension/ Worsening of Hypertension	1	04SEP2020	22/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001	GENRL	Pain/ Body Ache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1133 11331188	NERV	Headache/ Headache	1	31AUG2020	13/4	2	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1133 11331195	MUSC	Arthralgia/ JOINT PAIN BOTH ARMS	2	12SEP2020	4/C	1	Yes		NA	N	N/N
16-55/ C4591001 1133 11331198	GENRL	Chills/ CHILLS	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1133 11331198		Pyrexia/ FEVER	2	16SEP2020	8/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1133 11331207	INJ&P	Exposure during pregnancy/ Exposure During Pregnaey	1	20AUG2020	2/38		No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1133 11331230	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1133 11331230		Injection site pain/ injection site pain	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1133 11331263	GENRL	Malaise/ malaise	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	RESP	Cough/ cough	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331265	GENRL	Fatigue/ tiredness	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ injection site pain	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Musculoskeletal discomfort/ back discomfort	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ headaches	2	16SEP2020	1/5	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	2	20SEP2020	5/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Back pain/ back pain	2	19SEP2020	2/3	2	No	CND	NA/TC	R (21SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	04SEP2020	9/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	27AUG2020	1/5	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Pyrexia/ fever	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
NERV	Headache/ headaches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331292	GASTR	Diarrhoea/ DIARRHEA	1	17SEP2020	22/1	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C4591001 1133 11331313	GENRL	Chills/ CHILLS	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1133 11331317	NEOPL	Brain cancer metastatic/ Metastatic Brain Tumor#	2	08FEB2021	139/17	3	No	O	NA/TC	R (24FEB2021)	Y/N
16-55/ C4591001 1133 11331328	GENRL	Injection site pain/ Soreness injection site	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
	EAR	Tinnitus/ Tinnitus - intermittent	1	14SEP2020	17/C	2	No	O	NA	N	N/N
	NERV	Headache/ Headache	1	14SEP2020	17/60	1	Yes		NA/TCN	R (12NOV2020)	N/N
16-55/ C4591001 1133 11331335	GENRL	Asthenia/ WEAKNESS#	3	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	INFEC	Upper respiratory tract infection/ UPPER Respiratory Infection	1	20SEP2020	23/4	2	No	O	NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1133 11331346 16-55/ C4591001 1133 11331360	GENRL  MUSC	Chills/ CHILLS  Myalgia/ MUSCLE ACHES	2  2	23SEP2020  23SEP2020	1/3  1/3	1  2	Yes  Yes	  NA	NA  NA/TC	R  R (25SEP2020)	N/N  N/N
16-55/ C4591001 1133 11331365	GASTR  GENRL  NERV	Diarrhoea/ DIARRHEA  Chills/ CHILLS  Pyrexia/ FEVER  Headache/ HEADACHE	2  2  2	23SEP2020  23SEP2020  23SEP2020	1/4  1/4  1/4	1  2  2	Yes  Yes  Yes	  NA	NA  NA/TC/TCN  NA/TC/TCN  NA/TC	R  R (26SEP2020)  R (26SEP2020)  R (26SEP2020)	N/N  N/N  N/N
16-55/ C4591001 1133 11331367	GENRL  GASTR	Chills/ CHILLS  Pyrexia/ FEVER  Vomiting/ VOMITING (ONE EPISODE)	2  2	23SEP2020  24SEP2020	1/2  2/1	1  1	Yes  Yes	NA  NA	NA  NA/TC/TCN	R  R (24SEP2020)	N/N  N/N
16-55/ C4591001 1133 11331370	GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	1	Yes	NA	NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331376	GENRL	Pyrexia/ FEVER	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	INV	Blood glucose abnormal/ UNCONTROLLED BLOOD SUGAR LEVEL	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	MUSC	Arthralgia/ JOINT PAIN	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1133 11331385	GENRL	Pyrexia/ FEVER	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1133 11331387	EAR	Vertigo/ Vertigo	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N
	GASTR	Abdominal discomfort/ Stomach upset	2	30SEP2020	8/11	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1133 11331388	GENRL	Injection site pain/ PAIN IN INJECTION SITE	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
		Pain/ BODY ACHES	2	26SEP2020	2/15	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Musculoskeletal discomfort/ NECK DISCOMFORT	2	26SEP2020	2/5	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Tension headache/ tension HEADACHE	2	26SEP2020	2/3	1	Yes		NA/TC	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331398	GENRL	Pyrexia/ FEVER	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1133 11331408	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/Y
	GENRL	Chills/ CHILLS#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1133 11331413	NERV	Headache/ intermittent headache	1	16SEP2020	8/8	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ intermittent headaches	2	07OCT2020	8/17	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Sciatica/ LEFT LEG SCIATICA	2	01NOV2020	33/100	2	No	O	NA/TC/TCN	R (08FEB2021)	N/N
16-55/ C4591001 1133 11331419	INJ&P	Thermal burn/ left wrist burn	1	17SEP2020	9/5	1	No	O	NA	R (21SEP2020)	N/N
16-55/ C4591001 1133 11331441	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (URI)	2	02OCT2020	3/21	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1133 11331450	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	1/5	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331460	GENRL	Injection site pain/ Pain Injection site	2	09OCT2020	1/4	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Tension headache/ Tension Headache	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	METAB	Diabetes mellitus/ WORSENING OF DIABETES	2	11OCT2020	3/1	2	No	O	NA/TC	R (11OCT2020)	N/N
	GENRL	Chills/ chills	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
		Injection site pain/ injection site pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	1	19SEP2020	2/2	2	Yes		NA/TC/TCN	R (20SEP2020)	N/N
	GENRL	Pain/ body aches	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ fever	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	INFEC	Upper respiratory tract infection/ Upper Respiratory Infection	2	15OCT2020	7/6	1	No	O	NA/TCN	R (20OCT2020)	N/N
	16-55/ C4591001 1133 11331465	RESP	Rhinorrhoea/ RUNNY NOSE	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)
16-55/ C4591001 1133 11331474	GASTR	Diarrhoea/ DIARRHEA (1 EPISODE)	1	21SEP2020	4/1	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331478	NERV	Headache/ headache#	3	14FEB2021	13/1	2	No	O	NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1133 11331480	INJ&P	Wound/ LEFT EAR WOUND	2	16NOV2020	28/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1133 11331495	GASTR	Vomiting/ EMESIS	1	03OCT2020	11/2	2	No	O	NA/TC	R (04OCT2020)	N/N
	GENRL	Pyrexia/ FEVER	2	15OCT2020	2/6	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1133 11331496†	INJ&P	Foot fracture/ BROKEN PINKY ON LEFT FOOT	1	29SEP2020	7/35	2	No	O	NA/TCN	R (02NOV2020)	N/N
16-55/ C4591001 1133 11331505	GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	14OCT2020	1/13	2	Yes		NA/TC/TCN	R (26OCT2020)	N/N
	NERV	Headache/ HEADACHE	2	14OCT2020	1/7	2	Yes		NA/TC/TCN	R (20OCT2020)	N/N
16-55/ C4591001 1133 11331506	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/5	2	Yes		NA/TC/TCN	R (18OCT2020)	N/N
	GENRL	Influenza like illness/ FLU-LIKE SYMPTOMS	2	15OCT2020	2/2	2	Yes		NA/TC/TCN	R (16OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331524	GENRL	Injection site pain/ soreness at injection site	1	25OCT2020	3/4	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1133 11331526	EAR	Ear pain/ left ear pain	1	11NOV2020	20/15	1	No	O	NA/TCN	R (25NOV2020)	N/N
16-55/ C4591001 1133 11331528	GENRL	Pain/ BODY ACHES	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1133 11331532	GENRL	Fatigue/ FATIGUE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ SORENESS AT INJECTION SITE	1	23OCT2020	1/8	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1133 11331537	MUSC	Intervertebral disc disorder/ Lumbar disc disease	1	08NOV2020	17/C	2	No	O	NA/TC	RG	N/N
	BLOOD	Lymphadenopathy/ BILATERAL CERVICAL SWOLLEN LYMPH NODES	2	13NOV2020	3/3	1	No	O	NA	R (15NOV2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	2	13NOV2020	3/3	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Depression/ DEPRESSION#	4	19FEB2021	3/C	1	No	O	NA	N	N/N
16-55/ C4591001 1133 11331546	MUSC	Pain in extremity/ LEFT ARM PAIN	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1133 11331548	NERV	Paraesthesia/ Paresthesia right lower leg	2	18NOV2020	3/C	1	No	O	NA	N	N/N
16-55/ C4591001 1133 11331552	GENRL	Pyrexia/ FEVER#	3	05FEB2021	1/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1133 11331558	NERV	Paraesthesia/ LEFT ARM TINGLING	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1133 11331564	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1133 11331565	GENRL	Fatigue/ FATIGUE	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ SORENESS AT INJECTION SITE	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ BODY ACHES	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1133 11331585	GENRL	Injection site pain/ PAIN AT INJECTION SITE*		29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
		Fatigue/ FATIGUE	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
		Pain/ BODY ACHES	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
		Pyrexia/ FEVER	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
	RESP	Oropharyngeal pain/ SORE THROAT	2	19NOV2020	1/2	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1133 11331587	GENRL	Pain/ BODY ACHE	2	19NOV2020	1/2	2	Yes		NA/TC/TCN	R (20NOV2020)	N/N
	RESP	Rhinorrhoea/ RUNNING NOSE	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1133 11331589	GENRL	Pyrexia/ FEVER	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1133 11331591	NERV	Headache/ HEADACHE	2	19NOV2020	1/1	1	Yes		NA	R (19NOV2020)	N/Y
16-55/ C4591001	GENRL	Pain/ BODY ACHE	1	30OCT2020	2/1	2	Yes		NA/TC	R (30OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1133 11331592		Pyrexia/ FEVER	1	30OCT2020	2/1	2	Yes		NA/TC/TCN	R (30OCT2020)	N/N	
16-55/ C4591001 1133 11331595	NERV	Paraesthesia/ INTERMITENT BILATERAL HAND TINGLING	1	09NOV2020	12/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1133 11331596	GENRL	Injection site pain/ Soreness at injection site	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N	
16-55/ C4591001 1133 11331600	INFEC	Upper respiratory tract infection/ UPPER RESPIRATORY INFECTION (COUGH, NASAL CONGESTION AND HEADACHE)	1	07NOV2020	10/7	1	No	O	NA	R (13NOV2020)	N/N	
16-55/ C4591001 1133 11331602	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N	
	MUSC	Myalgia/ GENERAL MUSCLE ACHE	2	20NOV2020	2/3	1	Yes		NA	R (22NOV2020)	N/N	
	NERV	Headache/ HEADACHE	2	20NOV2020	2/3	1	Yes		NA	R (22NOV2020)	N/N	
16-55/ C4591001 1133 11331609	GENRL	Pain/ BODY ACHES	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Abdominal discomfort/ UPSET STOMACH	1	31OCT2020	3/4	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1133 11331610	INFEC	Upper respiratory tract infection/ upper respiratory infection	2	15DEC2020	29/6	1	No	O	NA	RS (20DEC2020)	N/N
16-55/ C4591001 1133 11331612	METAB	Hyperlipidaemia/ HYPERLIPIDEMIA	2	03DEC2020	15/C	2	No	O	NA/TC	N	N/N
	VASC	Hypertension/ HYPERTENSION	2	03DEC2020	15/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1133 11331621	GENRL	Fatigue/ fatigue	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ FEVER	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1133 11331622	NERV	Headache/ HEADACHE	1	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Dysgeusia/ DYSGEUSIA	2	19NOV2020	1/4	1	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1133 11331625	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	30OCT2020	2/3	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ headache#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1133 11331627 16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	20NOV2020	2/2	1	Yes		NA/TC/TCN	R (21NOV2020)	N/N
1133 11331629 16-55/ C4591001	GENRL	Pyrexia/ FEVER	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N
1133 11331631	NERV	Headache/ HEADACHE	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N
	RESP	Nasal congestion/ NASAL CONGESTION	2	20NOV2020	2/4	2	Yes		NA/TC	R (23NOV2020)	N/N
16-55/ C4591001 1133 11331637	MUSC	Muscle spasms/ LEFT ARM CRAMP	1	02NOV2020	4/18	1	No	O	NA	R (19NOV2020)	N/N
16-55/ C4591001 1133 11331638	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	31OCT2020	2/3	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1133 11331640	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	31OCT2020	2/5	2	Yes		NA/TC/TCN	R (04NOV2020)	N/N
	BLOOD	Lymphadenopathy/ BILATERAL SWOLLEN CERVICAL LYMPH NODES	2	20NOV2020	2/2	2	Yes		NA/TC/TCN	R (21NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1134 11341005	MUSC	Joint effusion/ Left Knee Pain secondary to joint effusion	1	14AUG2020	9/15	2	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1134 11341007	RESP	Asthma/ ASTHMA	2	15JAN2021	142/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1134 11341070	GASTR	Diarrhoea/ Diarrhea	1	18AUG2020	6/2	1	Yes		NA	R (19AUG2020)	N/N
	INV	Blood pressure increased/ ELEVATED BLOOD PRESSURE#	2	26JAN2021	148/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1134 11341093	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	4	07FEB2021	17/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1134 11341107	GASTR	Diarrhoea/ LOOSE STOOL	2	13DEC2020	96/1	1	No	O	NA	R (13DEC2020)	N/N
16-55/ C4591001 1134 11341112	GENRL	Pyrexia/ FEVER#	3	17DEC2020	1/2	2	Yes		NA/TC	R (18DEC2020)	N/N
	NERV	Headache/ HEADACHE#	3	17DEC2020	1/2	2	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001	NERV	Headache/ headache	1	25AUG2020	2/3	3	Yes		NA/TC/TCN	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341151	GENRL	Pyrexia/ fever	1	26AUG2020	3/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	14SEP2020	1/3	3	Yes		NA	R (16SEP2020)	N/N
	SKIN	Psoriasis/ psoriasis	2	16SEP2020	3/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1134 11341153	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N
	GASTR	Abdominal discomfort/ upset stomach	1	25AUG2020	2/28	2	Yes		NA/TC	R (21SEP2020)	N/N
		Diarrhoea/ diarrhea	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
		Diarrhoea/ loose stools	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Muscular weakness/ muscle weakness	1	25AUG2020	2/28	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ headache	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
			1	25AUG2020	2/1	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	4	09MAR2021	2/C	1	Yes		NA	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341154	MUSC	Myalgia/ muscle aches#	4	09MAR2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1134 11341173	GENRL	Chills/ chills#	4	01MAR2021	1/C	1	Yes		NA	N	N/N
		Injection site pain/ injection site pain#	4	01MAR2021	1/C	1	Yes		NA	N	N/N
		Pyrexia/ fever#	4	01MAR2021	1/C	1	Yes		NA	N	N/N
	MUSC	Myalgia/ muscle pain#	4	01MAR2021	1/C	1	Yes		NA	N	N/N
16-55/ C4591001 1134 11341174	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	26AUG2020	1/5	3	Yes		NA	R (30AUG2020)	N/N
	NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N
	MUSC	Pain in extremity/ ARM PAIN (LEFT)	1	28AUG2020	3/6	3	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Chest discomfort/ CHEST TIGHTNESS	1	30AUG2020	5/8	2	Yes		NA/TC	R (06SEP2020)	N/N
	METAB	Hypokalaemia/ HYPOKALEMIA	1	30AUG2020	5/3	1	No	O	NA/TC	R (01SEP2020)	N/N
16-55/ C4591001 1134 11341188	GENRL	Chills/ chills	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1134 11341195	INFEC	Bacterial vaginosis/ Bacterial Vaginosis	2	11OCT2020	27/24	1	No	O	NA/TC	R (03NOV2020)	N/N
	PSYCH	Anxiety/ Anxiety	2	20OCT2020	36/C	2	No	O	NA/TC	RG	N/N
	GENRL	Pyrexia/ LOW GRADE FEVER#	4	09MAR2021	2/1	2	Yes		NA/TC	R (09MAR2021)	N/N
16-55/ C4591001 1134 11341225	GENRL	Injection site pain/ Left Arm Soreness at the injection site	1	31AUG2020	1/4	2	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1134 11341228	MUSC	Intervertebral disc protrusion/ Worsening Herniated Lumbar Disc	1	12SEP2020	12/7	2	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1134 11341236	MUSC	Fibromyalgia/ worsening of fibromyalgia	2	16OCT2020	25/C	2	No	O	NA/TC	RG	N/N
	CARD	Postural orthostatic tachycardia syndrome/ Postural tachycardia syndrome (POTS)	2	DEC2020	71/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1134 11341248	GENRL	Chills/ chills	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
		Pain/ body aches	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1134 11341254	GENRL	Injection site warmth/ warmth at injection site	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/Y
	INFEC	Pneumonia/ right lung pneumonia	2	22OCT2020	29/21	2	No	O	NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1134 11341259	GENRL	Fatigue/ FATIGUE	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1134 11341290	GASTR	Nausea/ nausea	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ worsening headache	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1134 11341295	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ chills#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle soreness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341301	GENRL	Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes	NA	R	(03OCT2020)	N/N
	GENRL	Injection site erythema/ redness at injection site	2	03OCT2020	3/3	2	Yes	NA	R	(05OCT2020)	N/N
		Injection site pruritus/ itching at injection site	2	03OCT2020	3/4	1	Yes	NA	R	(06OCT2020)	N/N
	NERV	Head discomfort/ head pressure	2	03OCT2020	3/2	2	Yes	NA	R	(04OCT2020)	N/N
16-55/ C4591001 1134 11341308	GASTR	Nausea/ NAUSEA	1	09SEP2020	1/2	1	Yes	NA	R	(10SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	1	09SEP2020	1/2	1	Yes	NA	R	(10SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE	1	09SEP2020	1/3	2	Yes	NA/TC	R	(11SEP2020)	N/N
		Injection site swelling/ SWELLING AT INJECTION SITE	1	09SEP2020	1/2	2	Yes	NA	R	(10SEP2020)	N/N
16-55/ C4591001 1134 11341315	GENRL	Injection site pain/ left arm muscle pain at injection site	2	01OCT2020	1/3	2	Yes	NA/TC	R	(03OCT2020)	N/Y
16-55/ C4591001 1134 11341321	GENRL	Injection site pain/ Pain at injection site*		10SEP2020	1/4	1	Yes	NA	R	(13SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Shoulder Pain on Injection arm	2	02OCT2020	1/4	2	Yes	NA	R	(05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341325	SKIN	Hyperhidrosis/ Sweating	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/3	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1134 11341327	INFEC	Pneumonia/ DOUBLE PNEUMONIA#	2	10MAR2021	160/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1134 11341344	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pain/ body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1134 11341351	INV	Blood cholesterol increased/ high cholesterol	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N
	METAB	Folate deficiency/ folate deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N
		Vitamin B12 deficiency/ vitamin b12 deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N
		Vitamin D deficiency/ vitamin d deficiency	1	28SEP2020	14/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1134 11341364	GENRL	Injection site mass/ hard knot at injection site#	3	17FEB2021	1/12	1	Yes		NA	R (28FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1134 11341378	GASTR	Injection site pain/ soreness at injection site#	3	17FEB2021	1/12	1	Yes		NA	R (28FEB2021)	N/N
		Nausea/ NAUSEA	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ CHILLS	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ BODY ACHES	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		NERV	Headache/ HEADACHE	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)
NERV	Facial paralysis/ Bell's Palsy	2	04NOV2020	9/68	2	Yes		NA/TC	R (10JAN2021)	N/N	
16-55/ C4591001 1134 11341379	GENRL	Chills/ chills	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N
		Pyrexia/ low grade fever	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Pain/ body aches	2	29OCT2020	2/2	2	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1134 11341381	GENRL	Injection site erythema/ Injection Site Redness	2	26OCT2020	1/6	2	Yes		NA	R (31OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	26OCT2020	1/6	2	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ redness at injection site	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341392		Injection site pain/ pain at injection site	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	31OCT2020	2/2	2	Yes		NA	R (01NOV2020)	N/N
		Pyrexia/ fever	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1134 11341393	NERV	Presyncope/ vasovagal reaction*		09OCT2020	1/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1134 11341404	GENRL	Fatigue/ fatigue	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	1	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ HEADACHE	1	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1134 11341416	GENRL	Swelling face/ FACIAL SWELLING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N
	SKIN	Pruritus/ ITCHING	1	18OCT2020	4/2	2	Yes		NA/TC	R (19OCT2020)	N/N
	VASC	Hot flush/ HOT FLASHES	1	18OCT2020	4/2	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001	INJ&P	Ligament sprain/ SPRAINED LEFT ANKLE	1	05NOV2020	22/22	2	No	O	NA	R (26NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1134 11341420 16-55/ C4591001	VASC	Hypertension/ HYPERTENSION	2	NOV2020	1/C	1	No	O	NA/TC	N	N/N
1134 11341426 16-55/ C4591001	INJ&P	Ligament sprain/ Left lower back sprain	2	14NOV2020	4/48	2	No	O	NA	R (31DEC2020)	N/N
1134 11341436 16-55/ C4591001	VASC	Hypertension/ worsening of hypertension	2	01DEC2020	99/C	1	No	O	NA/TC	RG	N/N
1135 11351016 16-55/ C4591001	GENRL	Pyrexia/ fever	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
1135 11351025 16-55/ C4591001	NERV	Headache/ headache	2	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
1135 11351037 16-55/ C4591001	INFEC	Urinary tract infection/ urinary tract infection	1	07AUG2020	3/11	1	No	O	NA/TC	R (17AUG2020)	N/N
1135 11351038 16-55/ C4591001	GENRL	Pain/ bodyaches#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N
	NERV	Lethargy/ lethargy#	3	29DEC2020	1/2	1	Yes		NA/TC	R (30DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351041	GASTR	Dyspepsia/ exacerbation of heartburn	2	04SEP2020	8/5	1	No	O	NA/TC	R (08SEP2020)	N/N
16-55/ C4591001 1135 11351052	SKIN	Skin ulcer/ right foot ulcer	2	28AUG2020	2/7	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C4591001 1135 11351057	INFEC	Hordeolum/ left eye sty	1	15AUG2020	9/46	1	No	O	NA/TC	R (29SEP2020)	N/N
	GENRL	Pain/ bodyaches#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ fever#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1135 11351059	GENRL	Injection site pain/ pain at injection site#	4	11MAR2021	1/3	1	Yes		NA/TC	R (13MAR2021)	N/N
		Pain/ body aches#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
		Pyrexia/ fever#	4	11MAR2021	1/3	1	Yes		NA	R (13MAR2021)	N/N
16-55/ C4591001 1135 11351061	SKIN	Dermatitis contact/ allergic reaction to poison oak (left arm)	1	18AUG2020	12/16	2	No	O	NA/TC	R (02SEP2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351068	GENRL	Injection site pain/ pain at injection site#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ headache#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1135 11351105	INFEC	Urinary tract infection/ Urinary tract infection	1	13AUG2020	2/13	1	No	O	NA/TC	R (25AUG2020)	N/N
	MUSC	Back pain/ lower back pain	1	13AUG2020	2/83	1	No	O	NA/TCN	R (03NOV2020)	N/N
	REPRO	Prostatomegaly/ enlarged prostate	2	01NOV2020	63/C	1	No	O	NA/TC	RG	N/N
	INJ&P	Limb injury/ right shoulder injury#	2	15FEB2021	169/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1135 11351111	GENRL	Fatigue/ Fatigue#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Pain/ body aches#	3	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1135 11351121	INFEC	Herpes zoster/ shingles	1	17AUG2020	5/8	1	No	O	NA/TC	R (24AUG2020)	N/N
	PSYCH	Depression/ worsening of depression	2	15DEC2020	104/8	1	No	O	NA/TC	R (22DEC2020)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351142	MUSC	Fatigue/ fatigue#	4	10FEB2021	1/4	2	Yes		NA	R (13FEB2021)	N/N
		Myalgia/ muscle aches (generalized)#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Nausea/ Nausea	1	17AUG2020	1/3	1	No	O	NA	R (19AUG2020)	N/N
16-55/ C4591001 1135 11351144	GASTR	Dental caries/ dental caries	1	04SEP2020	19/1	1	No	O	NA/TC	R (04SEP2020)	N/N
	MUSC	Back pain/ lower back pain	1	10SEP2020	25/11	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1135 11351151	MUSC	Pain in extremity/ Left arm pain	1	22AUG2020	5/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C4591001 1135 11351158	MUSC	Pain in extremity/ soreness on both arms and legs	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1135 11351163	GENRL	Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ chills#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351166	GENRL	Pain/ bodyaches#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Chills/ chills	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Pain/ bodyaches	2	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
Headache/ headache		1	10SEP2020	22/2	2	Yes		NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1135 11351168	GENRL	Fatigue/ Fatigue	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	PSYCH	Attention deficit hyperactivity disorder/ Attention deficit disorder worsening	2	DEC2020	82/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1135 11351172	GASTR	Diarrhoea/ loose stool	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Pain/ bodyaches	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Diarrhoea/ loose stool	2	12OCT2020	33/1	1	No	O	NA	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351178	INFEC	Cellulitis/ left toe cellulitis	2	25SEP2020	16/4	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1135 11351179	NERV	Syncope/ syncope episode*		21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Pain/ bodyaches#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Chills/ chills#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pain/ bodyaches#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ fever#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Musculoskeletal chest pain/ muscle pain (chest)#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1135 11351184	GENRL	Pain/ Generalized pains	2	10DEC2020	88/2	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Pain/ bodyaches#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
		Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351190		Pyrexia/ Fever	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1135 11351198	NERV	Headache/ headache	1	24AUG2020	1/33	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1135 11351201	GENRL	Pain/ body aches	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1135 11351205	GASTR	Diarrhoea/ loose bowel movement	1	07SEP2020	14/1	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1135 11351222	GENRL	Injection site pain/ soreness left upper arm injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)	N/N
16-55/ C4591001 1135 11351225	GENRL	Chills/ chills#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ fever#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351227	NERV	Headache/ headache#	3	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
		Pain/ Body Aches	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	1	01SEP2020	2/4	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site pain/ pain at injection site	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1135 11351228		Pain/ body aches	2	22SEP2020	2/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1135 11351229	MUSC	Myalgia/ muscle pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Pain on Injection Site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body Aches	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351231	SKIN	Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		Rash/ localized rash (scalp, neck, face)	2	16JAN2021	118/1	1	No	O	NA/TC	R (16JAN2021)	N/N
	GENRL	Pain/ bodyaches#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1135 11351235	NERV	Pyrexia/ fever#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ headache#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Syncope/ vasovagal syncope*		31AUG2020	1/1	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1135 11351243	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1135 11351251	GENRL	Pain/ Body Aches	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ body aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351256	MUSC	Myalgia/ Muscle Aches	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1135 11351265	MUSC	Arthralgia/ pain on right knee	2	30OCT2020	36/60	1	No	O	NA/TC	R (28DEC2020)	N/N
	VASC	Accelerated hypertension/ accelerated hypertension	2	23JAN2021	121/5	3	No	O	NA/TC	R (27JAN2021)	Y/N
	VASC	Hypertension/ Hypertension	2	26JAN2021	124/2	2	No	O	NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1135 11351269	GENRL	Pain/ body aches	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Pyrexia/ low grade temperature	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Lethargy/ lethargy	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Constipation/ worsening of constipation	2	21JAN2021	119/10	1	No	O	NA/TC/TCN	R (30JAN2021)	N/N
16-55/ C4591001 1135 11351276	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351281	GENRL	Chills/ chills#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
		Pain/ bodyaches#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1135 11351282	GENRL	Fatigue/ fatigue	2	24SEP2020	1/4	2	Yes		NA/TC	R (27SEP2020)	N/N
		Injection site pain/ pain at injection site	2	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1135 11351285	GENRL	Pyrexia/ low grade temperature (99.1)	2	02MAR2021	159/2	1	No	O	NA	R (03MAR2021)	N/N
16-55/ C4591001 1135 11351290	GENRL	Injection site pain/ Injection site soreness	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1135 11351292	GENRL	Chills/ chills	1	04SEP2020	2/32	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ body aches	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		Pyrexia/ fever	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351293	GENRL	Injection site pain/ pain at injection site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Pain/ body aches#	3	19DEC2020	2/3	1	Yes		NA/TC	R (21DEC2020)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1135 11351297		Pain/ bodyaches#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	GENRL	Pain/ body aches	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1135 11351313		Pyrexia/ low grade temperature	2	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
	GENRL	Pyrexia/ Fever (101.3)#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1135 11351323	GASTR	Diarrhoea/ loose bowel movement	1	13SEP2020	6/1	1	No	O	NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351326	GASTR	Diarrhoea/ loose stool	2	02OCT2020	4/45	1	No	O	NA/TCN	R (15NOV2020)	N/N
		Gastrointestinal sounds abnormal/ borborygmus	2	02OCT2020	4/45	1	No	O	NA/TCN	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351330	GENRL	Injection site pain/ pain at injection site	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1135 11351332	INFEC	Urinary tract infection/ urinary tract infection	1	14SEP2020	6/8	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1135 11351349	GENRL	Chills/ Chills	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/3	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1135 11351359	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	1	01OCT2020	15/6	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1135 11351361	GENRL	Chills/ chills#	3	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351362	GENRL	Fatigue/ fatigue#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
		Chills/ chills#	4	13MAR2021	3/1	1	Yes		NA	R (13MAR2021)	N/N
		Fatigue/ fatigue#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Pyrexia/ low grade temperature#	4	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
		Myalgia/ generalized muscle pain#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Guillain-Barre syndrome/ Guillain barre syndrome	2	29DEC2020	84/C	3	No	O	NA/TC/TCN	RG	Y/N
	GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/2	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	1	Yes		NA/TC/TCN	R (09JAN2021)	N/N
		NERV	Headache/ Headache#	4	08JAN2021	2/2	1	Yes		NA/TC/TCN	R (09JAN2021)
GENRL	Injection site pain/ pain at injection site#	3	06FEB2021	3/4	2	Yes		NA	R (09FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351375	GENRL	Injection site pain/ pain at injection site#	4	25FEB2021	2/15	2	Yes		NA/TC	R (11MAR2021)	N/N
16-55/ C4591001	PSYCH	Anxiety/ worsening of anxiety	2	01NOV2020	23/15	1	No	O	NA/TC	R (15NOV2020)	N/N
1135 11351376	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
1135 11351377	NERV	Pain/ Body Aches	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
1135 11351381	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	16OCT2020	28/1	1	Yes		NA	R (16OCT2020)	N/N
1135 11351383	GENRL	Pain/ bodyaches#	3	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	GENRL										
1135 11351387											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351391	GENRL	Pyrexia/ fever (subjective) - low grade	2	01NOV2020	24/2	1	No	O	NA/TC	R (02NOV2020)	N/N
	GASTR	Toothache/ pain - right molar bottom tooth	2	03NOV2020	26/1	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1135 11351392	GENRL	Injection site pain/ soreness at injection site - left arm	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1135 11351403	MUSC	Back pain/ Exacerbation of lower back pain	1	22SEP2020	2/1	1	No	O	NA/TC	R (22SEP2020)	N/N
	GASTR	Diarrhoea/ loose bowel movements	1	24SEP2020	4/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1135 11351404	GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		Pain/ Body Aches	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GASTR	Nausea/ nausea	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N
	NERV	Dizziness/ dizziness	1	14OCT2020	24/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1135 11351405	GENRL	Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351416	GENRL	Pain/ body aches	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Chills/ Chills	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Fatigue/ fatigue	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1135 11351417	GENRL	Injection site pain/ soreness on injection site (left arm)	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1135 11351422	RESP	Nasal congestion/ nasal congestion	1	11OCT2020	19/2	1	No	O	NA/TC	R (12OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351423	GASTR	Nausea/ nausea	1	15OCT2020	23/3	1	No	O	NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N
	SKIN	Hyperhidrosis/ sweating	1	15OCT2020	23/1	1	No	O	NA	R (15OCT2020)	N/N
16-55/ C4591001 1135 11351432	GENRL	Pain/ bodyaches#	3	30DEC2020	2/33	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Chills/ chills#	4	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Dizziness/ dizziness#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1135 11351434	BLOOD	Lymphadenopathy/ cervical lymphadenopathy (bilateral)	4	19JAN2021	2/1	1	Yes		NA/TC	R (19JAN2021)	N/N
			1	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1135 11351435	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351439	RESP	Rhinitis allergic/ Exacerbating allergic rhinitis	1	28SEP2020	4/15	1	No	O	NA/TC	R (12OCT2020)	N/N	
16-55/ C4591001 1135 11351440	GENRL	Injection site erythema/ redness on the injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N	
		Injection site pain/ soreness at the injection site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N	
		Injection site swelling/ swelling at injection site	1	21OCT2020	1/15	1	Yes		NA/TCN	R (04NOV2020)	N/N	
	INFEC	Urinary tract infection/ urinary tract infection	2	27NOV2020	17/13	1	No	O	NA/TC	R (09DEC2020)	N/N	
16-55/ C4591001 1135 11351441	GENRL	Fatigue/ Tiredness	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N	
16-55/ C4591001 1135 11351443	MUSC	Myalgia/ muscle pain	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N	
	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	
16-55/ C4591001 1135 11351448	METAB	Hypokalaemia/ hypokalemia	1	03NOV2020	14/1	1	No	O	NA/TC	R (03NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351450	MUSC	Neck pain/ neck pain	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
	NERV	Headache/ headache	1	03NOV2020	14/2	3	No	O	NA/TC/TCN	R (04NOV2020)	N/N
	MUSC	Arthritis/ Right shoulder arthritis	2	07DEC2020	27/C	2	No	O	NA/TC	RG	N/N
	GASTR	Diarrhoea/ loose stool	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Pain in extremity/ left hand pain	2	10NOV2020	2/53	1	No	O	NA/TC	R (01JAN2021)	N/N
	GENRL	Fatigue/ fatigue	2	12NOV2020	4/2	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	13NOV2020	5/3	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351452	INFEC	Helicobacter infection/ H. pylori infection	2	29DEC2020	51/16	1	No	O	NA/TC	R (13JAN2021)	N/N
	GENRL	Chills/ chills	2	10NOV2020	2/3	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1135 11351453	GENRL	Pain/ bodyaches	2	10NOV2020	2/3	1	Yes		NA/TC	R (12NOV2020)	N/N
	GENRL	Fatigue/ fatigue	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	INV	Body temperature increased/ elevated temperature	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351457	NEOPL	Uterine leiomyoma/ uterine fibroids	1	11NOV2020	22/C	1	No	O	NA	RG	N/N
	GENRL	Chills/ chills	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351460	NERV	Headache/ headache	1	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1135 11351462	NERV	Headache/ Headache	2	12NOV2020	2/3	1	No	O	NA/TC	R (14NOV2020)	N/N
	METAB	Iron deficiency/ Iron deficiency	2	05FEB2021	87/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1135 11351465	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ body aches	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351469	MUSC	Myalgia/ muscle aches (generalized)#	3	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ headache#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1135 11351472	GENRL	Injection site pain/ soreness on injection site (left arm)	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
		Pain/ body aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351475	EAR	Vertigo/ vertigo*		22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Pain/ body aches	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351476	GENRL	Injection site pain/ pain at injection site	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ low grade temperature	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351482	GENRL	Chills/ chills	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1135 11351487	GENRL	Chills/ chills#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pain/ bodyaches#	3	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1135 11351490	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
		Pain/ body aches	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
		Pain/ bodyaches	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1135 11351491	GENRL	Chills/ chills	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ body aches	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351492	GENRL	Fatigue/ fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pain/ bodyaches#	3	28FEB2021	3/1	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1135 11351495	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	1/4	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Pain/ body aches	2	13NOV2020	1/4	1	Yes		NA/TC	R (16NOV2020)	N/N
Chills/ chills		2	14NOV2020	2/1	2	Yes		NA/TC	R (14NOV2020)	N/N	
Pyrexia/ low grade temperature		2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N	
16-55/ C4591001 1135 11351496	GENRL	Fatigue/ fatigue	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N
	INJ&P	Injection site pain/ pain on injection site left arm	1	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N
Foot fracture/ broken right middle toe		2	01DEC2020	20/14	1	No	O	NA	R (14DEC2020)	N/N	
GENRL	Injection site pain/ pain at injection site#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
NERV	Headache/ headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N	
GASTR	Vomiting/ vomiting#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351497	GENRL	Injection site pain/ Pain at injection site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351498	GENRL	Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ chills	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Pyrexia/ fever	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	MUSC	Myalgia/ muscle aches	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351499	PSYCH	Depression/ worsening of depression	2	JAN2021	50/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1135 11351501	GENRL	Chills/ chills	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
		Pain/ body aches	1	25OCT2020	3/3	1	Yes		NA/TC	R (27OCT2020)	N/N
	INV	Body temperature increased/ elevated temperature	1	25OCT2020	3/2	1	Yes		NA/TC	R (26OCT2020)	N/N
	NERV	Headache/ headache	1	25OCT2020	3/3	1	Yes		NA/TC	R (27OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351505	GENRL	Chills/ chills	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
		Pain/ body aches	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	INV	Body temperature increased/ elevated temperature	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ pain at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	No	O	NA	R (15NOV2020)	N/N
		Pain/ body aches	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Pyrexia/ low grade temp	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ worsening headache	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351508	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ body aches	1	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351509	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Injection site pain/ pain at injection site	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
		Pyrexia/ fever	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
	MUSC	Arthralgia/ joint aches (hands)	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	23OCT2020	1/4	1	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	13NOV2020	1/3	1	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	14NOV2020	2/2	1	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Injection site pain/ right arm injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	13NOV2020	2/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351514	GENRL	Pain/ body aches	1	24OCT2020	1/2	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache (worsening)	1	24OCT2020	1/3	1	No	O	NA/TC	R (26OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351516	RESP	Nasal congestion/ nasal congestion	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
	INFEC	Fungal infection/ yeast infection	2	15JAN2021	65/16	1	No	O	NA/TC	R (30JAN2021)	N/N
	INFEC	Ureaplasma infection/ urea plasma infection	2	28JAN2021	78/6	1	No	O	NA/TC	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	4	11MAR2021	1/2	1	Yes		NA	R (12MAR2021)	N/N
16-55/ C4591001 1135 11351517		Fatigue/ fatigue#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
	NERV	Headache/ headache#	4	11MAR2021	1/C	1	Yes		NA	N	N/N
	GENRL	Pain/ body aches	1	24OCT2020	1/1	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Dizziness/ dizziness	1	24OCT2020	1/1	1	No	O	NA	R (24OCT2020)	N/N
	NERV	Headache/ headache	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N
		Pain/ bodyaches	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N
NERV	Headache/ headache	2	16NOV2020	1/2	2	Yes		NA/TC	R (17NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
		Pain/ bodyaches#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
		Pyrexia/ fever#	4	12MAR2021	1/C	1	Yes		NA	N	N/N
	NERV	Migraine/ migraine (worsening)#	4	12MAR2021	1/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1135 11351518	GENRL	Injection site pain/ pain at injection site	1	24OCT2020	1/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Fatigue/ fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ pain at injection site	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Pain/ body aches	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1135 11351519	GENRL	Chills/ chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351520	MUSC	Myalgia/ muscle pain	1	25OCT2020	2/1	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Chills/ chills	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ pain at injection site	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
	GENRL	Pain/ bodyaches	2	14NOV2020	2/2	2	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1135 11351521	GENRL	Pyrexia/ low grade temperature	1	25OCT2020	2/2	1	Yes		NA	R (26OCT2020)	N/N
	NERV	Lethargy/ lethargy	1	25OCT2020	2/2	1	Yes		NA	R (26OCT2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
		Lethargy/ lethargy	2	14NOV2020	2/1	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1135 11351524	RESP	Asthma exercise induced/ exercise induced asthma	2	30NOV2020	18/C	1	No	O	NA/TC	RG	N/N
	NERV	Headache/ headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351525	MUSC	Arthralgia/ generalized joint pain#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ Chills	1	25OCT2020	2/1	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Diarrhoea/ loose stool	1	26OCT2020	3/1	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
	NERV	Headache/ headache	1	25OCT2020	2/2	1	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Pain/ body aches	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Migraine/ migraine (headache)	2	15NOV2020	3/2	2	No	O	NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1135 11351532	GENRL	Injection site pain/ pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351533	NERV	Paraesthesia/ tingling sensation entire body	2	14NOV2020	3/4	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Pain/ bodyaches	2	15NOV2020	4/3	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Arthralgia/ joint pain (generalized)	2	15NOV2020	4/3	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1135 11351534	GENRL	Chills/ chills#	3	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ muscle soreness (generalized)#	3	19FEB2021	1/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1135 11351535	GENRL	Injection site pain/ soreness on injection site (left arm)	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Pain/ bodyaches#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ muscle aches (generalized)#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1135 11351537	GENRL	Chills/ chills	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1135 11351538	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ generalized muscle pain#	3	01FEB2021	1/3	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1135 11351539	GENRL	Fatigue/ fatigue	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ soreness on the injection site (left arm)	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
		Malaise/ malaise	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1135 11351540	GENRL	Fatigue/ fatigue	1	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Arthralgia/ Joint pain (hands)	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1135 11351541	MUSC	Myalgia/ muscle pain	2	17NOV2020	1/2	1	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351542	GENRL	Fatigue/ fatigue	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	INFEC	Tonsillitis/ tonsillitis	1	03NOV2020	9/1	2	No	O	NA/TC	R (03NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	17NOV2020	1/23	1	Yes		NA	R (09DEC2020)	N/N
	METAB	Dehydration/ dehydration	2	28NOV2020	12/1	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N
16-55/ C4591001 1135 11351546	GENRL	Chills/ chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Chills/ chills	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Pain/ body aches	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Pyrexia/ fever	2	17NOV2020	2/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	MUSC	Exostosis/ right knee bone spur	2	29NOV2020	14/C	1	No	O	NA/TC	RG	N/N
	MUSC	Arthralgia/ worsening of right knee pain	2	30NOV2020	15/4	1	No	O	NA/TC	R (03DEC2020)	N/N
16-55/ C4591001 1135 11351548	GENRL	Fatigue/ fatigue	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1135 11351549	GENRL	Pyrexia/ low grade temperature	2	17NOV2020	2/1	1	Yes		NA/TC	R (17NOV2020)	N/N	
	NERV	Headache/ headache	2	17NOV2020	2/1	1	Yes		NA/TC	R (17NOV2020)	N/N	
	MUSC	Myalgia/ generalized muscle pain#	4	11MAR2021	1/2	1	Yes		NA/TC	R (12MAR2021)	N/N	
16-55/ C4591001 1135 11351550	GASTR	Diarrhoea/ diarrhea	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
16-55/ C4591001 1135 11351553		Nausea/ nausea	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Pain/ bodyaches	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
	NERV	Dizziness/ dizziness	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
		Headache/ headache	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N	
	GENRL	Fatigue/ fatigue	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N	
	16-55/ C4591001 1135 11351556	GENRL	Injection site pain/ soreness on injection site (left arm)	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	16-55/ C4591001	GASTR	Diarrhoea/ loose stool	2	22NOV2020	6/1	1	Yes		NA	R (22NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351559 16-55/ C4591001	METAB	Vitamin D deficiency/ hypovitaminosis, Vitamin D	2	23NOV2020	7/C	1	No	O	NA/TC	RG	N/N
1135 11351560 16-55/ C4591001	GASTR	Pancreatitis acute/ acute pancreatitis	2	21NOV2020	2/4	2	No	O	NA/TC	R (24NOV2020)	Y/N
1135 11351563 16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
1135 11351565 16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
1135 11351566 16-55/ C4591001	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
1135 11351567 16-55/ C4591001	MUSC	Myalgia/ muscle aches#	3	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
1135 11351568 16-55/ C4591001	NERV	Headache/ headache#	3	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
1135 11351569 16-55/ C4591001	INFEC	Fungal skin infection/ right thumb fungus skin lesion	2	11DEC2020	25/16	1	No	O	NA/TC	R (26DEC2020)	N/N
1135 11351570 16-55/ C4591001	MUSC	Bursitis/ left elbow bursitis	2	17NOV2020	1/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1135 11351568 16-55/ C4591001 1135 11351569	GENRL	Injection site pain/ pain at injection site	1	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ low grade temp	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Back pain/ right side back pain	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site reaction/ muscle twitching at injection site	1	30OCT2020	4/1	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1135 11351571	GENRL	Chills/ chills	1	27OCT2020	1/1	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ pain on the injection site (left arm)	1	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1135 11351572	GENRL	Injection site pain/ pain at injection site	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1135 11351573	INJ&P	Arthropod bite/ spider bite on right side of neck#	3	15FEB2021	6/3	2	No	O	NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
	NERV	Headache/ headache#	4	02MAR2021	2/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1136 11361001	GENRL	Injection site pain/ injection site pain#	2	21JAN2021	135/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1136 11361004	EYE	Eye pain/ right orbital pain#	3	23DEC2020	2/8	1	No	O	NA	R (30DEC2020)	N/N
16-55/ C4591001 1136 11361007	NERV	Migraine/ MIGRAINE HEADACHES*		18AUG2020	1/2	2	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1136 11361012	INJ&P	Contusion/ BRUISED LEFT ARM	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
		Contusion/ BRUISED LEFT HIP	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
		Contusion/ BRUISED LEFT SHOULDER	2	24SEP2020	17/53	2	No	O	NA/TC	R (15NOV2020)	N/N
	GENRL	Pain/ body aches#	2	21JAN2021	136/2	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ fever#	2	21JAN2021	136/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ left arm soreness#	2	11FEB2021	156/3	2	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1136 11361020	GENRL	Pyrexia/ mild fever#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	NERV	Seizure/ worsening of intermittent seizures	2	01DEC2020	82/56	1	No	O	NA/TC	R (25JAN2021)	N/N
1136 11361029	MUSC	Pain in extremity/ left foot pain	1	01SEP2020	13/C	1	No	O	NA/TC	N	N/N
1136 11361030	NERV	Headache/ headache#	3	02FEB2021	6/1	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	3	18FEB2021	22/2	1	Yes		NA	R (19FEB2021)	N/N
		Fatigue/ fatigue#	3	18FEB2021	22/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	RESP	Rhinorrhoea/ runny nose#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	2	03FEB2021	143/2	1	Yes		NA	R (04FEB2021)	N/N
1136 11361039											
16-55/ C4591001	MUSC	Pain in extremity/ sore arm after vaccine#	2	28JAN2021	140/3	1	Yes		NA	R (30JAN2021)	N/N
1136 11361040											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1136 11361054	INFEC	Diverticulitis/ WORSENING OF DIVERTICULITIS	2	07OCT2020	20/8	2	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1136 11361058	PSYCH	Insomnia/ insomnia#	3	26FEB2021	16/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1136 11361062	GENRL	Fatigue/ fatigue*		14SEP2020	1/5	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ headache*		14SEP2020	1/5	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1136 11361065	GENRL	Fatigue/ MILD FATIGUE	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ mild headache#	2	20JAN2021	107/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1136 11361072	GENRL	Fatigue/ FATIGUE#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1136 11361073	GENRL	Fatigue/ fatigue#	2	25FEB2021	107/3	1	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1136 11361076	GENRL	Injection site pain/ sore left arm at injection site#	2	25FEB2021	107/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1136 11361076	GENRL	Injection site pain/ injection site pain, left arm*		22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1136 11361082	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	01DEC2020	13/C	2	No	O	NA	UNK	N/N
16-55/ C4591001 1136 11361083	IMMUN	Seasonal allergy/ seasonal allergies	2	15DEC2020	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1136 11361086	GENRL	Injection site pain/ injection site pain	1	29OCT2020	2/5	2	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1136 11361091	GASTR	Diarrhoea/ diarrhea	1	30OCT2020	3/1	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1136 11361091	PSYCH	Depression/ worsening depression	2	01JAN2021	47/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1136 11361092	GENRL	Pyrexia/ fever	1	31OCT2020	4/1	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Pain/ body aches	1	16NOV2020	20/1	1	Yes		NA	R (16NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1136 11361094	GENRL	Pyrexia/ fever	1	16NOV2020	20/1	1	Yes		NA	R (16NOV2020)	N/N
		Fatigue/ fatigue	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N
	NERV	Headache/ headache	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N
	RESP	Paranasal sinus discomfort/ sinus pressure	1	30OCT2020	2/4	2	No	O	NA	R (02NOV2020)	N/N
	GENRL	Sneezing/ sneezing	1	30OCT2020	2/4	1	No	O	NA	R (02NOV2020)	N/N
		Chills/ chills#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		Fatigue/ fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
		Pain/ body aches#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ fever#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		MUSC	Myalgia/ muscle aches#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)
NERV	Hyperaesthesia/ skin sensitivity#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N	
16-55/ C4591001 1136 11361099	GENRL	Injection site pain/ injection site pain, left arm	1	30OCT2020	2/3	1	Yes		NA/TC	R (01NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1136 11361101	GENRL	Chills/ chills	2	17NOV2020	1/3	2	Yes		NA	R (19NOV2020)	N/N
		Fatigue/ fatigue	2	17NOV2020	1/3	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ injection site pain	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N
		Pyrexia/ fever	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1136 11361101	NERV	Headache/ mild headache#	3	01MAR2021	5/2	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1136 11361108	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	2	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1136 11361111	GENRL	Injection site induration/ induration by injection site	1	31OCT2020	3/7	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ pain at injection site	1	31OCT2020	3/7	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1139 11391015	GASTR	Abdominal pain/ Abdominal Pain	2	28AUG2020	8/7	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C4591001 1139 11391037	GENRL	Injection site bruising/ Bruising at injection site	1	04AUG2020	1/9	1	Yes		NA	R (12AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1139 11391041	RESP	Dyspnoea/ Incomplete Breaths on Inspiration	2	08SEP2020	16/18	2	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1139 11391071	REPRO	Prostatitis/ Acute prostatitis	2	01SEP2020	5/C	3	No	O	NA/TC/TCN	RG	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	03SEP2020	7/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1139 11391089	MUSC	Musculoskeletal discomfort/ Left Shoulder discomfort	1	26AUG2020	15/12	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1139 11391090	GASTR	Abdominal pain/ Abdominal pain	1	12AUG2020	1/4	2	Yes		NA	R (15AUG2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	05SEP2020	2/59	2	Yes		NA/TC	R (02NOV2020)	N/N
	NERV	Headache/ Intermittent Headaches	2	27SEP2020	24/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1139 11391106	MUSC	Back pain/ lower back pain	1	03NOV2020	22/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1139 11391138	INFEC	Sinusitis/ sinusitis	2	08JAN2021	23/18	2	No	O	NA/TC	R (25JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401009	GENRL	Injection site pain/ Injection Site Pain	1	31JUL2020	1/2	1	Yes		NA	R (01AUG2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N
	INFEC	Infected bite/ Cellulitis Status Post Bee Sting	2	30AUG2020	11/11	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1140 11401011	MUSC	Neck pain/ Neck Pain#	3	13FEB2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1140 11401016	MUSC	Myalgia/ Myalgia	1	31JUL2020	1/2	2	Yes		NA	R (01AUG2020)	N/N
	GASTR	Nausea/ nausea	2	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1140 11401017	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	MUSC	Pain in extremity/ Left arm pain#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1140 11401020	NEOPL	B-cell lymphoma/ B-Cell Lymphoma	2	03DEC2020	101/C	2	No	O	NA/TC	N	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401021	PSYCH	Insomnia/ Insomnia	2	12SEP2020	19/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1140 11401031	INJ&P	Skin laceration/ Laceration to left hand#	2	19JAN2021	149/25	1	No	O	NA	R (12FEB2021)	N/N
16-55/ C4591001 1140 11401050	GASTR	Diarrhoea/ Diarrhea	1	17AUG2020	13/1	1	Yes		NA	R (17AUG2020)	N/N
16-55/ C4591001 1140 11401057	GENRL	Injection site pain/ pain at injection site#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1140 11401061	GENRL	Injection site pain/ pain at injection site#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
16-55/ C4591001 1140 11401062	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1140 11401088	GENRL	Injection site pain/ Pain at injection site#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	30DEC2020	2/1	1	Yes		NA	R (30DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1140 11401092	GENRL	Pain/ Body Aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
	MUSC	Pain in extremity/ Sore Left Arm#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N	
		NERV	Pyrexia/ Fever 103F#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
		NERV	Lethargy/ lethargy#	4	09JAN2021	2/1	2	Yes		NA	R (09JAN2021)	N/N
		GENRL	Injection site pain/ Pain at injection site#	4	12JAN2021	2/4	2	Yes		NA/TC	R (15JAN2021)	N/N
		MUSC	Myalgia/ Generalized Muscle Aches	1	24AUG2020	11/7	2	No	O	NA	R (30AUG2020)	N/N
		GENRL	Fatigue/ Fatigue	1	26AUG2020	13/5	2	No	O	NA	R (30AUG2020)	N/N
		RESP	Upper-airway cough syndrome/ Post-nasal Drip	1	27AUG2020	14/8	1	No	O	NA	R (03SEP2020)	N/N
		GENRL	Injection site pain/ Left Arm Injection Site Pain#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N
16-55/ C4591001 1140 11401129	NERV	Headache/ headache#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401137	GENRL	Injection site pain/ Pain at Injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1140 11401144	GENRL	Injection site pain/ Pain at Injection Site*		04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1140 11401149	GENRL	Injection site pain/ pain at injection site	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Chills/ chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ fatigue	2	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1140 11401153	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401157		Fatigue/ Fatigue#	3	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1140 11401160	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1140 11401164	GENRL	Injection site pain/ Injection site pain#	4	04FEB2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1140 11401177	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/C	1	No	O	NA	N	N/N
16-55/ C4591001 1140 11401180	REPRO	Ovarian cyst/ Ovarian Cyst#	3	22FEB2021	8/C	2	No	O	NA	N	N/N
		Pelvic pain/ Pelvic Pain#	3	22FEB2021	8/C	2	No	O	NA	N	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1140 11401184	BLOOD	Lymphadenopathy/ Lymphadenopathy above Left Clavicle#	4	09MAR2021	2/C	1	Yes		NA	N	N/N	
	REPRO	Breast cyst/ Breast Cyst#	4	09MAR2021	2/C	1	No	O	NA	N	N/N	
	EAR	Hyperacusis/ Increased Sense of Hearing	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
	GASTR	Dyspepsia/ Heartburn	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
		Nausea/ Nausea	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
	NERV	Dizziness/ Lightheadedness	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
		Parosmia/ Increased Sense of Smell	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
	PSYCH	Anxiety/ Anxiety	2	16SEP2020	1/6	1	No	O	NA	R (21SEP2020)	N/N	
	16-55/ C4591001 1140 11401187	NERV	Headache/ Headache	2	13OCT2020	29/4	2	No	O	NA	R (16OCT2020)	N/N
	16-55/ C4591001 1140 11401198	MUSC	Myalgia/ muscle aches	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401203 16-55/ C4591001	NERV	Headache/ Headache	1	27AUG2020	1/1	2	Yes		NA	R (27AUG2020)	N/N
1140 11401206 16-55/ C4591001	GENRL	Malaise/ General Malaise	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
1140 11401209 16-55/ C4591001	GASTR	Nausea/ Nausea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
1140 11401214 16-55/ C4591001	NERV	Vomiting/ Vomiting	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
1140 11401219 16-55/ C4591001	NERV	Hypoaesthesia/ jaw numbness	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
1140 11401224 16-55/ C4591001	GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
1140 11401231 16-55/ C4591001	INJ&P	Limb injury/ Left shoulder strain	2	01NOV2020	41/4	2	No	O	NA	R (04NOV2020)	N/N
		Road traffic accident/ Motor Vehicle Accident	2	01NOV2020	41/1	2	No	O	NA	R (01NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1140 11401241	GENRL	Pyrexia/ Fever#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1140 11401243	GENRL	Chills/ Chills	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1140 11401246	MUSC	Pain in extremity/ sore arm-lasting less than 1 day#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1140 11401249	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1140 11401250	GENRL	Injection site pain/ pain at injection site#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N
16-55/ C4591001 1140 11401252	GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle aches	2	24SEP2020	1/3	3	Yes		NA/TC	R (26SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Vomiting/ vomiting	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	VASC	Hypertension/ Hypertension#	2	30JAN2021	129/C	2	No	O	NA	N	N/N
16-55/ C4591001 1140 11401279	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/1	1	Yes		NA/TC	R (21DEC2020)	N/N
16-55/ C4591001 1140 11401281	GENRL	Injection site pain/ Pain at Injection Site	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y
	NERV	Headache/ headache	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/Y
16-55/ C4591001 1140 11401282	RESP	Asthma exercise induced/ Exercise induced Asthma	2	NOV2020	1/C	2	No	O	NA/TC	RG	N/N
	GASTR	Abdominal pain upper/ Right Upper Abdominal Pain#	4	14FEB2021	11/4	3	No	O	NA	R (17FEB2021)	N/N
	RESP	Pulmonary embolism/ Bilateral Pulmonary Embolisms#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	VASC	Deep vein thrombosis/ Deep Vein Thrombosis Left Leg#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N
16-55/ C4591001 1140 11401285	GASTR	Diarrhoea/ Diarrhea#	3	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
	BLOOD	Lymphadenopathy/ enlarged lymph node axilla (R)#	4	04FEB2021	2/7	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1140 11401290	GENRL	Injection site pain/ Tenderness at Injection Site	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Fever	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1140 11401294	GENRL	Injection site pain/ Pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ myalgias	2	03NOV2020	1/4	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1140 11401298	MUSC	Arthralgia/ Diffuse Arthralgia's	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1140 11401304	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1140 11401306	EYE	Eye pain/ Bilateral Eye Pain	1	07NOV2020	17/56	1	No	O	NA	R (01JAN2021)	N/N	
		Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N	
	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N	
		Paraparesis/ Worsening of Chronic Spastic Paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	N	N/N	
16-55/ C4591001 1140 11401311	GENRL	Chills/ Chills#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
		Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
		Pain/ Body Aches#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N	
16-55/ C4591001 1140 11401321	GENRL	Injection site pain/ Pain at injection site#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N	
16-55/ C4591001 1141 11411005	NEOPL	Fibroadenoma of breast/ Left breast fibroadenoma	2	10SEP2020	21/1	2	No	O	NA/TC	R (10SEP2020)	N/N	
	SKIN	Acne cystic/ Cystic Acne on Face	2	02NOV2020	74/8	1	No	O	NA/TC	R (09NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N
		Injection site swelling/ injection site swelling#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
16-55/ C4591001 1141 11411006	GENRL	Injection site pain/ Injection site pain#	4	20JAN2021	1/3	1	Yes		NA/TC	R (22JAN2021)	N/N
	MUSC	Back pain/ Back Pain	1	31JUL2020	1/10	3	Yes		NA/TC	R (09AUG2020)	N/N
	INFEC	Gingivitis/ Gum Infection	2	01DEC2020	103/72	1	No	O	NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1141 11411007	GENRL	Injection site pain/ Injection Site Pain#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Injection site pain/ Injection Site Tenderness#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	MUSC	Joint range of motion decreased/ Decreased upward range of motion in vaccinated arm#	3	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	1/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1141 11411008	GENRL	Injection site pain/ injection site pain	1	31JUL2020	1/26	3	Yes		NA	R (25AUG2020)	N/N
	MUSC	Tendonitis/ Shoulder tendonitis	1	31JUL2020	1/67	1	Yes		NA	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Gastroesophageal reflux disease/ worsening epigastric pain r/t acid reflux#	2	09FEB2021	173/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1141 11411010	PSYCH	Anxiety/ Anxiousness	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N
		Depressed mood/ Low Mood	2	14SEP2020	14/93	2	No	O	NA/TCN	R (15DEC2020)	N/N
16-55/ C4591001 1141 11411012	GENRL	Vessel puncture site pain/ pinching sensation in left lower arm after blood draw*		31JUL2020	1/38	1	No	O	NA	R (06SEP2020)	N/N
		Vessel puncture site paraesthesia/ Tingling on lower left arm at blood draw site.*		31JUL2020	1/20	1	No	O	NA	R (19AUG2020)	N/N
16-55/ C4591001 1141 11411016	GENRL	Injection site pain/ injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature T. Max 100.1 F#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Diffuse Myalgia in vaccinated arm#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	1/3	1	Yes		NA	R (25DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411019	GENRL	Fatigue/ Fatigue#	3	24DEC2020	2/1	1	Yes	NA/TCN	R (24DEC2020)	N/N	
		Malaise/ Generalized malaise#	3	24DEC2020	2/1	1	Yes	NA	R (24DEC2020)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	14JAN2021	1/2	1	Yes	NA	R (15JAN2021)	N/N	
	GENRL	Chills/ chills#	4	15JAN2021	2/1	2	Yes	NA	R (15JAN2021)	N/N	
	INV	Body temperature increased/ elevated body temperature t max 99.7#	4	15JAN2021	2/1	1	Yes	NA/TC	R (15JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	15JAN2021	2/1	2	Yes	NA/TC	R (15JAN2021)	N/N	
	NERV	Headache/ headache#	4	15JAN2021	2/1	2	Yes	NA/TC	R (15JAN2021)	N/N	
16-55/ C4591001 1141 11411020	GASTR	Nausea/ nausea#	3	28JAN2021	2/1	2	Yes	NA	R (28JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	3	28JAN2021	2/1	1	Yes	NA	R (28JAN2021)	N/N	
		Injection site pain/ injection site pain#	3	28JAN2021	2/1	1	Yes	NA	R (28JAN2021)	N/N	
	MUSC	Arthralgia/ generalized joint pain#	3	28JAN2021	2/1	1	Yes	NA	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	20FEB2021	2/2	1	Yes	NA	R (21FEB2021)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ Joint pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1141 11411021	GENRL	Injection site pain/ muscle soreness injection area	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1141 11411022	GENRL	Injection site pain/ injection site soreness#	3	21DEC2020	1/2	2	Yes		NA	R (22DEC2020)	N/N
16-55/ C4591001 1141 11411023	GENRL	Inflammation/ acute bilateral hand inflammation	1	AUG2020	1/C	2	No	O	NA	RG	N/N
	NERV	Paraesthesia/ Tingling sensation left hand	1	10AUG2020	7/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1141 11411024	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	12JAN2021	2/2	2	Yes		NA	R (13JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ mild myalgia#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Arthralgias	2	17SEP2020	23/12	2	Yes		NA/TC/TCN	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411029	PSYCH	Anxiety/ Anxiety Flare up	2	18SEP2020	24/C	1	Yes		NA/TC/TCN	N	N/N
16-55/ C4591001 1141 11411030	MUSC	Arthralgia/ right wrist pain	2	19SEP2020	25/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1141 11411032	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ Injection site pain left deltoid#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1141 11411036	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/4	2	Yes		NA/TC	R (21DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Feeling abnormal/ brain fog#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Head discomfort/ minor head pressure#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N
		Chills/ Rigors#	4	07JAN2021	2/1	2	Yes		NA/TC	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411041	INV	Body temperature increased/ elevated body temperature#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/5	1	Yes		NA	R (26DEC2020)	N/N
		Malaise/ Malaise#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1141 11411042	NERV	Headache/ Headache#	2	22DEC2020	120/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23DEC2020	2/4	1	Yes		NA/TC	R (26DEC2020)	N/N
	SKIN	Dermatitis/ Dermatitis torso area#	2	22DEC2020	119/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1141 11411045	GENRL	Injection site pain/ muscle soreness left arm injection site#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1141 11411046	EAR	Tympanic membrane perforation/ Perforated ear drum right ear	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1141 11411048	INFEC	Otitis media acute/ Acute Otitis media	2	27AUG2020	2/14	2	Yes		NA/TC	R (09SEP2020)	N/N
	INJ&P	Ankle fracture/ left bimalleolar fracture	1	22AUG2020	16/82	3	No	O	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411050	MUSC	Fall/ Fall	1	22AUG2020	16/1	3	No	O	NA/TC	R (22AUG2020)	N/N
		Myalgia/ Myalgia#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GASTR	Diverticulum/ Diverticulosis	2	14SEP2020	19/C	1	No	O	NA	N	N/N
	GENRL	Large intestine polyp/ colon polyp	2	14SEP2020	19/1	1	No	O	NA/TC	R (14SEP2020)	N/N
		Injection site pain/ injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
		NERV	Headache/ headache#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)
	GENRL	Fatigue/ Fatigue#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
MUSC	Myalgia/ myalgia#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
16-55/ C4591001 1141 11411051	GENRL	Injection site pain/ injection site soreness#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headaches#	3	09FEB2021	8/3	2	No	O	NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1141 11411053	PSYCH	Anxiety/ Worsening Anxiety	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411054	NERV	Depression/ Worsening depression	2	02DEC2020	99/62	2	No	O	NA/TC/TCN	R (01FEB2021)	N/N
		Headache/ Headache#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Feeling hot/ warm sensation#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
MUSC	Myalgia/ myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
16-55/ C4591001 1141 11411056	GENRL	Injection site hyperaesthesia/ Hyperesthesia left deltoid region on injection site	2	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C4591001 1141 11411061	GENRL	Chills/ chills#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ injection site soreness deltoid#	4	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ headache#	4	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411064	GENRL	Feeling cold/ Cold Sensation#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
	NERV	Headache/ Headache#	3	04JAN2021	1/2	2	Yes		NA/TC	R (05JAN2021)	N/N
	PSYCH	Insomnia/ Insomnia#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
	GENRL	Feeling cold/ Cold Sensation#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
		Malaise/ Malaise#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Left Shoulder Area Myalgia#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Flank pain/ Right sided flank pain#	4	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	16-55/ C4591001 1141 11411067	MUSC	Plantar fasciitis/ worsening of plantar fasciitis left foot	2	14SEP2020	13/C	2	No	O	NA/TC	RG
GENRL		Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ injection site pain#	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ Headache (worse than typical)#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	14JAN2021	2/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Myalgia/ Generalized Myalgia#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Arm Pain (injection)#	4	16JAN2021	4/2	1	Yes		NA	R (17JAN2021)	N/N
16-55/ C4591001 1141 11411068	GENRL	Injection site pain/ muscle soreness injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1141 11411070	GENRL	Chills/ chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Fatigue/ fatigue#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ injection site pain#	3	23DEC2020	1/2	2	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	15JAN2021	2/1	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1141 11411074	GASTR	Abdominal discomfort/ Stomach discomfort#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Malaise/ Malaise#	4	25FEB2021	2/1	2	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever (101 F)#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25FEB2021	2/1	3	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	2	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1141 11411077	GENRL	Injection site pain/ Post Injection Upper Arm Pain	2	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site bruising/ Injection Site Bruise	2	10SEP2020	2/12	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1141 11411079	PSYCH	Gastrointestinal somatic symptom disorder/ Stress related gastroesophageal reflux	1	21AUG2020	8/31	1	No	O	NA/TC/TCN	R (20SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	3	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ Chills#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	19JAN2021	1/C	2	Yes		NA	RG	N/N
	MUSC	Myalgia/ Myalgias#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411080	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA	R (21JAN2021)	N/N
	SKIN	Night sweats/ Night sweats#	4	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	28DEC2020	1/3	2	Yes		NA	R (30DEC2020)	N/Y
	GASTR	Nausea/ Nausea#	4	21JAN2021	2/1	2	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/2	2	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1141 11411082	MUSC	Arthralgia/ Generalized Arthralgia#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1141 11411084	INJ&P	Chest injury/ trauma left rib cage	2	09SEP2020	8/8	1	No	O	NA/TC/TCN	R (16SEP2020)	N/N
16-55/ C4591001 1141 11411087	VASC	Hot flush/ Hot flushes after vaccination#	3	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411088	GENRL	Injection site pain/ injection site pain#	3	24DEC2020	2/3	1	Yes		NA	R (26DEC2020)	N/N
16-55/ C4591001 1141 11411089	MUSC	Myalgia/ myalgia low back	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	NERV	Headache/ Post vaccination headache	1	18AUG2020	2/1	1	Yes		NA	R (18AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
	VASC	Flushing/ Facial Flushing	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1141 11411091	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	2	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1141 11411092	CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	10SEP2020	2/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411093	MUSC	Myalgia/ Lower back myalgia#	4	28JAN2021	2/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	16SEP2020	7/2	1	Yes		NA	R (17SEP2020)	N/N
1141 11411094	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	INV	Body temperature increased/ Elevated body temperature#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	19DEC2020	2/2	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever (102F)#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	2/1	2	Yes		NA	R (07JAN2021)	N/N
	HEPAT	Cholelithiasis/ cholelithiasis#	4	02FEB2021	28/7	2	No	O	NA/TC/TCN	R (08FEB2021)	N/N
16-55/ C4591001	INJ&P	Arthropod bite/ Insect bite left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411096	SKIN	Erythema/ Erythema left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
		Urticaria/ urticaria left ankle	1	31AUG2020	14/16	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1141 11411098	GASTR	Nausea/ Nausea#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	INV	Body temperature increased/ Body Temperature Increased#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	2/1	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1141 11411099	MUSC	Pain in extremity/ Post vaccination left upper arm pain#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1141 11411102	GENRL	Injection site pain/ injection site pain	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	CARD	Tachycardia/ tachycardia	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Dizziness/ lightheadedness	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411103	GASTR	Hypoaesthesia oral/ numbness of tongue	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
		Hypoaesthesia teeth/ numbness of teeth	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain left arm	2	09SEP2020	1/5	2	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
		Nausea/ nausea	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
		Toothache/ toothache	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site bruising/ bruising at injection site	2	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ body aches (myalgia)	2	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	2/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1141 11411104	INJ&P	Ligament sprain/ Sprained L Ankle	2	07OCT2020	30/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411106	MUSC	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Myalgia/ Generalized Myalgia#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA/TC/TCN	R (23AUG2020)	N/N
	NERV	Nerve compression/ Pinched nerve right leg	1	26AUG2020	8/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1141 11411108	GENRL	Injection site pain/ Left Arm Pain at injection site	1	11SEP2020	24/3	1	Yes		NA/TC/TCN	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Pain/ Body Aches	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Dizziness/ Lightheadedness	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1141 11411110	NERV	Headache/ Headache, worsening	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site tenderness#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
GENRL		Pyrexia/ Fever (100.0F)#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Injection related reaction/ upper shoulder pain (injection- related)#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
		Injection related reaction/ uppper arm bicep pain (injection- related)#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	1/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1141 11411113	GENRL	Injection site pain/ injection site pain	2	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	BLOOD	Lymphadenopathy/ swollen left axillary lymph node	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1141 11411114	GENRL	Injection site pain/ injection site tenderness	1	22AUG2020	2/3	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	11SEP2020	1/5	2	Yes		NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	1/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1141 11411116	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Myalgia/ Generalized Myalgia#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411118	GENRL	Injection site pain/ injection site soreness#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/Y
	GENRL	Injection site pain/ injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1141 11411119	GENRL	Injection site pain/ Injection Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1141 11411120	GASTR	Nausea/ nausea	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Asthenia/ generalized weakness	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
		Chills/ chills	2	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411121	INV	Body temperature increased/ elevated body temperature	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site induration/ induration at injection Site	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection Site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Joint range of motion decreased/ limited range of motion left arm#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
		Myalgia/ left upper arm pain at deltoid muscle#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Asthenia/ Lack of energy#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
		Fatigue/ Fatigue#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	Pyrexia/ Fever (102F)#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N	
16-55/ C4591001 1141 11411122	IMMUN	Seasonal allergy/ Exacerbation of seasonal allergies	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411123	RESP	Nasal congestion/ nasal congestion	2	21SEP2020	8/7	1	No	O	NA/TC	R (27SEP2020)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	INFEC	Urinary tract infection/ urinary tract infection#	4	10MAR2021	29/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/1	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1141 11411127	GENRL	Chills/ Chills#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1141 11411128	CARD	Tachycardia/ Tachycardia	1	31AUG2020	8/44	2	No	O	NA	R (13OCT2020)	N/N
	GENRL	Chills/ chills (rigors)#	3	27JAN2021	2/1	2	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site erythema/ erythema (injection site)#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ injection site tenderness#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site erythema/ erythema at injection site#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
		Injection site pain/ Sore deltoid (injection site pain)#	4	18FEB2021	2/4	1	Yes		NA/TC	R (21FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.3F)#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	18FEB2021	2/4	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1141 11411129	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411130	GENRL	Injection site pain/ injection site pain	1	25AUG2020	1/5	2	Yes		NA/TCN	R (29AUG2020)	N/N
		Pyrexia/ low grade fever	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/5	2	Yes		NA	R (19SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	15SEP2020	1/3	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	16SEP2020	2/2	2	Yes		NA/TC/TCN	R (17SEP2020)	N/N
16-55/ C4591001 1141 11411131	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain Right Arm	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1141 11411132	GENRL	Fatigue/ fatigue#	3	29DEC2020	1/3	2	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ injection site pain#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	29DEC2020	1/3	2	Yes		NA	R (31DEC2020)	N/N
	NERV	Headache/ headache#	3	29DEC2020	1/3	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1141 11411135	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411136	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Body Muscle Aches	2	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site PAin	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	4/4	1	Yes		NA	R (20SEP2020)	N/N
	INV	Weight increased/ Adverse Drug Reaction-Weight Gain	2	NOV2020	49/	1	No	O	NA	R	N/N
	GASTR	Gastritis/ Gastritis#	2	25JAN2021	134/6	1	No	O	NA	R (30JAN2021)	N/N
	Irritable bowel syndrome/ Worsening Irritable Bowel Syndrome#	2	25JAN2021	134/30	1	No	O	NA	R (23FEB2021)	N/N	
16-55/ C4591001 1141 11411137	GENRL	Injection site pain/ Injection Site Pain Left Arm	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411139	GENRL	Fatigue/ Fatigue#	4	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ injection site pain#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Myalgia/ myalgia#	4	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1141 11411140	GENRL	Injection site pain/ Injection Site Pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	INJ&P	Thermal burn/ Burn Injury, left hand#	3	10JAN2021	20/6	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/6	1	Yes		NA	R (17JAN2021)	N/N
	MUSC	Myalgia/ muscle achiness#	4	12JAN2021	2/4	1	Yes		NA/TC	R (15JAN2021)	N/N
	PSYCH	Irritability/ irritability#	4	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N
	SKIN	Cold sweat/ cold sweats#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	BLOOD	Lymphadenopathy/ lymphadenopathy (left axillary, clavicle, elbow)#	4	13JAN2021	3/5	2	Yes		NA	R (17JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411141	GASTR	Diarrhoea/ Diarrhea	2	19SEP2020	3/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1141 11411142	GASTR	Abdominal pain/ Acute Abdominal Pain	2	22NOV2020	67/4	3	No	O	NA/TC	R (25NOV2020)	N/N
	GENRL	Injection site pain/ left deltoid pain at injection site#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	2	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1141 11411146	GENRL	Chills/ Chills#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1141 11411148	GENRL	Injection site pain/ arm pain at injection site	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pain/ body aches	2	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ elevated body temperature, max temp 99.8	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1141 11411149	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1141 11411151	GENRL	Pyrexia/ low grade fever	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ whole body myalgia	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	INV	Body temperature increased/ elevated body temperature#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Back pain/ Mid-region back pain#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411152	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/3	3	Yes		NA	R (08JAN2021)	N/N
	GENRL	Pyrexia/ Fever (tmax 102.7 F) and sweats#	4	07JAN2021	2/1	3	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	07JAN2021	2/2	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411153	CARD	Junctional ectopic tachycardia/ Junctional ectopic tachycardia	2	02OCT2020	12/97	4	No	O	NA/TC/TCN	RS (06JAN2021)	Y/N
	NERV	Dizziness/ Lightheadedness	2	02OCT2020	12/C	3	No	O	NA/TC	RG	N/N
	CARD	Tachycardia/ Tachycardia	2	03OCT2020	13/C	3	No	O	NA/TC	RG	N/N
	CARD	Tachycardia/ Tachycardia	2	13JAN2021	115/C	2	No	O	NA/TC	N	N/N
	NERV	Dizziness/ Dizziness	2	14JAN2021	116/16	2	No	CD	NA	R (29JAN2021)	N/N
		Dizziness/ Lightheadedness	2	14JAN2021	116/16	2	No	CD	NA	R (29JAN2021)	N/N
		Headache/ Headache	2	14JAN2021	116/16	3	No	CD	NA	R (29JAN2021)	N/N
	NERV	Presyncope/ Near syncopal episode#	3	2021	1/C	2	No	O	NA	N	N/N
	GENRL	Fatigue/ Fatigue#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ Dizziness#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N
		Headache/ Headache#	3	15FEB2021	7/11	3	No	CD	NA	R (25FEB2021)	N/N
16-55/ C4591001 1141 11411154	GENRL	Injection site pain/ injection site pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1141 11411156	NERV	Headache/ headache	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	20SEP2020	21/4	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain (Neck, Bilateral Hands)	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		Hyperaesthesia/ bilateral hand increased sensation to touch	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1141 11411158	GENRL	Feeling hot/ warmth sensation#	3	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ injection site tenderness#	3	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
		Malaise/ malaise#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411159	GENRL	Injection site pain/ Injection site pain left arm	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
		Pain/ body aches	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ headache	2	22SEP2020	1/3	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1141 11411161	RESP	Dyspnoea exertional/ shortness of breathe while exercising	1	21SEP2020	20/17	1	No	O	NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle pain (generalized right arm)#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/Y
	NERV	Dizziness/ Transient episodes lightheadedness#	3	15FEB2021	7/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1141 11411162	NERV	Dizziness/ Lightheadedness	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	16OCT2020	24/7	2	No	O	NA	R (22OCT2020)	N/N
	GENRL	Pyrexia/ fever#	3	27JAN2021	1/2	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411163	MUSC	Myalgia/ myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Arthralgia/ Worsening bilateral knee pain (persistent)	1	SEP2020	1/C	2	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/1	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain left arm	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature, temp. max 99.7	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1141 11411164	GENRL	Injection site pain/ Injection pain left arm.	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Tendonitis/ tendonitis left arm	1	02SEP2020	1/39	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	2	13JAN2021	1/4	2	Yes		NA	R (16JAN2021)	N/N
		Injection site pain/ sore arm (injection site)#	2	13JAN2021	1/5	1	Yes		NA	R (17JAN2021)	N/N
	INV	Body temperature increased/ body temperature increased (F)#	2	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411165	NERV	Dizziness/ lightheaded#	2	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	INV	Body temperature increased/ body temperature increased (tmax 100.1F)#	4	07JAN2021	1/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1141 11411166	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	2	Yes		NA	R (20SEP2020)	N/N
	INV	Body temperature increased/ Elevated body temperature	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1141 11411167	GENRL	Injection site pain/ Injection site pain.	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411168	INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	
	SKIN	Hyperhidrosis/ Sweating	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N	
	16-55/ C4591001 1141 11411169	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	16-55/ C4591001 1141 11411170	GASTR	Nausea/ Nausea#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Asthenia/ Lack of Energy#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Injection site swelling/ Swelling at injection site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
	GENRL	Malaise/ Malaise#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N	
MUSC	Myalgia/ Generalized Myalgias#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N		
NERV	Headache/ Headache#	3	12FEB2021	2/2	2	Yes		NA	R (13FEB2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411171	GASTR	Diarrhoea/ Diarrhea#	3	13FEB2021	3/1	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Pyrexia/ Fever (T Max 104 F)#	3	13FEB2021	3/1	3	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site pain/ injection pain left upper arm	1	03SEP2020	1/4	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	20SEP2020	18/6	2	Yes		NA	R (25SEP2020)	N/N
	GASTR	Abdominal pain upper/ gastralgia	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/C	2	Yes		NA	RG	N/N
	INV	Body temperature increased/ elevated body temperature	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Back pain/ back pain	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	23SEP2020	2/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1141 11411172	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
		Malaise/ Malaise#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Generalized Myalgia#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1141 11411173	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1141 11411174	GENRL	Chills/ chills	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
		Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
		Pain/ body aches	2	25SEP2020	1/3	3	Yes		NA/TC	R (27SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature, max temp 99.0	2	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1141 11411175	GENRL	Injection site pain/ Injection Site Pain#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1141 11411176	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411177	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	25SEP2020	2/4	2	Yes		NA/TC	R (28SEP2020)	N/N
	MUSC	Arthralgia/ Bilateral Knee Arthralgia	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
		Back pain/ Back Ache	2	25SEP2020	2/4	1	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	26SEP2020	3/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site swelling/ Swelling at the Injection Site	2	27SEP2020	4/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1141 11411179	GENRL	Injection site pain/ muscle soreness injection arm	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headaches	1	14SEP2020	7/11	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411181	BLOOD	Lymph node pain/ tender left lymph node axillary	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature, max temp 103.3	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Left arm injection site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	22JAN2021	1/2	1	Yes		NA/TCN	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1141 11411182		Feeling hot/ Warm Sensation#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Back pain/ back pain	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
	INFEC	Vaginal infection/ Vaginal Infection	1	17SEP2020	10/8	1	No	O	NA/TC	R (24SEP2020)	N/N
	INJ&P	Limb injury/ puncture injury (stepped on nail) left foot	2	09DEC2020	70/15	1	No	O	NA/TC	R (23DEC2020)	N/N
	NERV	Headache/ Headaches	1	25SEP2020	17/8	1	No	O	NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411185	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Chills/ Chills	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ Muscle Soreness	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
	Injection site pain/ Injection Site Pain	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N	
	MUSC	Myalgia/ Muscle Aches	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	10SEP2020	2/5	2	Yes		NA/TC	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411186	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Injection Site Soreness Left Arm	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/3	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411187	GENRL	Injection site swelling/ Injection site swelling	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	4/2	2	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	02OCT2020	2/1	2	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411188	GENRL	Injection site pain/ injection site soreness	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411192	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	MUSC	Myalgia/ Generalized Myalgia	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection site pain left arm deltoid	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	INV	Body temperature increased/ Elevated body Temperature	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N	
16-55/ C4591001 1141 11411194	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/3	2	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ injection site pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	INV	Body temperature increased/ elevated body temperature 101.3F#	4	12JAN2021	2/1	1	Yes		NA/TC	R (12JAN2021)	N/N
16-55/ C4591001 1141 11411195	INFEC	Sinusitis/ Sinus Infection	1	30SEP2020	21/10	2	No	O	NA/TC	R (09OCT2020)	N/N
	SKIN	Alopecia/ patchy hair loss	2	28FEB2021	138/C	1	No	O	NA	N	N/N
16-55/ C4591001 1141 11411197	GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ injection site pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411198	GENRL	Injection site pain/ Injection site pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		Injection site swelling/ swelling injection area	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/3	2	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	01OCT2020	2/5	2	Yes		NA	R (05OCT2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	01OCT2020	2/3	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
		Injection site macule/ Skin Macule at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	04OCT2020	5/4	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1141 11411199	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ injection site pain#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Generalized myalgia#	4	29JAN2021	1/3	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ Worsening headache (from baseline)#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411201 16-55/ C4591001 1141 11411202	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	14SEP2020	4/11	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1141 11411203	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection site pain left extremity	1	12SEP2020	2/3	2	Yes		NA	R (14SEP2020)	N/N
	INV	Body temperature increased/ Elevated body temperature	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	30SEP2020	20/3	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1141 11411204	SKIN	Pityriasis rosea/ Neck rash pityriasis rosea	2	07DEC2020	68/55	1	No	O	NA/TC	R (30JAN2021)	N/N
		Pityriasis rosea/ Truncal rash pityriasis rosea	2	07DEC2020	68/55	1	No	O	NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	2	09FEB2021	132/1	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ injection site sore arm deltoid area#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411205	NERV	Headache/ headache#	2	09FEB2021	132/1	2	Yes		NA	R (09FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain left arm	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	1	15SEP2020	2/3	2	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ headache	1	29SEP2020	16/2	1	No	O	NA/TC	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1141 11411206	NERV	Headache/ headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411208	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	01FEB2021	1/4	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Chills/ Chills (Rigors)#	4	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1141 11411209		Pyrexia/ Fever (103.1)#	4	14JAN2021	2/1	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1141 11411211	GENRL	Injection site pain/ injection site pain	2	07OCT2020	1/3	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pyrexia/ low grade fever, max temp 99.9	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ left deltoid muscle soreness#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever (100.6 F)#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	1/4	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411212	GENRL	Injection site bruising/ Bruise at Injection Site	1	16SEP2020	2/6	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1141 11411213	GENRL	Injection site pain/ injection site pain left upper arm	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	16SEP2020	2/1	2	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
		Myalgia/ Muscle Pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GASTR	Tooth impacted/ Impacted Wisdom Teeth	2	16OCT2020	4/1	2	No	O	NA/TC/TCN	R (16OCT2020)	N/N
	INFEC	Endometritis/ Endometritis#	2	08MAR2021	147/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001	INV	Body temperature increased/ elevated body temperature, max temp 99.3	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411214	GENRL	Fatigue/ fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
	PSYCH	Mental fatigue/ Mental fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	04FEB2021	1/3	2	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ tenderness at injection site#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1141 11411215	GENRL	Fatigue/ fatigue	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias#	4	19JAN2021	1/2	2	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20JAN2021	2/1	3	Yes		NA/TC	R (20JAN2021)	N/N
	INV	Body temperature increased/ body temperature increased (99.1)#	4	20JAN2021	2/1	3	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1141 11411217	GENRL	Fatigue/ fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411218	GENRL	Fatigue/ fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ injection site pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ low grade fever	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature, temperature 100.4	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Muscular weakness/ muscle weakness	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site erythema	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site myalgia	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	METAB	Decreased appetite/ Loss of Appetite	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ injection site soreness	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411219		Injection site pain/ injection site pain#	4	24FEB2021	2/2	3	Yes		NA/TC	R (25FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.6F)#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness Right Arm	1	16SEP2020	1/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site warmth/ Warm Sensation at Injection Site	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	VASC	Flushing/ General Flushing	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1141 11411220	GENRL	Injection site pain/ Injection site pain left arm	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Chills/ Chills	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pain/ Body aches	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body Aches	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1141 11411221	GENRL	Chills/ chills#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411222	BLOOD	Fatigue/ Fatigue#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ Fever (100.9 F)#	3	21JAN2021	2/2	1	Yes		NA/TC	R (22JAN2021)	N/N
		Lymphadenopathy/ left axillary lymph node enlargement#	3	23JAN2021	4/3	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia, Bilateral Knees	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Myalgia/ Myalgia	1	17SEP2020	2/3	1	Yes		NA/TC	R (19SEP2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection Site Soreness	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1141 11411223	GENRL	Injection site pain/ Injection Site Soreness	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
NERV	Headache/ Headache	1	17SEP2020	2/7	1	Yes		NA/TC	R (23SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411224	GENRL	Injection site pain/ Injection Site Soreness	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1141 11411226	GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1141 11411227	GENRL	Injection site pain/ Pain at injection site left arm	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
	PSYCH	Anxiety/ Worsening anxiety	1	18SEP2020	2/4	1	Yes		NA/TC	R (21SEP2020)	N/N
		Depression/ Worsening depression	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/Y
	MUSC	Myalgia/ Generalized Myalgias	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411229	PSYCH	Depression/ Worsening depression	2	24OCT2020	16/C	2	No	O	NA/TC	N	N/N	
	GASTR	Nausea/ nausea (in evening)#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N	
	GENRL	Injection site pain/ injection site soreness#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N	
16-55/ C4591001 1141 11411230	GENRL	Injection site pain/ injection site soreness left arm	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N	
16-55/ C4591001 1141 11411231	MUSC	Myalgia/ muscle aches	1	18SEP2020	1/14	1	Yes		NA	R (01OCT2020)	N/N	
	INV	Body temperature increased/ elevated body temperature, temperature 99.1	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N	
	BLOOD	Lymphadenopathy/ enlarged left interior neck lymph node	1	30SEP2020	13/C	1	Yes		NA	N	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/Y	
	MUSC	Back pain/ Myalgia in Entire Back	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N	
	MUSC	Back pain/ Right Sided Upper Back Pain	2	17OCT2020	2/1	2	No	O	NA	R (17OCT2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain Right Arm	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1141 11411235	GENRL	Injection site pain/ injection site soreness	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1141 11411236	NERV	Paraesthesia/ Facial Tingling	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	10OCT2020	2/5	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1141 11411237	GENRL	Fatigue/ Fatigue	1	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1141 11411238	MUSC	Myalgia/ generalized myalgias#	3	12FEB2021	1/1	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Right wrist pain	1	SEP2020	1/C	1	No	O	NA/TCN	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411239 16-55/ C4591001 1141 11411240	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site swelling/ Swelling at Injection Site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	IMMUN	Seasonal allergy/ Seasonal Allergies	1	01OCT2020	10/32	1	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	13OCT2020	1/34	1	Yes		NA	R (15NOV2020)	N/N
		Malaise/ Malaise	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1141 11411241	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
	INV	Body temperature increased/ body temperature increased	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgias	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411242	NERV	Headache/ Headache	2	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	INFEC	Puncture site infection/ infected ear piercing right ear	2	27OCT2020	13/12	1	No	O	NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ sore deltoid left arm (injection area)#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1141 11411243	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain Left Arm	1	24SEP2020	1/3	2	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Axillary pain/ Left Sided Axilla Pain	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Neck pain/ L Sided Cervical Pain	2	15OCT2020	2/5	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001 1141 11411245	GENRL	Fatigue/ fatigue#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411246	GENRL	Injection site pain/ injection site pain#	3	16DEC2020	1/2	2	Yes		NA/TC	R (17DEC2020)	N/N
		Chills/ chills (rigor)#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
	MUSC	Injection site pain/ injection site pain#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
		Myalgia/ myalgia#	4	04JAN2021	1/2	1	Yes		NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1141 11411247	GENRL	Injection site pain/ Injection Site Pain Right Arm	1	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
	GENRL	Pain/ Body Aches	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ injection site soreness	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1141 11411247	GENRL	Fatigue/ fatigue	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1141 11411248	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/3	2	Yes		NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1141 11411249	GENRL	Injection site pain/ Injection site myalgia left arm	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site swelling/ Swelling at Injection Site Left Arm	1	26SEP2020	2/2	1	Yes		NA/TC	R (27SEP2020)	N/N
		Injection site warmth/ Warm Sensation at injection site left Arm	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
		Injection site warmth/ Warmth at Injection Site	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Musculoskeletal stiffness/ L Upper Arm Stiffness	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Feeling cold/ Feeling Cold	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Arthralgia/ L Sided Shoulder Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		Neck pain/ L Sided Neck Pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Dizziness/ Lightheaded	2	14OCT2020	2/1	2	Yes		NA/TCN	R (14OCT2020)	N/N
16-55/ C4591001 1141 11411250	GENRL	Fatigue/ Fatigue after blood draw*		05OCT2020	1/1	1	No	O	NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	03FEB2021	1/3	2	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	2/3	2	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1141 11411251	MUSC	Myalgia/ generalized body aches (myalgia)#	3	04FEB2021	2/3	2	Yes		NA/TC	R (06FEB2021)	N/N	
	NERV	Headache/ headache#	3	04FEB2021	2/3	1	Yes		NA/TC	R (06FEB2021)	N/N	
	MUSC	Myalgia/ generalized body aches (myalgia)#	4	24FEB2021	1/4	2	Yes		NA/TC	R (27FEB2021)	N/N	
	NERV	Headache/ headache#	3	24FEB2021	22/4	1	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N	
	GENRL	Injection site pain/ injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N	
	16-55/ C4591001 1141 11411255	GENRL	Injection site pain/ injection site pain left arm	1	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/Y
	GENRL	Injection site pain/ Injection site soreness	2	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1141 11411256	GENRL	Injection site pain/ Injection site soreness#	3	17FEB2021	1/3	2	Yes		NA	R (19FEB2021)	N/Y	
	GENRL	Injection site bruising/ Bruising at injection site	1	05NOV2020	2/4	1	Yes		NA	R (08NOV2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411257	MUSC	Muscle spasms/ Muscle cramping in right shoulder	1	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	1	08NOV2020	5/2	2	Yes		NA/TC	R (09NOV2020)	N/N
	MUSC	Musculoskeletal chest pain/ Localized Rib pain#	2	29DEC2020	26/35	2	No	O	NA/TC	R (01FEB2021)	N/N
	GENRL	Chills/ Chills#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Chills/ Chills	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	1	13OCT2020	2/1	1	Yes		NA/TC	R (13OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	02NOV2020	1/5	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ Erythema at injection site	2	03NOV2020	2/5	2	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site swelling/ Swelling at injection site	2	03NOV2020	2/5	2	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ left deltoid muscle pain (injection site) (woke her in the night)#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1141 11411260	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/2	2	Yes	NA	NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes	NA	NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/3	1	Yes	NA	NA	R (20FEB2021)	N/N
	INV	Body temperature increased/ elevated body temperature (99.9F)#	4	18FEB2021	2/3	1	Yes	NA	NA	R (20FEB2021)	N/N
	RESP	Rhinorrhoea/ Rhinorrhea#	4	18FEB2021	2/3	1	Yes	NA	NA	R (20FEB2021)	N/N
	GENRL	Injection site bruising/ Bruise at injection site#	4	20FEB2021	4/C	1	Yes	NA	NA	N	N/N
16-55/ C4591001 1141 11411262	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	2/2	1	Yes	NA	NA	R (06FEB2021)	N/N
16-55/ C4591001 1141 11411263	GENRL	Injection site pain/ Left Arm Soreness at Injection Site	1	19OCT2020	1/3	2	Yes	NA	NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	10NOV2020	2/2	1	Yes	NA/TC	NA/TC	R (11NOV2020)	N/N
	INV	Body temperature increased/ Elevated Body Temperature	2	10NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (10NOV2020)	N/N
	MUSC	Myalgia/ Generalized Myalgia	2	10NOV2020	2/2	2	Yes	NA/TC	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411264	GENRL	Fatigue/ Fatigue	2	11NOV2020	3/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Pain in extremity/ Upper Arm Soreness L Side, deltoid muscle area	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site haemorrhage/ Ecchymosis at Injection Site	1	22OCT2020	3/5	1	Yes		NA	R (26OCT2020)	N/N
	EAR	Otorrhoea/ Ear discharge	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	2	Yes		NA	R (11NOV2020)	N/N
		Injection site pain/ Injection site soreness	2	10NOV2020	1/9	1	Yes		NA	R (18NOV2020)	N/N
	INV	Body temperature increased/ Elevated body temperature	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site haemorrhage/ Ecchymosis at injection site	2	11NOV2020	2/8	1	Yes		NA	R (18NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	2	11NOV2020	2/8	1	Yes		NA	R (18NOV2020)	N/N
	SKIN	Hyperhidrosis/ Diaphoresis	2	11NOV2020	2/1	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1141 11411265	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1141 11411266	MUSC	Arthralgia/ Left Shoulder Pain in vaccinated arm	1	21OCT2020	1/4	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/1	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1141 11411269	GENRL	Injection site erythema/ Slight Erythema at Injection Site	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Injection site pain/ injection site soreness	1	27OCT2020	1/2	2	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Dizziness/ Light Headed	2	18NOV2020	1/2	1	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1141 11411270	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Injection site pain/ injection site soreness left deltoid#	4	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Chills/ chills#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421007	INV	Fatigue/ Fatigue#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
		Malaise/ malaise#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N
		Body temperature increased/ elevated body temperature tmax 100.0F#	4	14JAN2021	2/1	1	Yes		NA/TC	R (14JAN2021)	N/N
		Myalgia/ muscles aches#	4	14JAN2021	2/1	2	Yes		NA/TC	R (14JAN2021)	N/N
		Lymphadenopathy/ enlarged lymph node left arm axillary#	4	15JAN2021	3/3	1	Yes		NA	R (17JAN2021)	N/N
	SKIN	Pruritus/ Diffuse itching#	3	30DEC2020	1/2	2	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	31DEC2020	2/7	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Pain/ Body aches#	3	31DEC2020	2/3	1	Yes		NA	R (02JAN2021)	N/N
		Pain/ Body Aches#	4	21JAN2021	2/4	2	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/1	2	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1142 11421010	GENRL	Injection site pain/ Injection site pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	2/5	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421020	GASTR	Nausea/ nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1142 11421022	GENRL	Injection site pain/ injection site pain#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Malaise/ malaise#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		Pyrexia/ fever#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1142 11421041	GENRL	Injection site pain/ injection site pain#	2	20DEC2020	114/5	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Pain/ Body aches#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	04FEB2021	23/2	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1142 11421045	GENRL	Injection site pain/ injection site pain#	3	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Ecchymosis/ ecchymosis at left antecubital fossa#	3	27FEB2021	2/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1142 11421049	NERV	Headache/ headache#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/3	1	Yes		NA	R (21DEC2020)	N/N
16-55/ C4591001 1142 11421051	GENRL	Pain/ body aches#	4	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1142 11421052	SKIN	Rash/ rash	1	18AUG2020	13/8	2	No	O	NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1142 11421056	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	2	Yes		NA	R (01JAN2021)	N/N
	GENRL	Chills/ chills#	4	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Malaise/ malaise#	4	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1142 11421059	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421060	GENRL	Injection site pain/ injection site pain#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Pain/ body aches#	4	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ fatigue#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ injection site pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
16-55/ C4591001 1142 11421066	GENRL	Pain/ body aches#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ injection site pain#	3	05JAN2021	1/2	2	Yes		NA	R (06JAN2021)	N/N
		Chills/ chills#	4	26JAN2021	1/1	2	Yes		NA	R (26JAN2021)	N/Y
16-55/ C4591001 1142 11421067	GENRL	Injection site pain/ injection site pain#	4	26JAN2021	1/1	2	Yes		NA	R (26JAN2021)	N/Y
		Fatigue/ fatigue#	4	19JAN2021	8/8	3	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1142 11421078	GENRL	Injection site pain/ injection site pain#	3	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421079 16-55/ C4591001 1142 11421084	INJ&P	Craniocerebral injury/ Closed head injury	1	19AUG2020	8/1	3	No	O	NA	R (19AUG2020)	N/N
1142 11421084	PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N
16-55/ C4591001 1142 11421090	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA/TC/TCN	R (18DEC2020)	N/N
1142 11421090	NERV	Headache/ headache#	3	30DEC2020	14/2	1	No	O	NA/TCN	R (31DEC2020)	N/N
1142 11421090	GENRL	Chills/ chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
1142 11421090	NERV	Headache/ headache#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1142 11421092	GENRL	Chills/ chills#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N
1142 11421092		Fatigue/ fatigue#	3	18DEC2020	1/3	1	Yes		NA/TC/TCN	R (20DEC2020)	N/N
1142 11421092		Injection site pain/ injection site pain#	2	18DEC2020	107/3	3	Yes		NA/TC/TCN	R (20DEC2020)	N/N
1142 11421092	MUSC	Arthralgia/ Generalized joint pain#	3	18DEC2020	1/3	2	Yes		NA/TC	R (20DEC2020)	N/N
1142 11421092		Myalgia/ muscle aches#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421096	SKIN	Hyperhidrosis/ sweating#	3	18DEC2020	1/3	2	Yes		NA/TC/TCN	R (20DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1142 11421107	GENRL	Injection site pain/ injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	INJ&P	Thermal burn/ 2 in burn to left calf	2	17NOV2020	71/	2	No	O	NA/TC/TCN	R	N/N
16-55/ C4591001 1142 11421115	INJ&P	Muscle strain/ muscle strain#	2	07MAR2021	181/C	2	No	O	NA/TC	RG	N/N
	MUSC	Myalgia/ muscle ache#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
16-55/ C4591001 1142 11421119	GENRL	Pain/ body aches#	4	22JAN2021	2/4	2	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	4	22JAN2021	2/4	2	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1142 11421119	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	2	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1142 11421130	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/3	2	Yes		NA	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421138	GENRL	Chills/ chills#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
		Pain/ body aches#	4	09JAN2021	2/1	3	Yes		NA	R (09JAN2021)	N/N
	GENRL	Swelling face/ Facial swelling#	3	26JAN2021	14/2	3	No	O	NA/TC	R (27JAN2021)	N/N
	IMMUN	Hypersensitivity/ Allergic reaction#	3	26JAN2021	14/2	3	No	O	NA/TC	R (27JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
	NERV	Paraesthesia/ generalized tingling sensation#	4	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
	MUSC	Arthralgia/ left shoulder pain	1	28AUG2020	8/C	2	No	O	NA/TC	RG	N/N
	GENRL	Pyrexia/ fever#	4	05FEB2021	2/3	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Arthralgia/ worsening right shoulder pain#	4	05FEB2021	2/8	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1142 11421142		Back pain/ worsening back pain#	4	05FEB2021	2/8	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421157		Fatigue/ fatigue#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
		Pain/ body aches#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ fever#	4	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1142 11421158	GENRL	Axillary pain/ left axillary pain	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1142 11421161	GENRL	Injection site erythema/ Redness at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1142 11421163	GENRL	Chills/ chills	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
		Injection site erythema/ injection site redness	1	01SEP2020	2/11	2	Yes		NA/TC/TCN	R (11SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	02SEP2020	3/6	2	Yes		NA/TC/TCN	R (07SEP2020)	N/N
		Injection site swelling/ injection site swelling	1	02SEP2020	3/6	2	Yes		NA/TC/TCN	R (07SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA/TC/TCN	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421166	GENRL	Pain/ body aches	2	24SEP2020	2/3	2	Yes		NA/TC/TCN	R (26SEP2020)	N/N
		Pyrexia/ fever of 101.4 F	2	25SEP2020	3/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	GASTR	Nausea/ nausea	2	23SEP2020	2/3	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/3	2	Yes		NA/TCN	R (25SEP2020)	N/N
	GENRL	Pain/ full body aches	2	24SEP2020	3/3	2	Yes		NA/TCN	R (26SEP2020)	N/N
16-55/ C4591001 1142 11421173	GENRL	Injection site pain/ injection site pain	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/Y
	GENRL	Injection site bruising/ injection site bruising	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	2	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1142 11421175	GENRL	Injection site pain/ injection site pain#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	06FEB2021	2/2	2	Yes		NA	RS (07FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/15	2	Yes		NA	R (17SEP2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421181	GENRL	Injection site swelling/ injection site swelling	1	04SEP2020	2/3	2	Yes	NA		R (06SEP2020)	N/N
	GENRL	Malaise/ malaise	2	26SEP2020	2/2	2	Yes	NA		R (27SEP2020)	N/N
		Pain/ generalized body aches	2	26SEP2020	2/2	2	Yes	NA/TC		R (27SEP2020)	N/N
		Pyrexia/ fever of 100.5 F	2	26SEP2020	2/2	1	Yes	NA/TC		R (27SEP2020)	N/N
16-55/ C4591001 1142 11421182	GENRL	Injection site pain/ Injection site pain#	4	08JAN2021	2/1	2	Yes	NA		R (08JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	08JAN2021	2/1	2	Yes	NA		R (08JAN2021)	N/N
16-55/ C4591001 1142 11421183	GENRL	Chills/ chills#	4	11JAN2021	1/2	1	Yes	NA		R (12JAN2021)	N/N
		Pyrexia/ fever#	4	11JAN2021	1/2	1	Yes	NA		R (12JAN2021)	N/N
16-55/ C4591001 1142 11421184	GENRL	Asthenia/ generalized weakness	2	24SEP2020	1/2	1	Yes	NA		R (25SEP2020)	N/N
		Pyrexia/ fever of 101.0 F	1	24SEP2020	22/3	2	Yes	NA		R (26SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	1/2	1	Yes	NA		R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421185	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Pain/ body aches	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1142 11421188	NERV	Headache/ headache	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1142 11421202	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1142 11421205	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N
	GENRL	Injection site pain/ injection site pain#	3	01JAN2021	2/3	2	Yes		NA	R (03JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1142 11421212 16-55/ C4591001 1142 11421219	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Pain/ Body aches	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1142 11421222	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/3	2	Yes		NA	R (08OCT2020)	N/N
	SKIN	Rash/ Rash on neck	2	06OCT2020	2/4	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1142 11421230	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1142 11421231	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Malaise/ Malaise	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421233	GENRL	Injection site pain/ Injection Site Pain	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Pain/ Body aches	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1142 11421234	GENRL	Injection site pain/ injection site pain#	3	03MAR2021	2/3	2	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1142 11421235	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ injection site (left deltoid) soreness	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1142 11421244	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1142 11421245	GENRL	Pain/ Body aches	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1142 11421248	GENRL	Injection site pain/ injection site (left deltoid) soreness	1	21SEP2020	1/4	2	Yes		NA/TCN	R (24SEP2020)	N/N
	SKIN	Hyperhidrosis/ profuse sweating	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421250	GENRL	Fatigue/ fatigue	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Muscular weakness/ muscle weakness	2	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Injection site erythema/ injection site redness	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		Injection site pruritus/ injection site itching	2	16OCT2020	4/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	18DEC2020	1/2	2	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	4	08JAN2021	1/6	2	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Neck pain/ unilateral neck pain#	4	09JAN2021	2/5	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	10JAN2021	3/3	2	Yes		NA	R (12JAN2021)	N/N
	16-55/ C4591001 1142 11421251	GENRL	Injection site pain/ injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)
	GENRL	Injection site pain/ injection site pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Pain/ body aches#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421253	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1142 11421256	BLOOD	Lymphadenopathy/ left axillary lymph node swelling#	3	17DEC2020	2/3	2	Yes		NA	R (19DEC2020)	N/N
	BLOOD	Lymphadenopathy/ right cervical lymph node swelling#	3	24DEC2020	9/2	2	Yes		NA	R (25DEC2020)	N/N
	BLOOD	Lymphadenopathy/ swollen left axillary lymph node#	4	07JAN2021	3/4	2	Yes		NA	R (10JAN2021)	N/N
	BLOOD	Lymphadenopathy/ swollen right cervical lymph node#	4	12JAN2021	8/8	2	No	O	NA	R (19JAN2021)	N/N
16-55/ C4591001 1142 11421258	GENRL	Malaise/ Malaise	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1142 11421264	NERV	Somnolence/ sleepiness#	3	18DEC2020	1/1	2	Yes		NA/TCN	R (18DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	19DEC2020	2/3	3	Yes		NA	R (21DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
		Pain/ body aches#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ fever#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1142 11421265	GENRL	Malaise/ malaise#	4	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1142 11421271	BLOOD	Blood loss anaemia/ anemia secondary to menorrhoea	1	2020	1/C	2	No	O	NA/TC/TCN	RG	N/N
	GENRL	Chest pain/ chest pain, atypical	2	05DEC2020	41/2	2	No	O	NA/TC	R (06DEC2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Vomiting/ vomiting#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ chills#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ fatigue#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Pain/ body aches#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421276	GENRL	Pyrexia/ fever#	4	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ injection site pain#	3	29DEC2020	1/2	2	Yes		NA	R (30DEC2020)	N/N
	NERV	Dizziness/ light-headedness#	4	20JAN2021	1/C	1	Yes		NA	N	N/Y
	GENRL	Pain/ body aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ headache#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1142 11421284	SURG	Injection/ injection#	3	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1142 11421287	GENRL	Injection site pain/ injection site pain#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
		Malaise/ malaise#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	13JAN2021	2/1	2	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1142 11421289	GENRL	Asthenia/ weakness	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Fatigue/ fatigue	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1142 11421292	GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Pain/ generalized body aches	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Pain/ body aches#	3	22DEC2020	2/2	2	Yes		NA	R (23DEC2020)	N/N
		Chills/ chills#	4	13JAN2021	2/3	3	Yes		NA	R (15JAN2021)	N/N
		Pain/ body aches#	4	13JAN2021	2/3	3	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1142 11421295	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
		Fatigue/ fatigue#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ injection site pain#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1142 11421306	GENRL	Injection site pain/ injection site pain#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N
		Chills/ chills#	3	20JAN2021	22/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1142 11421313	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/4	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451002	INJ&P	Chemical burns of eye/ chemical injury to Right Eye#	2	23JAN2021	144/5	2	No	O	NA	R (27JAN2021)	N/N
16-55/ C4591001 1145 11451017	GENRL	Fatigue/ fatigue	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1145 11451019	GENRL	Fatigue/ Fatigue	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site pain	2	08SEP2020	1/6	3	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	08SEP2020	1/3	3	Yes		NA	R (10SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1145 11451022	GENRL	Chills/ Chills	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N
		Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection site pain	1	18AUG2020	1/3	2	Yes		NA/TC	R (20AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451025	GENRL	Fatigue/ Fatigue	1	19AUG2020	2/2	3	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Injection site pain	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	2/2	2	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1145 11451026	GENRL	Injection site pain/ Injection site pain	1	18AUG2020	1/1	1	Yes		NA	R (18AUG2020)	N/Y
	GENRL	Injection site swelling/ injection site swelling	2	11SEP2020	3/7	1	Yes		NA	R (17SEP2020)	N/N
	IMMUN	Seasonal allergy/ worsening of seasonal allergies	2	28SEP2020	20/2	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1145 11451030	GENRL	Chills/ chills	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ headache	1	22AUG2020	2/1	2	Yes		NA	R (22AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pain in extremity/ left arm pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ headache	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451031	RESP	Paranasal sinus discomfort/ Sinus pressure	1	21AUG2020	1/1	1	No	O	NA	R (21AUG2020)	N/Y
16-55/ C4591001 1145 11451033	GENRL	Fatigue/ Fatigue	1	21AUG2020	1/2	1	No	O	NA	R (22AUG2020)	N/N
	SKIN	Rash/ Rash	1	24AUG2020	4/8	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1145 11451034	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
		Injection site erythema/ Injection site redness	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	1/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1145 11451037	GENRL	Fatigue/ Fatigue	1	25AUG2020	2/1	1	Yes		NA	R (25AUG2020)	N/N
	GENRL	Injection site pain/ Arm pain at injection site	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1145 11451042	GASTR	Ileus/ Ileus	2	25DEC2020	102/4	3	No	O	NA	R (28DEC2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451043	GENRL	Injection site pain/ left arm injection site pain	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1145 11451053	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1145 11451057	GENRL	Injection site pain/ left arm injection site pain	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1145 11451059	EYE	Photophobia/ Photophobia	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain	1	28AUG2020	1/4	2	Yes		NA	R (31AUG2020)	N/Y
	NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1145 11451063	MUSC	Arthralgia/ Knee pain	1	08SEP2020	12/4	2	No	O	NA	R (11SEP2020)	N/N	
	MUSC	Joint swelling/ Knee swelling	1	11SEP2020	15/1	2	No	O	NA	R (11SEP2020)	N/N	
	INFEC	Appendicitis/ appendicitis	2	04JAN2021	109/4	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N	
	MUSC	Intervertebral disc protrusion/ disc herniation	1	14SEP2020	15/C	2	No	O	NA/TC	RG	N/N	
	NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N	
	NERV	Dizziness/ dizziness	1	24SEP2020	25/2	2	No	CD	NA	R (25SEP2020)	N/N	
16-55/ C4591001 1145 11451064	GENRL	Injection site pain/ pain at injection site	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
	GENRL	Pyrexia/ fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N	
16-55/ C4591001 1145 11451067	GENRL	Injection site pain/ left arm injection site pain#	3	22JAN2021	2/2	2	Yes		NA/TC	R (23JAN2021)	N/N	
16-55/ C4591001 1145 11451068	GENRL	Injection site pain/ mild pain on injection site in left arm	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N	
	MUSC	Pain in extremity/ Left arm soreness#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451071	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1145 11451074	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1145 11451075	GENRL	Fatigue/ Fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1145 11451079	MUSC	Pain in extremity/ Arm pain	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	2/2	3	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451080	MUSC	Pyrexia/ fever	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1145 11451081	GENRL	Injection site pain/ Injection site pain*		09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1145 11451086	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
	MUSC	Injection site pain/ injection site pain	1	29SEP2020	21/2	2	Yes		NA	R (30SEP2020)	N/N
		Myalgia/ muscle ache	2	29SEP2020	1/2	3	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1145 11451086	GASTR	Nausea/ nausea*		09SEP2020	1/23	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1145 11451086	GENRL	Fatigue/ fatigue	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Injection site pain/ injection site pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Headache/ headache	1	29SEP2020	21/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1145 11451086	GENRL	Fatigue/ fatigue	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451088	RESP	Upper-airway cough syndrome/ post nasal drip	2	19OCT2020	21/3	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Pain/ aches#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/Y
	MUSC	Pain in extremity/ right arm pain#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ chills#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1145 11451090	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	SKIN	Fixed eruption/ fixed drug eruption:	2	01OCT2020	3/9	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1145 11451091	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ injection site pain*		10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ chills	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ fever	2	29SEP2020	1/3	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1145 11451093	SKIN	Hyperhidrosis/ sweating	1	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1145 11451094	MUSC	Pain in extremity/ Left arm pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1145 11451107	GENRL	Injection site pain/ injection site pain left arm	1	18SEP2020	1/4	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Chills/ shivering	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ left arm injection site pain	1	08OCT2020	21/2	1	Yes		NA	R (09OCT2020)	N/N
		Pain/ body aches	1	08OCT2020	21/2	2	Yes		NA	R (09OCT2020)	N/N
	GASTR	Vomiting/ vomitting	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1145 11451108	MUSC	Arthralgia/ joint pain	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451112	GENRL	Fatigue/ fatigue	1	23OCT2020	2/3	2	Yes		NA	R (25OCT2020)	N/N
		Injection site pain/ injection site pain	1	23OCT2020	2/3	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1146 11461002	INV	Blood pressure increased/ Elevation of baseline blood pressure	2	15SEP2020	15/58	2	No	O	NA/TC	R (11NOV2020)	N/N
	NERV	Headache/ Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1146 11461004	EYE	Conjunctivitis allergic/ Allergic conjunctivitis	2	25NOV2020	85/8	2	No	O	NA/TC	R (02DEC2020)	N/N
16-55/ C4591001 1146 11461007	EYE	Eye irritation/ Burning eyes status post injection #1	1	12AUG2020	1/5	1	Yes		NA	R (16AUG2020)	N/N
	EYE	Eye irritation/ Burning eyes status post injection #2	2	31AUG2020	1/5	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1146 11461020	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461021	NERV	Headache/ Headache	1	14AUG2020	1/8	2	Yes		NA	R (21AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	20AUG2020	7/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1146 11461044	EYE	Eye pain/ Bilateral eye pain	2	06OCT2020	29/14	1	No	O	NA	R (19OCT2020)	N/N
	INV	Blood pressure increased/ blood pressure elevation	2	20OCT2020	43/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
		Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461054	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/5	1	Yes		NA	R (23AUG2020)	N/Y
	GENRL	Injection site pain/ Injection sit pain post 2nd injection	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1146 11461055	MUSC	Pain in extremity/ Arm Pain#	3	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1146 11461058	GENRL	Injection site pain/ injection site pain left arm	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461061	GASTR	Diarrhoea/ Diarrhea	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1146 11461063	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1146 11461070	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Pain/ Body aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1146 11461071	GENRL	Injection site pain/ injection site pain	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1146 11461075	INFEC	Hordeolum/ sty left eye	2	15SEP2020	8/22	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1146 11461076	GENRL	Fatigue/ Fatigue#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461078	GENRL	Chills/ Chills#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1146 11461082	GENRL	Injection site pain/ injection site pain occurring >30 min after injection	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ Chills occurring >30 minutes post injection	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1146 11461083	GENRL	Chills/ Chills#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	08FEB2021	4/3	1	Yes		NA	R (10FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N
	GENRL	Chills/ Chills#	4	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N
		Pyrexia/ Fever#	4	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1146 11461084	GENRL	Injection site pain/ Injection site pain > 30 minutes post injection	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1146 11461085	RESP	Sinus congestion/ Congested Sinuses	2	08NOV2020	59/4	1	No	O	NA	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461086	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain, left#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1146 11461091	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1146 11461092	GASTR	Diarrhoea/ Diarrhea	1	28AUG2020	8/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain >30 minutes post vaccine	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1146 11461096	GENRL	Injection site pain/ Injection site pain	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle Aches#	3	27JAN2021	2/3	2	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461102 16-55/ C4591001 1146 11461116	GENRL	Pain/ Body aches > 30 minutes post vaccine 2	2	14SEP2020	1/2	1	Yes	NA	NA	R (15SEP2020)	N/N
16-55/ C4591001 1146 11461117	GENRL	Injection site pain/ Injection site pain	1	27AUG2020	2/2	1	Yes	NA	NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills starting > 30 minutes post vaccine 2	2	16SEP2020	1/2	1	Yes	NA	NA	R (17SEP2020)	N/N
		Pain/ Body aches	2	16SEP2020	1/2	1	Yes	NA	NA	R (17SEP2020)	N/N
	NERV	Headache/ headache >30 minutes post vaccine 2	2	16SEP2020	1/2	1	Yes	NA	NA	R (17SEP2020)	N/N
16-55/ C4591001 1146 11461118	GENRL	Injection site pain/ injection site pain	1	27AUG2020	2/2	1	Yes	NA	NA	R (28AUG2020)	N/N
	GENRL	Pyrexia/ fever of 100.7F	1	28AUG2020	3/2	2	Yes	NA/TC	NA/TC	R (29AUG2020)	N/N
	GENRL	Fatigue/ fatigue post vaccine	2	15SEP2020	1/3	1	Yes	NA	NA	R (17SEP2020)	N/N
		Injection site pain/ injection site pain >30 minutes posit vaccine	2	15SEP2020	1/3	1	Yes	NA	NA	R (17SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ elevated temp post injection to 99.5	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1146 11461119	GENRL	Pyrexia/ Fever#	4	02MAR2021	1/2	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1146 11461123	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1146 11461124	INJ&P	Post procedural haemorrhage/ Mild nose bleed s/p nasal swab*		27AUG2020	1/1	1	No	O	NA/TCN	R (27AUG2020)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1146 11461130	MUSC	Back pain/ Right mid to low back pain	2	14OCT2020	30/3	1	No	O	NA/TCN	R (16OCT2020)	N/N
16-55/ C4591001 1146 11461133	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	2021	106/C	3	No	O	NA	N	N/N
	PREG	Abortion spontaneous/ spontaneous abortion#	2	21JAN2021	126/1	3	No	O	NA	R (21JAN2021)	Y/N
	REPRO	Vaginal haemorrhage/ Vaginal Bleeding#	2	21JAN2021	126/2	2	No	O	NA	R (22JAN2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461141	GENRL	Injection site pain/ Injection site pain began >30 minutes after vaccine administration	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1146 11461144	GENRL	Pain/ Body Aches#	4	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Low grade fever#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1146 11461146	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1146 11461150	NERV	Headache/ headache- day 8-9 post vaccine	1	05SEP2020	9/3	1	Yes		NA	R (07SEP2020)	N/N
	EYE	Vitreous detachment/ Posterior Vitriol Detachment	2	21SEP2020	6/C	2	No	O	NA	N	N/N
	SKIN	Dermatitis contact/ Poison Ivy Rash	2	08OCT2020	23/17	1	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Throbbing at injection site#	3	30JAN2021	2/1	1	Yes		NA/TCN	R (30JAN2021)	N/N
	MUSC	Pain in extremity/ Left Arm Pain#	3	30JAN2021	2/1	1	Yes		NA/TCN	R (30JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461155		Injection site pain/ Site injection pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		Pain/ Body aches#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1146 11461157	GENRL	Chills/ Chills#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461159	GENRL	Injection site pain/ Injection site pain >30 minutes after vaccine administration	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ fatigue >30 minutes after vaccine administration	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection site pain >30 minutes post vaccine administration	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever 99.5 occurred after vaccine	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches >30 minutes after vaccine	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Pain in left knee	1	SEP2020	1/	2	No	O	NA	R	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461170	GASTR	Food poisoning/ food poisoning	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
		Nausea/ Nausea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1146 11461176	GENRL	Vaccination site induration/ 6cm induration secondary to flu vaccine	2	06OCT2020	16/5	2	No	CND	NA	R (10OCT2020)	N/N
16-55/ C4591001 1146 11461177	RENAL	Haematuria/ Hematuria#	4	20FEB2021	6/1	1	No	O	NA	R (20FEB2021)	N/N
16-55/ C4591001 1146 11461183	GENRL	Chills/ Chills	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pain/ Body aches	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1146 11461184	GENRL	Pain/ Body aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Pain in extremity/ Sore arm#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1146 11461187	INFEC	Herpes simplex/ Herpes Simplex 1	1	14SEP2020	13/8	1	No	O	NA/TC	R (21SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1146 11461197	MUSC	Bursitis/ Bursitis of the knee	1	22SEP2020	20/29	2	No	O	NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 1146 11461200	CARD	Atrioventricular block first degree/ 1 Degree AV block	2	27SEP2020	3/1	2	No	O	NA	R (27SEP2020)	N/N	
		Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N	
	NERV	Syncope/ syncope	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N	
16-55/ C4591001 1146 11461201	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
		Pain/ Body Aches#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
	MUSC	Pain in extremity/ Arm Pain#	4	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1146 11461204	PSYCH	Depression/ Worsening of depression	2	13OCT2020	22/14	2	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1146 11461206	RESP	Upper-airway cough syndrome/ Post nasal drip	2	27OCT2020	35/4	1	No	O	NA	R (30OCT2020)	N/N	
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	07OCT2020	15/8	2	No	O	NA/TC	R (14OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461212 16-55/ C4591001	INFEC	Hordeolum/ Stye of the left eye	1	23SEP2020	20/8	1	No	O	NA/TCN	R (30SEP2020)	N/N
1146 11461218 16-55/ C4591001	NERV	Headache/ Mild Headache	1	23SEP2020	20/1	1	No	O	NA/TC	R (23SEP2020)	N/N
1146 11461219 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
1146 11461237		Injection site pain/ Injection site pain	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pain/ Body aches	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1146 11461238	GENRL	Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Body aches	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Low grade fever of 100.8	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1146 11461239	GENRL	Pain/ Bodyaches	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461241	NERV	Headache/ Headaches post vaccine #2	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	2/3	1	Yes		NA/TC	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1146 11461243		Injection site pain/ Injection site pain	2	07OCT2020	2/3	1	Yes		NA	R (09OCT2020)	N/N
	GASTR	Nausea/ Nausea#	4	02MAR2021	1/3	1	Yes		NA/TC	R (04MAR2021)	N/N
	GENRL	Chills/ Chills#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
		Fatigue/ Fatigue#	4	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1146 11461245		Pain/ Body Aches#	4	02MAR2021	1/3	1	Yes		NA/TC	R (04MAR2021)	N/N
	INV	Blood pressure increased/ Elevated blood pressure	2	02NOV2020	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1146 11461248	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever of 101.5 post injection #2	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461250	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1146 11461255	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		Fatigue/ Fatigue	2	10OCT2020	2/2	2	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1146 11461270	GENRL	Chills/ Chills#	4	09FEB2021	1/3	2	Yes		NA/TC	R (11FEB2021)	N/N
		Fatigue/ Fatigue#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
		Pain/ Body aches#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
		Pyrexia/ Fever (100.2)#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1146 11461271	GENRL	Injection site pain/ injection site pain left arm	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461272	MUSC	Myalgia/ Muscle aches	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	09NOV2020	1/2	1	Yes		NA/TC	R (10NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Pain/ Bodyaches	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461273	NERV	Headache/ Headache	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	NERV	Headache/ Headache	2	14NOV2020	2/3	1	Yes		NA/TC	R (16NOV2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	2/3	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05FEB2021	2/3	1	Yes		NA/TC/TCN	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461274	MUSC	Pain/ Body Aches#	4	05FEB2021	2/4	2	Yes		NA	R (08FEB2021)	N/N
		Pain in extremity/ Pain upper left thigh	1	28OCT2020	10/C	2	No	O	NA	RG	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1146 11461276	GASTR	Pain/ Body aches#	4	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
		Diarrhoea/ Diarrhea	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain, left side	2	09NOV2020	1/3	1	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Chills/ Chills#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1146 11461278	NERV	Parosmia/ Increased smell sensitivy	2	13NOV2020	5/41	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461279		Fatigue/ Fatigue post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
		Injection site pain/ Injection site pain post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
	NERV	Headache/ Headache post vaccination #1	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
	GENRL	Chills/ Chills	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1146 11461280	GASTR	Flatulence/ Gas	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
		Nausea/ Nausea	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	3/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461281	GENRL	Injection site pain/ injection site pain, left deltoid	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461285	GENRL	Chills/ Chills post vaccine 2	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1146 11461287	GASTR	Diarrhoea/ Diarrhea day 2 following vaccination #1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
	GASTR	Nausea/ Nausea on day 2 following vaccination#1	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1146 11461288	GASTR	Nausea/ Nausea day 2 following vaccine 2	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue day 2 following vax 2	2	13NOV2020	2/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N
	MUSC	Fatigue/ Fatigue post vax 2	2	20NOV2020	2/5	1	Yes		NA	R (24NOV2020)	N/N
	MUSC	Myalgia/ Muscle Soreness	2	20NOV2020	2/1	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461291	NERV	Headache/ Headache	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1146 11461293	NERV	Headache/ Headache#	4	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GASTR	Large intestine polyp/ Colon Polyp	1	16NOV2020	28/1	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1146 11461294	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain, left side	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N
		GENRL	Chills/ Chills	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)
16-55/ C4591001 1146 11461295	GENRL	Injection site pain/ Injection site pain, left arm	2	11NOV2020	1/2	1	Yes		NA/TC	R (12NOV2020)	N/N
		Chills/ Chills	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461297	NERV	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
		Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache#	4	28FEB2021	3/5	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1146 11461299	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/33	1	Yes		NA	R (14DEC2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461300	GENRL	Pain/ Body Aches#	3	23JAN2021	2/2	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1146 11461302	GENRL	Injection site pain/ Injection site pain, left arm	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461305	INFEC	COVID-19/ COVID-19	2	14JAN2021	66/7	2	No	O	NA	R (20JAN2021)	Y/N
	MUSC	Pain in extremity/ Arm Pain#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Pyrexia/ fever	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461306	NERV	Headache/ headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14NOV2020	3/3	1	Yes		NA	R (16NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	06MAR2021	2/1	1	Yes		NA	R (06MAR2021)	N/N
	NERV	Headache/ Headache#	4	06MAR2021	2/1	1	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1146 11461308	GENRL	Pain/ Bodyaches	1	24OCT2020	3/3	1	Yes		NA	R (26OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461313	GENRL	Injection site pain/ Injection site pain day 1 post vaccine*		22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Chills/ Chills	2	14NOV2020	2/4	1	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain	2	14NOV2020	2/4	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1146 11461315	GENRL	Chills/ Chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
		Pain/ Bodyaches	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461316	GENRL	Injection site pain/ Left sided injection site pain.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26OCT2020	5/2	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
		Pain/ Body aches	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461317	GASTR	Diarrhoea/ Mild diarrhea evening of vax 1	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache day 2 after vax 1	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Pain in extremity/ Arm Pain after vaccination#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INFEC	Ear infection/ Ear Infection#	3	10FEB2021	16/2	1	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1146 11461318	GENRL	Fatigue/ fatigue post vaccination 1	1	24OCT2020	3/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Pain/ Body aches#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ Body aches#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461320	MUSC	Pain in extremity/ Arm Pain#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever of 100.0F	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1146 11461323	NERV	Headache/ Mild Steady headache	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N
	SKIN	Urticaria/ Generalized hives#	2	05FEB2021	85/13	1	No	O	NA/TC	R (17FEB2021)	N/N
	NERV	Dizziness/ Dizziness	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1146 11461324	GASTR	Diarrhoea/ Diarrhea/Loose Stool#	3	26JAN2021	5/4	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Arthralgia/ Joint pain knees, bilateral#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	3/3	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Pyrexia/ Fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1146 11461326	GENRL	Injection site pain/ Injection site pain right arm	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/Y
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Dizziness/ Dizziness	2	11NOV2020	1/4	1	Yes		NA	R (14NOV2020)	N/N
		Headache/ Headache	2	11NOV2020	1/4	1	Yes		NA/TC	R (14NOV2020)	N/N
	INFEC	Ear infection/ Ear Infection	2	08JAN2021	59/7	1	No	O	NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1146 11461327	GENRL	Chills/ Chills	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461328	NERV	Injection site pain/ Right arm tenderness (injection site)	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
		Pain/ Body aches	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	1/3	2	Yes		NA/TC	R (15NOV2020)	N/N
		Headache/ Headache	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1146 11461329	GENRL	Chills/ Chills#	4	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N
		Nausea/ Nausea	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Dizziness/ Dizziness	2	15NOV2020	3/3	1	Yes		NA	R (17NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461331	MUSC	Pain in extremity/ Arm Pain#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1146 11461336	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N
	NERV	Headache/ Headache	2	14NOV2020	2/3	2	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1146 11461337	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/8	2	Yes		NA	R (20NOV2020)	N/N
	EAR	Vertigo/ Vertigo	2	14NOV2020	2/5	1	Yes		NA/TC	R (18NOV2020)	N/N
16-55/ C4591001 1146 11461339	GENRL	Fatigue/ fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1146 11461340	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pyrexia/ Feverish feeling	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461342	NERV	Dizziness/ Dizziness	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	NERV	Headache/ Headache	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
	INFEC	Urinary tract infection/ UTI	2	06DEC2020	21/6	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1146 11461343	GENRL	Chills/ Chills#	2	25JAN2021	69/1	1	Yes		NA/TC	R (25JAN2021)	N/N
16-55/ C4591001 1146 11461346	GENRL	Pyrexia/ Fever 100.5 F	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461346	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/2	2	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461348	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	16NOV2020	1/6	1	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Injection site pain	2	16NOV2020	1/3	1	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	16NOV2020	1/6	1	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	17NOV2020	2/5	2	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1146 11461349	NERV	Dizziness/ Very mild dizziness after vaccine 1	1	26OCT2020	1/1	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1146 11461351	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1146 11461354	GENRL	Fatigue/ Fatigue post vaccine 1	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Injection site pain	1	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pain/ Body aches post vaccine 1	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461356	GENRL	Fatigue/ Fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N
		Pain/ Body aches	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
		Pyrexia/ Fever 99.4 F	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain of left arm	1	27OCT2020	1/4	2	Yes		NA	R (30OCT2020)	N/N
		Chills/ Chills	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461358	NERV	Injection site pain/ Injection site pain	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ Bodyaches	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
		Headache/ Headache	2	18NOV2020	2/2	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461358	MUSC	Pain in extremity/ Arm Pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1146 11461359	GENRL	Fatigue/ Fatigue	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ Injection site pain post vaccine	2	18NOV2020	1/2	2	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ Worsening Headaches	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461360	GENRL	Injection site pain/ Injection Site Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
		Pain/ Body aches#	4	16FEB2021	1/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1146 11461364	GENRL	Chills/ Chills	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1146 11461366	NERV	Headache/ Headache	2	17NOV2020	2/4	2	No	O	NA/TC	R (20NOV2020)	N/N
	RESP	Cough/ Cough	2	17NOV2020	2/4	1	No	O	NA	R (20NOV2020)	N/N
		Nasal congestion/ Nasal congestion	2	17NOV2020	2/4	2	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461369	GENRL	Fatigue/ Fatigue	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
		Feeling abnormal/ Felt foggy	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	28OCT2020	1/3	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461372		Injection site pain/ Injection site pain	1	28OCT2020	1/3	1	Yes	NA		R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/5	1	Yes	NA		R (20NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	2/4	1	Yes	NA		R (20NOV2020)	N/N
	MUSC	Neck pain/ Neck pain	2	17NOV2020	2/4	1	Yes	NA		R (20NOV2020)	N/N
16-55/ C4591001 1146 11461373	MUSC	Pain in extremity/ Arm Pain#	3	03FEB2021	1/2	1	Yes	NA/TC		R (04FEB2021)	N/N
16-55/ C4591001 1146 11461374	GENRL	Injection site pain/ Injection site pain post vaccine 1	1	28OCT2020	1/3	1	Yes	NA		R (30OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	18NOV2020	2/2	1	Yes	NA		R (19NOV2020)	N/N
16-55/ C4591001 1146 11461375	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/1	1	Yes	NA		R (28JAN2021)	N/N
16-55/ C4591001 1146 11461376	GENRL	Injection site pain/ Injection site pain post vaccine 1	1	29OCT2020	1/2	1	Yes	NA		R (30OCT2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Mild Arm Pain#	3	08FEB2021	1/1	1	Yes	NA		R (08FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1146 11461379	GENRL	Pyrexia/ Fever#	4	01MAR2021	1/2	1	Yes		NA/TC	R (02MAR2021)	N/N
	MUSC	Pain in extremity/ Arm Soreness#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1146 11461381	GENRL	Injection site pain/ Injection site pain	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1146 11461382	MUSC	Muscle spasms/ leg cramping both calves	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Muscle twitching/ muscle twitching in chest area post vaccine 2	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	18NOV2020	2/3	1	Yes		NA	R (20NOV2020)	N/N
		Pain/ Bodyaches	2	18NOV2020	2/3	2	Yes		NA	R (20NOV2020)	N/N
	MUSC	Muscle spasms/ leg cramping both calves	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	2/3	2	Yes		NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1146 11461386	GENRL	Chills/ Chills	2	18NOV2020	1/2	1	Yes		NA	R (19NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
16-55/ C4591001 1146 11461387	GASTR	Fatigue/ Fatigue	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N		
		Pain/ Body Aches	2	18NOV2020	1/3	2	Yes		NA/TC	R (20NOV2020)	N/N		
		Diarrhoea/ Diarrhea	2	20NOV2020	1/4	2	Yes		NA	R (23NOV2020)	N/N		
		Headache/ Headache	2	20NOV2020	1/2	1	Yes		NA/TC	R (21NOV2020)	N/N		
		Myalgia/ Muscle aches	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N		
16-55/ C4591001 1146 11461388	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N		
		GENRL	Pyrexia/ Fever after vaccine#	4	16FEB2021	1/1	1	Yes		NA/TC	R (16FEB2021)	N/N	
			GASTR	Diarrhoea/ Diarrhea post vaccine 1	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
				Injection site pain/ Injection site pain post vaccine 1	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
				INFEC	Hordeolum/ Stye right eye	2	18NOV2020	1/8	1	No	O	NA	R (25NOV2020)
GENRL	Injection site pain/ Injection Site Pain#	3	05JAN2021		1/2	1	Yes		NA	R (06JAN2021)	N/N		
	GENRL	Fatigue/ Fatigue#	3	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461390	GENRL	Injection site pain/ Injection Site Pain#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	30OCT2020	2/3	1	Yes		NA	R (01NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1146 11461391		Fatigue/ Fatigue/Tiredness	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ headache day 2 post vaccine 1 (lasted 4 hours)	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
	MUSC	Muscle twitching/ Intermittent muscle twitching left chest	2	01DEC2020	15/21	1	No	O	NA	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1146 11461395	MUSC	Myalgia/ Muscle Pain#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Chills/ Chills	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1146 11461397	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
			2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N
		Injection site pain/ Injection site pain	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
			2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N
			2	19NOV2020	2/4	2	Yes		NA	R (22NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	19NOV2020	2/3	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Back pain/ Back ache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	VASC	Essential hypertension/ essential hypertension	2	21AUG2020	3/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1147 11471003	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	NOV2020	70/C		No	O	NA	UNK	N/N
16-55/ C4591001 1147 11471007	GASTR	Diarrhoea/ Diarrhea#	2	12MAR2021	201/2	1	No	O	NA	R (13MAR2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1147 11471019	MUSC	Myalgia/ Muscle ache	2	24AUG2020	1/5	3	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1147 11471021	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1147 11471046	GENRL	Malaise/ Malaise#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N
		Pyrexia/ Fever#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10MAR2021	1/2	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1147 11471047	PSYCH	Anxiety/ Anxiety (New Diagnosis)	2	28AUG2020	3/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1147 11471049	INV	Blood thyroid stimulating hormone increased/ elevated TSH	2	18SEP2020	22/C	1	No	O	NA	N	N/N
16-55/ C4591001 1147 11471053	NERV	Migraine/ migraine (exacerbation)	2	10OCT2020	44/2	1	No	O	NA	R (11OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1147 11471073	INV	Blood creatinine decreased/ Decreased Creatinine (31.6)	2	02SEP2020	3/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1147 11471092	RESP	Rhinitis allergic/ Allergic Rhinitis	2	11SEP2020	11/8	1	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1147 11471112	RESP	Oropharyngeal pain/ Sore throat*		12AUG2020	-12/13	1	No	O	NA	R (24AUG2020)	N/N	
16-55/ C4591001 1147 11471121	INFEC	Abscess neck/ Nape abscess	2	25SEP2020	22/2	1	No	O	NA/TC	R (26SEP2020)	N/N	
16-55/ C4591001 1147 11471153	INFEC	Influenza/ Flu A&B	2	21SEP2020	12/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1147 11471166	INV	Blood cholesterol increased/ elevated cholesterol	2	06OCT2020	26/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1147 11471180	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	17/6	1	Yes		NA	R (14SEP2020)	N/N	
16-55/ C4591001	GENRL	Chills/ Chills#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1147 11471211	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1147 11471216	BLOOD	Anaemia/ anemia (new diagnosis)	1	11SEP2020	9/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1147 11471258	GENRL	Injection site pain/ Pain at injection site#	3	26FEB2021	1/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1147 11471259	EYE	Eye pain/ Ocular pain, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
		Ocular hyperaemia/ Ocular redness, bilateral	2	05JAN2021	25/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1147 11471272	INJ&P	Ligament sprain/ Sprained Ankle	2	14JAN2021	18/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1149 11491001	GENRL	Pyrexia/ Fever	2	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Pain in extremity/ Pain in left arm	2	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491012	GENRL	Chills/ Chills	2	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	25AUG2020	1/19	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	01SEP2020	8/25	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Flank pain/ Flank Pain	2	15SEP2020	22/8	1	No	CND	NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	20SEP2020	27/3	1	No	CND	NA	R (22SEP2020)	N/N
16-55/ C4591001 1149 11491020	GENRL	Chills/ chills	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
		Fatigue/ fatigue	2	31AUG2020	5/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1149 11491025	GENRL	Fatigue/ fatigue	1	08AUG2020	2/3	1	Yes		NA	R (10AUG2020)	N/N
	GENRL	Injection site erythema/ injection site redness	1	12AUG2020	6/2	1	Yes		NA	R (13AUG2020)	N/N
16-55/ C4591001 1149 11491030	GENRL	Injection site pain/ Soreness at injection site#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491033	GASTR	Nausea/ Nausea#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	3/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Left arm soreness at injection site#	3	19JAN2021	1/3	1	Yes		NA	R (21JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Pyrexia/ Fever 100.2#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1149 11491037	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1149 11491044	GASTR	Nausea/ nausea	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ left arm pain at injection site with touch	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1149 11491047	GENRL	Injection site pain/ Tenderness at injection site#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1149 11491051	GENRL	Injection site pain/ Pain at injection site#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1149 11491054	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/3	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	11JAN2021	1/4	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1149 11491057	GASTR	Diarrhoea/ loose stool	1	12AUG2020	1/1	1	Yes		NA	R (12AUG2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491069	NERV	Headache/ Headache#	3	11FEB2021	1/2	1	Yes	NA	R (12FEB2021)	N/N	
16-55/ C4591001 1149 11491070	GENRL	Fatigue/ Fatigue#	3	12FEB2021	1/3	1	Yes	NA	R (14FEB2021)	N/N	
	MUSC	Pain in extremity/ Arm pain#	3	12FEB2021	1/3	1	Yes	NA	R (14FEB2021)	N/N	
	NERV	Headache/ Headache#	3	12FEB2021	1/3	1	Yes	NA	R (14FEB2021)	N/Y	
	GENRL	Chills/ Chills#	3	13FEB2021	2/2	1	Yes	NA	R (14FEB2021)	N/N	
		Pain/ Body aches#	3	13FEB2021	2/2	1	Yes	NA	R (14FEB2021)	N/N	
		Pyrexia/ Fever#	3	13FEB2021	2/2	1	Yes	NA	R (14FEB2021)	N/N	
16-55/ C4591001 1149 11491075	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/2	1	Yes	NA	R (02FEB2021)	N/N	
16-55/ C4591001 1149 11491076	MUSC	Pain in extremity/ right arm pain	1	17AUG2020	1/3	2	Yes	NA	R (19AUG2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site, right arm#	3	21DEC2020	1/3	1	Yes	NA	R (23DEC2020)	N/N	
	GENRL	Pyrexia/ Fever#	4	28JAN2021	2/1	1	Yes	NA	R (28JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491077	GENRL	Chills/ Chills	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
		Pain/ Body Aches	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
		Pyrexia/ Fever	1	18AUG2020	2/3	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1149 11491083	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/28	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1149 11491085	GENRL	Injection site pain/ Tenderness at injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1149 11491086	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ left arm pain at injection site related to motion	2	09SEP2020	2/6	1	Yes		NA	R (14SEP2020)	N/N
		Pain/ body aches	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491088	GASTR	Abdominal discomfort/ Upset Stomach	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18AUG2020	1/3	1	Yes		NA	R (20AUG2020)	N/N
		Injection site pain/ Left arm pain at injection site	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/Y
16-55/ C4591001 1149 11491089	GENRL	Injection site pain/ Left arm pain at injection site	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
	GASTR	Vomiting/ Emesis	1	06SEP2020	19/31	1	No	O	NA	R (06OCT2020)	N/N
	GASTR	Nausea/ Nausea#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
		Pyrexia/ Fever (99.9)#	4	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	INFEC	Herpes simplex/ Herpes outbreak#	4	06FEB2021	3/2	1	No	O	NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1149 11491092	NERV	Lethargy/ Lethargic	1	23AUG2020	5/1	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ Tired	1	26AUG2020	8/1	1	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491093	PSYCH	Insomnia/ Difficulty sleeping	1	31AUG2020	13/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Tired	1	01SEP2020	14/1	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Musculoskeletal pain/ joint/muscle pain in arms and legs	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1149 11491098		Myalgia/ left triceps pain	1	20AUG2020	2/5	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Injection site pain/ injection site pain with motion	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1149 11491114	GENRL	Injection site pain/ Pain at Injection site#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/Y
16-55/ C4591001 1149 11491115	GENRL	Injection site pain/ Soreness at injection site#	4	20JAN2021	1/4	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1149 11491116	MUSC	Pain in extremity/ Left arm pain*		20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1149 11491120	GENRL	Injection site pain/ Soreness at injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491121	MUSC	Myalgia/ Generalized myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1149 11491125	GENRL	Injection site pain/ Soreness at injection site#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1149 11491128	MUSC	Pain in extremity/ left arm soreness	1	24AUG2020	1/2	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1149 11491133	GENRL	Fatigue/ Fatigue#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Pyrexia/ Low grade fever 100.1#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1149 11491136	MUSC	Myalgia/ left arm muscle pain with motion	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N
	GASTR	Nausea/ nausea	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Headache/ headache/ left-post occipital pain	1	27AUG2020	3/1	1	Yes		NA	R (27AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491140	GENRL	Fatigue/ Fatigue#	3	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/Y
		Injection site pain/ Pain at injection site#	3	17FEB2021	1/1	1	Yes		NA	R (17FEB2021)	N/Y
16-55/ C4591001 1149 11491146	GENRL	Injection site haemorrhage/ Left arm bleeding at injection site	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
		Injection site pain/ Left arm injection site pain	1	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1149 11491150	GENRL	Chills/ Chills#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Injection site pain/ Arm Soreness at injection site#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Generalized muscle aches#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1149 11491155	GENRL	Injection site pain/ IM pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491157	GASTR	Abdominal discomfort/ Upset stomach	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
		Diarrhoea/ Diarrhea	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Sore left arm at injection site#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1149 11491158	GENRL	Fatigue/ General Fatigue#	3	03FEB2021	2/6	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1149 11491165	GENRL	Injection site pain/ left arm pain at injection site with movement	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1149 11491175	GENRL	Injection site pain/ Tenderness at injection site (left arm)#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1149 11491176	GENRL	Injection site pain/ Left arm pain at injection site	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491178		Injection site pain/ Sore at injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1149 11491180	GENRL	Injection site pain/ left arm pain at injection site.	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1149 11491181	GENRL	Injection site pain/ Left arm pain at injection site with touch	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1149 11491186	GENRL	Injection site pain/ left arm injection site pain with touch	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Musculoskeletal chest pain/ muscle chest pain	2	23SEP2020	1/3	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491188	NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ Fever (101.9)#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1149 11491191	GENRL	Injection site pain/ Left arm injection site pain with touch	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1149 11491202	MUSC	Arthralgia/ Joint pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1149 11491203	GENRL	Pain in extremity/ Left arm pain	1	05SEP2020	2/4	1	Yes		NA/TC	R (08SEP2020)	N/N
		Chills/ chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ body aches	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1149 11491204	GENRL	Pain/ Body aches	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Pyrexia/ Fever/chills Myalgia/ Myalgia#	2 3	25SEP2020 09FEB2021	1/3 1/3	1 1	Yes Yes		NA/TC NA/TC	R (27SEP2020) R (11FEB2021)	N/N N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491207	GENRL	Injection site pain/ Arm Soreness at injection site#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1149 11491208	GENRL	Fatigue/ Fatigue#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	4	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1149 11491209	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site with movement	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1149 11491210	GENRL	Injection site pain/ left arm pain at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Fatigue/ fatigue	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491211	NERV	Injection site pain/ Left arm injection site pain with motion	2	26SEP2020	2/4	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ fever	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
		Headache/ headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Fatigue/ Tired (general)#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GASTR	Injection site pain/ Pain at injection site#	3	02FEB2021	1/4	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1149 11491218	GENRL	Nausea/ Nausea#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1149 11491219	MUSC	Pain in extremity/ Left arm soreness	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491220	NERV	Headache/ Headache	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1149 11491221		Injection site pain/ left arm pain at injection site	1	09SEP2020	2/4	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Paraesthesia oral/ Buccal paresthesia	1	13SEP2020	4/27	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Musculoskeletal chest pain/ Chest pain (muscular not cardiac)	1	14SEP2020	5/3	3	Yes		NA	R (16SEP2020)	N/N
	GASTR	Gingival pain/ Gingival pain	1	22SEP2020	13/4	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1149 11491227	GENRL	Fatigue/ fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491234	MUSC	Myalgia/ myalgia	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Left arm injection pain	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Low Fever (99.6 F)	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1149 11491238	GENRL	Injection site pain/ Left arm injection site pain with motion	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever (99.6 F)	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Feeling hot/ Hot ears	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1149 11491247		Injection site pain/ left arm pain at injection site	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	RESP	Pharyngeal swelling/ Swelling in throat (no shortness of breath)	1	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site, left arm#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GASTR	Nausea/ Nausea	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491254	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes	NA	R (19SEP2020)	N/N	
		Injection site pain/ pain in left arm at injection site	1	18SEP2020	1/1	1	Yes	NA	R (18SEP2020)	N/N	
16-55/ C4591001 1149 11491256	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes	NA	R (10FEB2021)	N/N	
16-55/ C4591001 1149 11491258	GENRL	Injection site erythema/ Injection site erythema	2	09OCT2020	1/2	1	Yes	NA	R (10OCT2020)	N/Y	
		Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes	NA	R (10OCT2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain#	3	21DEC2020	1/3	1	Yes	NA	R (23DEC2020)	N/N	
16-55/ C4591001 1149 11491270	GENRL	Injection site pain/ Left arm pain at injection site	1	22SEP2020	2/1	1	Yes	NA	R (22SEP2020)	N/N	
	NERV	Headache/ headache	1	22SEP2020	2/1	1	Yes	NA	R (22SEP2020)	N/N	
16-55/ C4591001 1149 11491271	GENRL	Injection site pain/ left arm pain at injection site related to motion	1	28SEP2020	8/8	1	Yes	NA	R (05OCT2020)	N/N	
	GENRL	Pyrexia/ fever	2	14OCT2020	3/2	1	Yes	NA	R (15OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	14OCT2020	3/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1149 11491273	GENRL	Fatigue/ fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1149 11491274	GENRL	Injection site pain/ Left arm injection site pain with touch and movement	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint pain	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
		Myalgia/ Myalgia	2	13OCT2020	1/2	3	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1149 11491275	GENRL	Injection site pain/ Right arm injection site pain with touch	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Right arm injection site pain with movement and touch	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1149 11491281	GENRL	Injection site pain/ Left arm injection site pain with touch	1	23SEP2020	2/4	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	1	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491285	MUSC	Myalgia/ Myalgia	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Flank pain/ left flank pain	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1149 11491286	GENRL	Pain in extremity/ Left arm pain	1	23SEP2020	1/5	1	Yes		NA/TC	R (27SEP2020)	N/N
		Nodule/ hypopigmented nodule lesion right dorsal 2nd metacarpal	1	30SEP2020	8/7	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1149 11491289	GENRL	Injection site pain/ Left arm pain at injection site	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1149 11491294	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain with touch	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1149 11491305	MUSC	Myalgia/ muscle aches	2	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ left arm injection site pain with movement	1	24SEP2020	1/22	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C4591001	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1149 11491308 16-55/ C4591001 1149 11491310	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1149 11491311	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1149 11491314	GENRL	Injection site pain/ left arm injection site pain	1	24SEP2020	1/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	1	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1149 11491315	GENRL	Chills/ chills	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ fatigue	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1149 11491316	GENRL	Pyrexia/ Fever	1	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ right arm pain at injection site	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1149 11491328	GENRL	Injection site pain/ Left arm injection site pain with touch	1	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1149 11491329	GENRL	Injection site pain/ mild pain in left arm (injection site)	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1149 11491335†	GENRL	Injection site pain/ mild pain at site of injection (right arm)	1	27OCT2020	2/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1149 11491340	NERV	Headache/ Headache*		27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	29OCT2020	3/1	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1150 11501001	MUSC	Myalgia/ General Muscle Pain	1	17AUG2020	1/3	1	Yes		NA	R (19AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N
16-55/ C4591001 1150 11501003	GENRL	Injection site pain/ Pain at injection site	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501004	RESP	Cough/ cough	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
		Nasal congestion/ nasal congestion	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
		Oropharyngeal pain/ sore throat	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
		Rhinorrhoea/ runny nose	1	05SEP2020	20/5	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501005	GENRL	Injection site pain/ arm soreness (injection site, left arm)	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever (100.1)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1150 11501006	GENRL	Pain/ Body Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501007	GASTR	Pyrexia/ Fever (100.0 F)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Diarrhoea/ Diarrhea	2	15SEP2020	8/1	1	No	O	NA	R (15SEP2020)	N/N
	GENRL	Pain/ Body Aches#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1150 11501008	NERV	Headache/ Headache#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	24FEB2021	2/6	1	Yes		NA	R (01MAR2021)	N/N
16-55/ C4591001 1150 11501009	GASTR	Diarrhoea/ Diarrhea	1	25AUG2020	8/1	1	Yes		NA	R (25AUG2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	1	03SEP2020	17/1	1	No	O	NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
GENRL	Fatigue/ Fatigue#	3	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501010	GENRL	Pyrexia/ Fever#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501011	GENRL	Injection site pain/ Arm soreness (injection site,left)	1	19AUG2020	2/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1150 11501013	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pain/ Body Aches	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever (101.5 F)	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Arm soreness (injection site, left arm)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1150 11501014	GENRL	Injection site pain/ Burning sensation at injection site (left arm)	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501015	GENRL	Injection site pain/ Pain at injection site	2	12SEP2020	3/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1150 11501016	GENRL	Injection site pain/ Injection Site Soreness	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501017	GENRL	Injection site pain/ Pain at injection site	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501018	GENRL	Injection site pain/ Arm soreness (injection site)	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pain/ Body Aches#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever (101.6)#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501019	GENRL	Fatigue/ fatigue	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ muscle aches	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Pain/ Body Aches	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	SKIN	Eczema/ Eczema	2	DEC2020	83/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1150 11501020	GENRL	Fatigue/ fatigue	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1150 11501021	GENRL	Fatigue/ fatigue	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	20JAN2021	1/4	2	Yes		NA	R (23JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501022	NERV	Headache/ Headache#	3	23JAN2021	4/1	1	Yes		NA	R (23JAN2021)	N/N
	RENAL	Nephrolithiasis/ Kidney Stones	2	02DEC2020	86/7	3	No	O	NA/TC	R (08DEC2020)	Y/N
	GENRL	Fatigue/ Fatigue#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	19JAN2021	1/2	2	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/4	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1150 11501024	NERV	Headache/ Headache#	4	09FEB2021	2/4	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Fatigue/ Tiredness	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
		Injection site pain/ Arm soreness (Injection site left arm)	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Tiredness	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501025	MUSC	Pyrexia/ Fever (101.5)	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Myalgia/ Muscle Aches	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1150 11501026	MUSC	Myalgia/ Muscle Aches	2	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
Injection site pain/ Pain at injection site#		4	22FEB2021	1/1	2	Yes		NA	R (22FEB2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1150 11501027	GENRL	Injection site pain/ Arm soreness (left injection site)	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Chills/ Chills	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501028	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1150 11501029	GENRL	Injection site pain/ Arm soreness in injection site	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1150 11501032	GENRL	Injection site pain/ pain at injection site	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	25AUG2020	2/5	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1150 11501033	GENRL	Injection site pain/ Injection Site Pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501034	GENRL	Injection site pain/ Injection Site Pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501036	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1150 11501037	GENRL	Injection site pain/ Arm soreness (injection L site arm)	1	24AUG2020	1/2	2	Yes		NA	R (25AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph nodes under left armpit	2	18SEP2020	5/75	1	No	O	NA	R (01DEC2020)	N/N
16-55/ C4591001 1150 11501038	GASTR	Nausea/ Nausea#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501039	GASTR	Injection site pain/ Injection Site Pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
		Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1150 11501040	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
	GENRL	Pain/ Body Aches	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501040	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	CARD	Supraventricular tachycardia/ Worsening Supraventricular Tachycardia	1	02SEP2020	9/C	2	Yes		NA	RG	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Pain/ Body Aches	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501041	GENRL	Pyrexia/ fever (101.0)	1	11SEP2020	18/1	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1150 11501043	INJ&P	Concussion/ concussion	1	05SEP2020	12/6	1	No	O	NA	R (10SEP2020)	N/N
		Fall/ Fall from stairs at home	1	05SEP2020	12/1	1	No	O	NA/TCN	R (05SEP2020)	N/N
		Ligament sprain/ ankle sprain (left)	1	05SEP2020	12/4	1	No	O	NA	R (08SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501044	GENRL	Injection site pain/ pain at injection site	1	25AUG2020	1/3	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Pain at injection site (right arm)	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	SKIN	Hyperhidrosis/ Sweats	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501045	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ Redness at injection site#	3	03FEB2021	2/6	2	Yes		NA	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
		Pain/ Generalized Body Aches#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501046	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	2/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1150 11501047	GENRL	Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501048	GENRL	Pain/ Body Aches#	4	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ pain at injection site	1	26AUG2020	2/3	2	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/Y
		Chills/ Chills	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1150 11501049	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
		Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1150 11501050	MUSC	Myalgia/ Muscle Aches#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501051	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	METAB	Decreased appetite/ Loss of Appetite	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Tremor/ Body Shakes	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	20SEP2020	5/1	2	Yes		NA	R (20SEP2020)	N/N
	PSYCH	Depression/ Depression	2	NOV2020	47/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1150 11501052	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	2	Yes		NA	R (05FEB2021)	N/N
	PSYCH	Restlessness/ Restlessness#	3	04FEB2021	1/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501053	NERV	Pain/ Generalized Body Aches#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
		Headache/ Headache#	4	23FEB2021	1/3	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Arm soreness (left arm) injection site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Arm soreness (Left arm, injection site)	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1150 11501054	GENRL	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site#	3	01MAR2021	1/2	2	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001 1150 11501056	GENRL	Fatigue/ Fatigue	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Injection site pain/ Pain at injection site	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
		Headache/ Headache	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501057		Pain/ Body Aches#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Pain/ Body Aches#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001	GASTR	Nausea/ nausea	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
1150 11501058		Fatigue/ fatigue	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ arm pain: injection site, left arm	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Arm Pain (Injection Site)	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
		Pain/ Body Aches	2	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	1	27AUG2020	2/4	1	Yes		NA	R (30AUG2020)	N/N
1150 11501059		Headache/ Headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	NERV										

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501060	GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ arm soreness (injection site), Left arm	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Vomiting/ Vomiting	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1150 11501061	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1150 11501062	MUSC	Myalgia/ Muscle Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501063	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Pain/ Body Aches	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1150 11501064	GENRL	Injection site pain/ arm soreness (left arm); injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1150 11501065	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
		Pain/ Body Aches#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1150 11501067	GENRL	Injection site pain/ pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal Pain	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501068	GENRL	Chills/ Chills	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	RESP	Nasal congestion/ Congested Nose	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
		Oropharyngeal pain/ Sore Throat	2	19SEP2020	3/3	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
		Chills/ chills	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
		Pain/ Body aches	1	28AUG2020	2/1	2	Yes		NA	R (28AUG2020)	N/N
	INFEC	Ear infection/ Right ear infection	1	14SEP2020	19/18	2	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501069	GENRL	Injection site pain/ arm soreness (left arm, injection site)	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	11NOV2020	55/C		No	O	NA	RG	N/N
16-55/ C4591001 1150 11501070	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
		Fatigue/ Fatigue#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1150 11501071	GENRL	Injection site pain/ Injection Site Pain#	3	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1150 11501073	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pyrexia/ low grade fever (99.9)	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ headache	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		Pain/ Body Aches	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1150 11501074	GENRL	Injection site pain/ Pain at injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1150 11501075	GENRL	Injection site pain/ pain at injection site	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	01SEP2020	2/1	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Burning sensation at injection site	2	30SEP2020	9/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1150 11501077	GASTR	Diarrhoea/ diarrhea	1	15SEP2020	15/2	1	No	O	NA	R (16SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501078	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GASTR	Nausea/ nausea	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ chills	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ pain at injection site	1	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
	NERV	Migraine/ migraine	1	01SEP2020	1/2	3	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1150 11501079	MUSC	Myalgia/ Muscle Aches	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	1/3	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N
	NERV	Dizziness/ dizziness	1	03SEP2020	3/2	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
		Pain/ Body Aches#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	3	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1150 11501080	GENRL	Injection site pain/ Pain at injection site#	3	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	3	26FEB2021	2/1	2	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1150 11501081	GENRL	Injection site pain/ Pain at injection site#	3	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501082	GENRL	Pain/ Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ Low grade fever	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Body Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501083	NERV	Headache/ Headache	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection Site*		01SEP2020	1/4	2	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/3	2	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1150 11501084		Injection site pain/ Pain at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N
	RESP	Cough/ Cough	1	19SEP2020	19/5	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1150 11501085		Oropharyngeal pain/ Sore Throat	1	19SEP2020	19/5	2	No	O	NA	R (23SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	04OCT2020	4/139		No	O	NA	R (19FEB2021)	N/N
	PREG	Abortion spontaneous/ Spontaneous Miscarriage	2	19FEB2021	142/1	2	No	O	NA	R (19FEB2021)	Y/N
	GENRL	Chills/ chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501087	NERV	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes	NA	NA	R (04SEP2020)	N/N
		Injection site pain/ arm soreness (left) injection site	1	03SEP2020	2/2	1	Yes	NA	NA	R (04SEP2020)	N/N
		Headache/ headache	1	03SEP2020	2/2	1	Yes	NA	NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes	NA	NA	R (24SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	1/2	1	Yes	NA	NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes	NA	NA	R (24SEP2020)	N/N
		Injection site pain/ Arm soreness (Right arm, injection site)	1	03SEP2020	2/2	1	Yes	NA	NA	R (04SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes	NA	NA	R (26SEP2020)	N/N
		Pain/ Body Aches	2	25SEP2020	1/2	1	Yes	NA	NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes	NA	NA	R (26SEP2020)	N/N
16-55/ C4591001 1150 11501088	GENRL	Fatigue/ fatigue	1	02SEP2020	1/2	1	Yes	NA	NA	R (03SEP2020)	N/N
		Injection site pain/ left arm pain (injection site)	1	02SEP2020	1/2	1	Yes	NA	NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501089	PSYCH	Insomnia/ trouble sleeping	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Nausea/ nausea	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	PSYCH	Irritability/ irritable mood	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1150 11501090	GASTR	Abdominal pain upper/ Stomach Pain	2	24SEP2020	2/22	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	3	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501091	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1150 11501092	GENRL	Injection site pain/ arm soreness (L arm, injection site)	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501093	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	RESP	Oropharyngeal pain/ Sore Throat	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1150 11501093	BLOOD	Lymphadenopathy/ Swollen lymph nodes (left armpit)#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site pain#	3	03FEB2021	2/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1150 11501094	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Neck pain/ Cervical neck pain	2	NOV2020	40/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1150 11501096	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/4	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection Site	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501097	NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1150 11501098	GENRL	Fatigue/ fatigue	1	03SEP2020	1/3	3	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1150 11501099	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	2/2	3	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/4	3	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501101	NERV	Pain/ Body Aches	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Headache/ Headache	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	PSYCH	Insomnia/ Trouble Sleeping	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1150 11501102	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1150 11501103	GENRL	Injection site pain/ Pain at injection site#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left injection site arm soreness	1	09SEP2020	2/1	3	Yes		NA	R (09SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501104	GENRL	Injection site pain/ Arm soreness (Left arm/injection site)	1	09SEP2020	1/2	1	Yes	NA	NA	R (10SEP2020)	N/N
1150 11501106	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes	NA	NA	R (02OCT2020)	N/N
16-55/ C4591001 1150 11501107	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/3	2	Yes	NA	NA	R (29JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	1/3	2	Yes	NA	NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/3	2	Yes	NA	NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/3	2	Yes	NA	NA	R (19FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	17FEB2021	1/3	2	Yes	NA	NA	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	2	Yes	NA	NA	R (19FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/2	2	Yes	NA	NA	R (19FEB2021)	N/N
16-55/ C4591001 1150 11501110	GENRL	Fatigue/ Fatigue	2	03OCT2020	3/2	1	Yes	NA	NA	R (04OCT2020)	N/N
		Pain/ Body Aches	2	03OCT2020	3/2	1	Yes	NA	NA	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Sciatica/ Sciatica Nerve Pain	2	08OCT2020	8/13	1	No	O	NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site Pain#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ Fever (101.9)#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1150 11501111	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	2/2	2	Yes		NA	R (13SEP2020)	N/N
	NERV	Dizziness/ Lightheaded	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1150 11501112	GENRL	Injection site pain/ Pain at injection site#	3	17FEB2021	1/4	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501113	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1150 11501114	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1150 11501115	GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1150 11501116		Injection site pain/ Injection site pain	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ Fever (101.0)	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GASTR	Nausea/ Nausea#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1150 11501117	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	2/4	2	Yes		NA	R (19OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501122 16-55/ C4591001	GENRL	Injection site pain/ Burning Sensation of Injection Site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/Y
1150 11501137	GENRL	Injection site erythema/ Redness at injection site#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	09FEB2021	1/3	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
1150 11501139	GENRL	Injection site pain/ Pain at injection site	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
1150 11501140		Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	29OCT2020	1/2	2	Yes		NA	R (30OCT2020)	N/N
1150 11501144	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501148	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	1	Yes	NA	NA	R (20FEB2021)	N/N
		Pain/ Generalized Body Aches#	3	19FEB2021	2/2	1	Yes	NA	NA	R (20FEB2021)	N/N
	NERV	Dizziness/ Dizziness#	3	19FEB2021	2/2	1	Yes	NA	NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501149	GENRL	Injection site pain/ Pain at injection site#	3	16FEB2021	1/3	2	Yes	NA	NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	17FEB2021	2/2	1	Yes	NA	NA	R (18FEB2021)	N/N
		Pain/ Generalized Body Aches#	3	17FEB2021	2/2	1	Yes	NA	NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	3	17FEB2021	2/2	1	Yes	NA	NA	R (18FEB2021)	N/N
16-55/ C4591001 1150 11501151	GENRL	Injection site pain/ Pain at injection site#	3	23FEB2021	1/3	2	Yes	NA	NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	24FEB2021	2/1	1	Yes	NA	NA	R (24FEB2021)	N/N
16-55/ C4591001 1150 11501153	GENRL	Injection site pain/ Pain at injection site#	3	24FEB2021	1/3	1	Yes	NA	NA	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression#	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
16-55/ C4591001 1150 11501155	GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1150 11501158	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501159	GENRL	Injection site pain/ Pain at injection site#	3	18FEB2021	1/3	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1150 11501169	GENRL	Injection site pain/ Injection Site Pain#	3	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1150 11501170	GENRL	Injection site pain/ Injection Site Pain#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1152 11521010	NERV	Headache/ headache, intermittent	1	13AUG2020	2/21	2	No	O	NA/TC	R (02SEP2020)	N/N
16-55/ C4591001 1152 11521012	INJ&P	Procedural pain/ post-surgical pain left shoulder	2	21SEP2020	20/22	2	No	O	NA/TC	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521014	GENRL	Fatigue/ Fatigue	1	16AUG2020	5/93	1	Yes		NA	R (16NOV2020)	N/N
	RESP	Throat irritation/ Scratchy Throat	2	28SEP2020	27/2	1	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1152 11521022	MUSC	Arthralgia/ bilateral hip joint pain	2	19NOV2020	79/5	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001 1152 11521024	INJ&P	Upper limb fracture/ broken right arm#	2	15JAN2021	136/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1152 11521029	NERV	Migraine/ intermittent migraine	2	03SEP2020	2/3	2	No	O	NA/TC	R (05SEP2020)	N/N
16-55/ C4591001 1152 11521046	SKIN	Rash/ body rash	2	03SEP2020	3/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1152 11521053	GASTR	Nausea/ Nausea	2	13FEB2021	166/C	2	No	O	NA/TC	RG	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	15FEB2021	168/C	1	No	O	NA	N	N/N
16-55/ C4591001	MUSC	Exostosis/ Bilateral heel spur pain#	2	09FEB2021	162/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521063		Exostosis/ Bilateral heel spurs#	2	09FEB2021	162/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521076	RESP	Nasal polyps/ Nasal polyps	2	03DEC2020	92/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1152 11521077	GASTR	Toothache/ tooth pain	1	27AUG2020	15/1	2	No	O	NA/TC/TCN	R (27AUG2020)	N/N
16-55/ C4591001 1152 11521081	INJ&P	Chest injury/ Bruised Ribs	2	22FEB2021	174/C	1	No	O	NA/TC	N	N/N
		Contusion/ Bruised knee	2	22FEB2021	174/C	1	No	O	NA/TC	N	N/N
		Fall/ Fall	2	22FEB2021	174/1	1	No	O	NA	R (22FEB2021)	N/N
		Tooth fracture/ Cracked tooth (molar 14)	2	22FEB2021	174/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1152 11521085	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
16-55/ C4591001 1152 11521110	GENRL	Pyrexia/ Fever (101.2 f)	1	19AUG2020	1/2	2	Yes		NA/TC	R (20AUG2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgias	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Chills/ chills	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521121	GASTR	Oesophagitis/ esophagitis	2	17DEC2020	99/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521137	GENRL	Injection site pain/ Injection Site Pain	2	16DEC2020	97/5	2	No	O	NA/TC	R (20DEC2020)	N/N
16-55/ C4591001 1152 11521138	INFEC	Urinary tract infection/ Urinary Tract Infection	1	14SEP2020	25/7	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1152 11521147	INJ&P	Contusion/ Antecubital bruise of the right arm	2	08OCT2020	29/15	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1152 11521149	PSYCH	Depression/ worsening depression	2	28SEP2020	18/18	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1152 11521150	PSYCH	Anxiety/ worsened anxiety	2	16NOV2020	67/26	1	No	O	NA/TC	R (11DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521165	GASTR	Nausea/ nausea	2	22SEP2020	9/3	2	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1152 11521167	MUSC	Myalgia/ myalgias#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1152 11521180	GASTR	Nausea/ Nausea#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
	GENRL	Chills/ Chills#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
		Fatigue/ Fatigue#	3	08MAR2021	1/3	2	Yes		NA	R (10MAR2021)	N/N
		Injection site pain/ Injection site pain#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
	NERV	Headache/ Headache#	3	08MAR2021	1/2	2	Yes		NA/TC	R (09MAR2021)	N/N
16-55/ C4591001 1152 11521182	GENRL	Injury associated with device/ needle stick injury (finger)	1	26AUG2020	3/1	1	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C4591001 1152 11521183	INFEC	Genital herpes/ genital herpes diagnosed	1	04SEP2020	12/7	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	25JAN2021	4/25	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521188 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN*		25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
1152 11521192	GENRL	Injection site pain/ INJECTION SITE PAIN	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	2	17DEC2020	95/1	1	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ HEADACHE	2	08JAN2021	117/1	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
1152 11521206		Injection site pain/ injection site pain	2	14SEP2020	1/8	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001	RESP	Throat irritation/ irritated throat	1	02SEP2020	8/6	1	No	O	NA	R (07SEP2020)	N/N
1152 11521209											
16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection Site#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
1152 11521220	NERV	Headache/ Headache#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521222	BLOOD	Lymphadenopathy/ swollen lymph nodes (neck-both sides)#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N
	GENRL	Fatigue/ fatigue#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N
		Injection site pain/ injection site pain.#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N
	MUSC	Myalgia/ myalgia#	3	10MAR2021	2/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1152 11521227	GENRL	Injury associated with device/ needle stick injury, right foot	2	27SEP2020	11/1	2	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1152 11521240	GASTR	Diarrhoea/ Diaherrea#	4	11JAN2021	1/1	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1152 11521256	GENRL	Pyrexia/ Fever	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1152 11521263	GENRL	Chills/ Chills	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521271	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	2	Yes		NA/TC	R (22SEP2020)	N/N
	PSYCH	Anxiety/ anxiety	2	01NOV2020	42/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521276	MUSC	Myalgia/ Myalgia	1	05SEP2020	6/6	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Neuropathy peripheral/ neuropathy	1	05SEP2020	6/6	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521282	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	02DEC2020	71/C	2	No	O	NA/TC	N	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1152 11521284	GENRL	Chills/ Chills	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N
		Pyrexia/ Fever	1	31AUG2020	1/3	1	Yes		NA/TC	R (02SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521298	PSYCH	Depression/ Worsening depression	2	DEC2020	70/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1152 11521308	GENRL	Injection site pain/ injection site pain	1	04SEP2020	2/4	3	Yes		NA/TC	R (07SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	6/5	2	No	O	NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	08SEP2020	6/4	2	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1152 11521316	GENRL	Pain/ Body aches	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	INFEC	Viral infection/ Viral infection#	2	23FEB2021	155/C	2	No	O	NA/TC	RG	N/N
	NERV	Facial paralysis/ Bell's palsy - L side#	2	23FEB2021	155/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1152 11521318	PSYCH	Insomnia/ worsening insomnia	1	03SEP2020	1/8	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1152 11521327	NERV	Migraine/ Worsening Migraine	2	30OCT2020	37/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521329		Injection site pain/ Injection Site Pain	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1152 11521332	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/1	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	VASC	Hypertension/ Hypertension#	2	01MAR2021	161/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521335	GENRL	Chills/ Chills	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
		Pain/ Body Aches	2	23SEP2020	2/1	2	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1152 11521338	GENRL	Chills/ Chills	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/3	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	23SEP2020	2/3	2	Yes		NA/TC	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521347	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	18DEC2020	88/1	2	Yes		NA	R (18DEC2020)	N/N
		Fatigue/ Fatigue	2	18DEC2020	88/3	2	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ Myalgia	2	19DEC2020	89/2	2	Yes		NA/TC	R (20DEC2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	19DEC2020	89/2	2	Yes		NA	R (20DEC2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08JAN2021	109/2	2	No	O	NA/TC	R (09JAN2021)	N/N
	PSYCH	Anxiety/ Body anxiety	2	08JAN2021	109/2	2	No	O	NA	R (09JAN2021)	N/N
16-55/ C4591001 1152 11521354	MUSC	Musculoskeletal stiffness/ Neck stiffness#	2	18FEB2021	148/C	1	No	O	NA	N	N/N
16-55/ C4591001 1152 11521355	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001	SKIN	Pruritus/ itchy scalp	2	05OCT2020	8/25	2	Yes		NA/TC/TCN	R (29OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521365		Rash/ rash back of neck	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
		Rash/ rash bilateral arms	2	05OCT2020	8/25	2	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1152 11521371	GENRL	Chills/ Chills	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
		Pain/ Body Aches	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521373	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521374	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	2/3	1	Yes		NA/TC	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521377	NERV	Headache/ Headaches#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1152 11521382	GENRL	Injection site pain/ Injection Site Pain	2	28SEP2020	1/4	1	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	28SEP2020	1/1	2	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Chest pain/ Chest Pain	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Pyrexia/ Fever (102.5 F)	2	29SEP2020	2/7	3	Yes		NA	R (05OCT2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	2/4	2	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1152 11521384	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
		Pyrexia/ Fever	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1152 11521401	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	2	30SEP2020	3/7	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1152 11521404	INJ&P	Foot fracture/ Fractured left second toe	2	29DEC2020	93/C	3	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1152 11521412	GASTR	Nausea/ Nausea#	4	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
		Pain/ Body Aches#	4	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headaches#	4	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1152 11521416	GENRL	Pyrexia/ Fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521424	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521430	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Hypogeusia/ Diminished sense of taste#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1152 11521434	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/2	2	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521435	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ injection Site Pain	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ FEVER	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	RESP	Upper respiratory tract congestion/ Head Congestion	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1152 11521436	GASTR	Proctalgia/ Rectal Pain	2	03NOV2020	36/12	2	No	O	NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1152 11521437	INJ&P	Limb injury/ injured right arm	1	27SEP2020	19/4	1	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1152 11521449	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	1/1	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pain/ Body Aches#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	PSYCH	Anxiety/ Anxiety#	4	10FEB2021	2/1	1	No	O	NA	R (10FEB2021)	N/N
16-55/ C4591001 1152 11521450	GENRL	Fatigue/ Fatigue	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	10OCT2020	2/3	2	Yes		NA/TC	R (12OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12OCT2020	4/1	2	Yes		NA	R (12OCT2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	26DEC2020	79/C	3	No	O	NA	N	N/N
16-55/ C4591001 1152 11521461	INJ&P	Muscle strain/ Muscle Strain (right chest)#	3	04FEB2021	9/5	1	No	O	NA	R (08FEB2021)	N/N
16-55/ C4591001 1152 11521464	GENRL	Injection site pain/ Injection Site Pain	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
	RESP	Upper respiratory tract congestion/ Head Congestion	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/4	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1152 11521467	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	5/6	3	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001	CARD	Palpitations/ Heart Palpitations	1	11OCT2020	18/21	2	No	O	NA	R (31OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521474 16-55/ C4591001	NERV	Headache/ Headache	2	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
1152 11521480 16-55/ C4591001	GASTR	Dyspepsia/ worsened heartburn	2	10NOV2020	26/22	2	No	O	NA/TC	R (01DEC2020)	N/N
1152 11521482 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
1152 11521490	GENRL	Injection site pain/ Injection Site Pain	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22OCT2020	2/1	2	Yes		NA/TC	R (22OCT2020)	N/N
		Pain/ Body Aches	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	GASTR	Abdominal pain upper/ Stomach Cramps	2	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521492	GENRL	Diarrhoea/ Diarrhea	2	23OCT2020	3/1	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	2	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1152 11521504	GENRL	Chills/ Chills#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11JAN2021	1/4	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ Headaches#	4	14JAN2021	4/29	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1152 11521511	VASC	Hypertension/ Hypertension#	4	18JAN2021	8/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Light Headaches	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
		Pyrexia/ Fever	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
NERV	Dizziness/ Light Headed	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521512	NERV	Headache/ Headache#	4	05JAN2021	1/3	2	Yes		NA/TCN	R (07JAN2021)	N/N
	EYE	Eye pain/ Eye Ache#	4	06JAN2021	2/2	2	Yes		NA/TCN	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	2	Yes		NA/TCN	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	06JAN2021	2/2	2	Yes		NA/TCN	R (07JAN2021)	N/N
16-55/ C4591001 1152 11521517	GENRL	Chills/ Chills	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ Fatigue	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Fever 101.7F	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04NOV2020	1/3	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1152 11521522	NERV	Paraesthesia/ tingling left fingers	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C4591001	NERV	Headache/ intermittent headache	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1152 11521529	GENRL	Injection site pain/ Injection Site Pain	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Pain/ Body Aches	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1152 11521534	INFEC	Skin infection/ skin infection right axilla	1	01NOV2020	17/30	1	No	O	NA/TC	R (30NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1152 11521549	GASTR	Nausea/ Nausea	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Pain/ Body Aches	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	VASC	Flushing/ generalized flushing	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521551	GENRL	Pyrexia/ Fever (101.9 F)	1	21OCT2020	1/4	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen Lymph Nodes (Left Jaw)#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
		Lymphadenopathy/ Swollen Lymph Nodes (Left Neck)#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
	EAR	Ear pain/ Left Ear Pain#	4	22JAN2021	15/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1152 11521557	GENRL	Chills/ Chills#	4	05JAN2021	1/4	2	Yes		NA/TCN	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	1/4	2	Yes		NA	R (08JAN2021)	N/N
		Feeling abnormal/ Brain Fog#	4	05JAN2021	1/1	2	Yes		NA	R (05JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint soreness#	4	05JAN2021	1/5	2	Yes		NA/TCN	R (09JAN2021)	N/N
16-55/ C4591001 1152 11521560	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1152 11521591	NERV	Headache/ Headache#	3	12MAR2021	2/1	2	Yes		NA/TC	R (12MAR2021)	N/N
16-55/ C4591001 1152 11521643	ENDO	Autoimmune thyroiditis/ Hashimoto's disease	2	12FEB2021	47/C	2	No	O	NA	N	N/N
16-55/ C4591001 1156 11561002	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
		Injection site pain/ INJECTION-SITE SORENESS	1	19AUG2020	1/4	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
	GENRL	Pyrexia/ FEVER	1	24AUG2020	6/1	1	Yes		NA	R (24AUG2020)	N/N
	RESP	Cough/ COUGH	1	24AUG2020	6/1	1	No	O	NA	R (24AUG2020)	N/N
16-55/ C4591001 1156 11561006	RESP	Pulmonary embolism/ PULMONARY EMBOLISM	1	31AUG2020	12/3	3	No	O	NA/TC	R (02SEP2020)	N/N
	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N
	MUSC	Musculoskeletal stiffness/ right shoulder stiffness	1	05SEP2020	17/3	1	No	O	NA/TCN	R (07SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1156 11561007	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N
	RESP	Haemoptysis/ HEMOPTYSIS	2	04OCT2020	25/1	2	No	O	NA	R (04OCT2020)	N/N
16-55/ C4591001 1156 11561008	GENRL	Chills/ Chills	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Myalgia/ muscle aches	1	27AUG2020	8/2	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1156 11561009	GENRL	Injection site pain/ Injection Site Pain (left deltoid)	1	03SEP2020	15/6	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1156 11561015	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1156 11561018	REPRO	Dysfunctional uterine bleeding/ DYSFUNCTIONAL UTERINE BLEEDING	1	10SEP2020	18/22	2	No	O	NA/TC	R (01OCT2020)	N/N
	INFEC	Urinary tract infection/ ACUTE URINARY TRACT INFECTION	2	30SEP2020	16/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1156 11561048	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1156 11561054	MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	RESP	Dyspnoea/ Shortness of breath	1	04SEP2020	8/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1156 11561057	MUSC	Arthralgia/ arthralgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1156 11561073	MUSC	Arthralgia/ arthralgia	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ MYALGIA#	3	19JAN2021	5/2	1	Yes		NA/TC	R (20JAN2021)	N/N
16-55/ C4591001 1156 11561076	RESP	Oropharyngeal pain/ sore throat	1	03SEP2020	3/2	1	Yes		NA/TCN	R (04SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1156 11561086	MUSC	Myalgia/ myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	INFEC	Conjunctivitis bacterial/ BACTERIAL CONJUNCTIVITIS	2	03OCT2020	11/12	1	No	O	NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1156 11561089	GENRL	Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1156 11561090	GENRL	Injection site pain/ Injection Site Pain (Left Shoulder)	1	04SEP2020	2/5	1	Yes		NA	R (08SEP2020)	N/N
	MUSC	Back pain/ Back Pain	2	08OCT2020	7/6	1	No	O	NA/TCN	R (13OCT2020)	N/N
	RENAL	Urethral discharge/ Urethral Discharge	2	08OCT2020	7/10	1	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1156 11561111	INFEC	Otitis externa/ external otitis	1	11SEP2020	4/6	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1156 11561113	REPRO	Vaginal discharge/ Vaginal discharge	2	29SEP2020	2/22	1	No	O	NA/TC	R (20OCT2020)	N/N
	INFEC	Vaginal infection/ ACUTE VAGINITIS	2	20OCT2020	23/7	1	No	O	NA/TC	R (26OCT2020)	N/N
	METAB	Hypercholesterolaemia/ HYPERCHOLESTEROLEMIA	2	20OCT2020	23/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1156 11561121	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/9	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Arthralgia/ left shoulder pain	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1156 11561124	RESP	Oropharyngeal pain/ sore throat	1	10SEP2020	2/5	1	Yes		NA	R (14SEP2020)	N/N
	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
16-55/ C4591001 1156 11561131	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
	BLOOD	Lymphadenopathy/ CERVICAL LYMPHADENOPATHY#	3	26FEB2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1156 11561159	SKIN	Rash/ FACIAL RASH#	3	26FEB2021	2/C	1	No	O	NA	RG	N/N
	GASTR	Diarrhoea/ diarrhea	1	27SEP2020	7/2	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1156 11561166	SKIN	Dermal cyst/ sebaceous cyst	1	06OCT2020	14/C	1	No	O	NA	RG	N/N
	GASTR	Vomiting/ VOMITING	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1156 11561172	GASTR	Gastritis/ GASTRITIS	1	28SEP2020	4/C	1	No	O	NA/TC	RG	N/N
	NEOPL	Acrochordon/ ACROCHORDON	1	28SEP2020	4/67	1	No	O	NA	R (03DEC2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1156 11561175	GASTR	Aphthous ulcer/ APHTHOUS ULCERS	2	07DEC2020	53/12	2	No	O	NA/TC	R (18DEC2020)	N/N	
16-55/ C4591001 1156 11561194	INFEC	Tinea versicolour/ PITYRIASIS VERICOLOR	2	04NOV2020	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1156 11561230	GENRL	Fatigue/ FATIGUE	1	12OCT2020	1/6	1	Yes		NA	R (17OCT2020)	N/N	
	GENRL	Chills/ CHILLS	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N	
16-55/ C4591001 1156 11561231	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE	2	05NOV2020	2/5	2	Yes		NA	R (09NOV2020)	N/N	
16-55/ C4591001 1156 11561252	INFEC	Otitis externa/ OTITIS EXTERNA OF LEFT EAR	2	29NOV2020	26/9	1	No	O	NA/TC	R (07DEC2020)	N/N	
16-55/ C4591001 1156 11561294	GENRL	Injection site pain/ PAIN IN SITE OF INJECTION	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N	
	MUSC	Myalgia/ MYALGIA	1	03NOV2020	1/4	2	Yes		NA/TC	R (06NOV2020)	N/N	
16-55/ C4591001	INFEC	Bacterial vulvovaginitis/ BACTERIAL VAGINITIS	2	08DEC2020	15/C	1	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1156 11561296 16-55/ C4591001	GENRL	Pyrexia/ FEVER	1	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N
1156 11561300 16-55/ C4591001	NERV	Headache/ HEADACHE	2	07JAN2021	2/42	1	Yes		NA/TC	R (17FEB2021)	N/N
1156 11561329 16-55/ C4591001	GENRL	Chills/ Chills#	3	21JAN2021	3/2	1	Yes		NA	R (22JAN2021)	N/N
1157 11571054 16-55/ C4591001	SKIN	Rash vesicular/ Vesicular Rash Below the lower lip#	3	08JAN2021	18/32	1	No	O	NA	R (08FEB2021)	N/N
1157 11571083 16-55/ C4591001	MUSC	Myalgia/ Myalgia	1	02SEP2020	2/6	1	Yes		NA	R (07SEP2020)	N/N
1157 11571113	GENRL	Chills/ Chills	2	23SEP2020	1/3	2	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1157 11571114	GASTR	Nausea/ Nausea	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1157 11571115	GENRL	Pain/ Body Aches	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1157 11571125	GENRL	Injection site pain/ Pain at the injection site	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ General Muscle Aches	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1157 11571126	IMMUN	Allergy to arthropod bite/ Allergic reaction to mosquito bite	2	01OCT2020	9/10	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1157 11571130	NERV	Headache/ Headache	1	16SEP2020	16/5	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1157 11571132	GENRL	Injection site erythema/ Redness at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
		Injection site swelling/ Swelling at injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	INFEC	Sinusitis/ Sinusitis	2	03OCT2020	12/13	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1157 11571141	GENRL	Injection site erythema/ Redness at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1157 11571156	GENRL	Injection site induration/ Induration at injection site	2	27OCT2020	1/8	1	Yes		NA	R (03NOV2020)	N/N
		Chills/ Chills	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N
		Myalgia/ Myalgia	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N
		Headache/ Headache	2	28OCT2020	2/5	1	Yes		NA/TC	R (01NOV2020)	N/N
	GENRL	Injection site pain/ Pain at study vaccine injection site ( Right arm)#	4	02MAR2021	1/5	1	Yes		NA	R (06MAR2021)	N/N
	GENRL	Chills/ Chills#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Fatigue/ Fatigue#	4	03MAR2021	2/2	1	Yes		NA	R (04MAR2021)	N/N
Pyrexia/ Fever#		4	03MAR2021	2/2	1	Yes		NA/TC	R (04MAR2021)	N/N	
Headache/ Headache#		4	03MAR2021	2/3	1	Yes		NA	R (05MAR2021)	N/N	
16-55/ C4591001 1161 11611011	EAR	Excessive cerumen production/ Excess cerumen, lt EAC	1	16OCT2020	77/C	1	No	O	NA	N	N/N
16-55/ C4591001 1161 11611016	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	17JAN2021	60/C	1	No	O	NA	UNK	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1161 11611020	BLOOD	Lymphadenopathy/ 1+right distal cervical lymph node enlarged	1	08NOV2020	98/C	1	No	O	NA	N	N/N
16-55/ C4591001 1161 11611027	GASTR	Nausea/ nausea#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
		Vomiting/ vomiting#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	21JAN2021	2/6	2	Yes		NA/TC	R (26JAN2021)	N/N
	NERV	Dizziness/ dizziness#	3	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N
		Headache/ headache#	3	21JAN2021	2/4	2	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1161 11611034	NERV	Neuropathy peripheral/ Bilateral Peripheral Neuropathy	2	01DEC2020	8/C	1	No	O	NA	N	N/N
		Restless legs syndrome/ Restless Leg Syndrome	2	01DEC2020	8/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1162 11621019	INFEC	Sinusitis/ sinus infection	2	06OCT2020	42/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ Esophageal pain/Acid Reflux	1	13AUG2020	10/2	1	No	O	NA	R (14AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1162 11621025 16-55/ C4591001	NERV	Headache/ Headache	2	05SEP2020	2/3	1	No	O	NA	R (07SEP2020)	N/N
1162 11621103 16-55/ C4591001	RESP	Nasal congestion/ Nasal Congestion	2	02OCT2020	31/2	1	No	O	NA	R (03OCT2020)	N/N
1162 11621121 16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	SEP2020	1/C		No	O	NA	UNK	N/N
1162 11621128 16-55/ C4591001	NERV	Tension headache/ Stress induced Headache	2	14SEP2020	6/2	1	No	O	NA	R (15SEP2020)	N/N
1162 11621137 16-55/ C4591001	GENRL	Pyrexia/ Fever	1	20AUG2020	4/2	1	Yes		NA	R (21AUG2020)	N/N
1162 11621142 16-55/ C4591001	NERV	Headache/ Headache	2	14OCT2020	35/1	1	No	O	NA	R (14OCT2020)	N/N
1162 11621151 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
1162 11621158											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1162 11621166	EAR	Injection site pain/ Left shoulder soreness (injection site pain)	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Pyrexia/ Slight increased fever	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N	
		Vertigo/ Intermittent Vertigo	2	27SEP2020	19/26	1	No	O	NA	R (22OCT2020)	N/N	
	GASTR	Diarrhoea/ Diarrhea	2	11OCT2020	26/2	1	No	O	NA	R (12OCT2020)	N/N	
	16-55/ C4591001 1162 11621205	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
		NERV	Headache/ Headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
		RENAL	Nephrolithiasis/ Kidney Stones	2	25NOV2020	69/2	1	No	O	NA/TC	R (26NOV2020)	N/N
	16-55/ C4591001 1162 11621216	INFEC	Urinary tract infection/ urinary tract infection	2	29NOV2020	73/11	1	No	O	NA/TC	R (09DEC2020)	N/N
		INFEC	Urinary tract infection/ Urinary tract infection	2	04DEC2020	73/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	NERV	Migraine/ Migraine	2	12OCT2020	19/17	1	No	O	NA/TC	R (28OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1162 11621279 16-55/ C4591001	INFEC	Pharyngitis streptococcal/ Strep Throat	2	12OCT2020	18/11	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N
1162 11621283 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
1162 11621324	RESP	Oropharyngeal pain/ Sore throat	1	14SEP2020	5/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/Y
1162 11621392	RESP	Oropharyngeal pain/ Sore throat	1	18SEP2020	2/2	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Arm soreness	1	17SEP2020	1/C	1	Yes		NA/TC/TCN	N	N/N
1162 11621401 16-55/ C4591001	GENRL	Chills/ Chills	1	02OCT2020	12/1	1	No	O	NA	R (02OCT2020)	N/N
1162 11621416 16-55/ C4591001	NERV	Hypoaesthesia/ Leg Numbness	1	05OCT2020	6/2	1	No	O	NA	R (06OCT2020)	N/N
1162 11621464											



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1162 11621583	NERV	Headache/ headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1163 11631039	GENRL	Injection site pain/ Left Deltoid injection Site pain#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001 1163 11631040	INFEC	Urinary tract infection/ UTI	1	22AUG2020	17/7	2	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1163 11631059	IMMUN	Drug hypersensitivity/ Allergic Reaction to study investigational product	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N
	SKIN	Dermatitis allergic/ Allergic Reaction upper body rash	1	08AUG2020	2/18	2	Yes		NA/TC	R (25AUG2020)	N/N
16-55/ C4591001 1163 11631069	PSYCH	Depression/ DEPRESSION	1	01SEP2020	23/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1163 11631077	GENRL	Pyrexia/ FEVER	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1166 11661003		Pyrexia/ Low grade fever	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ CHILLS	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
1166 11661009		Pyrexia/ FEVER	2	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Muscle fatigue/ MUSCLE FATIGUE	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
1166 11661028		Hot flush/ Exacerbation of hot flashes	2	02OCT2020	22/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001	VASC										
1166 11661030		Urinary tract infection/ URINARY TRACT INFECTION	2	27OCT2020	47/20	1	No	O	NA/TC	R (15NOV2020)	N/N
	INFEC	Urinary tract infection/ URINARY TRACT INFECTION#	3	28DEC2020	8/12	1	No	O	NA/TC	R (08JAN2021)	N/N
16-55/ C4591001	NERV	Dysgeusia/ Metallic taste	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
1166 11661036		Insomnia/ Insomnia	1	21AUG2020	2/9	2	Yes		NA	R (29AUG2020)	N/N
	PSYCH										

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1166 11661046	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1166 11661047	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N
16-55/ C4591001 1166 11661063	GENRL	Pyrexia/ Fever	2	25SEP2020	1/31	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1166 11661068	INJ&P	Joint injury/ Left knee injury	2	21JAN2021	120/C	2	No	O	NA	RG	N/N
	GENRL	Pyrexia/ fever#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1166 11661072	GENRL	Pyrexia/ FEVER#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1166 11661076	INJ&P	Contusion/ LEFT UPPER CHEST BRUISING.	1	25SEP2020	11/32	1	No	O	NA/TC	R (26OCT2020)	N/N
		Road traffic accident/ Motor vehicle accident (MVA)	1	25SEP2020	11/1	1	No	O	NA	R (25SEP2020)	N/N
		Skin abrasion/ SUPERFICIAL ABRAISONS, dorsal wrist, right.	1	25SEP2020	11/15	1	No	O	NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Skin abrasion/ SUPERFICIAL ABRAISONS, dorsal wrists, left	1	25SEP2020	11/15	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1166 11661078	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	2	18DEC2020	75/C		No	O	NA	UNK	N/N
16-55/ C4591001 1166 11661087	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1166 11661091	GENRL	Fatigue/ FATIGUE	2	05NOV2020	2/2	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1166 11661097	GENRL	Injection site pain/ INJECTION SITE PAIN (POST- INJECTION; EXACT START TIME UNKNOWN)	1	23OCT2020	1/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1166 11661106	MUSC	Muscle fatigue/ BILATERAL LEG MUSCLE FATIGUE	1	16NOV2020	19/2	1	No	O	NA	R (17NOV2020)	N/N
16-55/ C4591001 1166 11661109	GENRL	Injection site pain/ INJECTION SITE PAIN	2	20NOV2020	2/2	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1167 11671009	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Cholelithiasis/ Cholelithiasis	1	21AUG2020	5/2	2	No	O	NA/TCN	RS (22AUG2020)	N/N
	HEPAT	Hepatitis acute/ Acute hepatitis#	4	25FEB2021	53/C	2	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1167 11671021	INJ&P	Muscle strain/ Back Strain	2	14OCT2020	36/23	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1167 11671036	GENRL	Pyrexia/ fever#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1167 11671051	INFEC	Herpes zoster oticus/ Ramsay-Hunt Syndrome	2	05DEC2020	82/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1167 11671065	NERV	Headache/ Headache#	4	06JAN2021	3/1	2	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1167 11671073	MUSC	Back pain/ Lumbago	2	NOV2020	46/C	2	No	O	NA/TC	RG	N/N
	INV	Antinuclear antibody positive/ Positive ANA#	4	11JAN2021	5/C	2	No	O	NA	N	N/N
		C-reactive protein increased/ Elevated C Reactive Protein#	4	11JAN2021	5/C	1	No	O	NA	N	N/N
16-55/ C4591001	INFEC	Cellulitis/ Cellulitis nose	2	27SEP2020	6/21	2	No	O	NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1167 11671120 16-55/ C4591001	METAB	Type 2 diabetes mellitus/ Worsening Type 2 diabetes	1	09SEP2020	7/94	2	No	O	NA/TC	R (11DEC2020)	N/N
1167 11671130	VASC	Hypertension/ Hypertension with microalbumin	1	09SEP2020	7/C	1	No	O	NA/TC	RG	N/N
	GASTR	Nausea/ Nausea	1	22SEP2020	20/1	1	No	CD	NA	R (22SEP2020)	N/N
	GENRL	Chest pain/ Chest pain	1	22SEP2020	20/1	2	No	CD	NA	R (22SEP2020)	N/N
16-55/ C4591001	GENRL	Pain/ body aches#	4	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
1167 11671134		Pyrexia/ fever#	4	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	2/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N
1167 11671175											
16-55/ C4591001	GASTR	Nausea/ nausea, not COVID related	1	15AUG2020	3/1	1	No	O	NA	R (15AUG2020)	N/N
1168 11681016											
16-55/ C4591001	SKIN	Urticaria/ HIVES(NECK)	2	22SEP2020	19/5	1	No	CD	NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1168 11681024	GENRL	Peripheral swelling/ swelling in bilateral upper extremities#	3	12JAN2021	8/C	2	No	O	NA	RG	N/N
	MUSC	Arthralgia/ mild bilateral hand joint pain#	3	12JAN2021	8/33	2	No	O	NA/TC/TCN	RS (13FEB2021)	N/N
	MUSC	Arthralgia/ worsening bilateral hand joint pain#	4	14FEB2021	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1168 11681054	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	SKIN	Cold sweat/ cold sweat	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1168 11681073	SKIN	Rash/ upper body rash	2	13SEP2020	3/2	1	Yes		NA/TC	R (14SEP2020)	N/N
	SKIN	Rash/ intermittent upper body rash	2	18SEP2020	8/25	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1168 11681105	GENRL	Fatigue/ FATIGUE	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE ACHES	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681109	GENRL	Injection site pain/ INJECTION SITE PAIN	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Pain in extremity/ Intermittent pain in both feet	1	06SEP2020	10/6	1	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1168 11681118	GENRL	Peripheral swelling/ Intermittent Swelling in the L hand	1	09SEP2020	13/3	1	No	O	NA	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	03SEP2020	3/2	2	Yes		NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1168 11681132	GENRL	Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1168 11681138		Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	GASTR	Nausea/ nausea	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ low grade fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Back pain/ low back pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1168 11681162 16-55/ C4591001	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
1168 11681176 16-55/ C4591001	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
1168 11681195	GENRL	Pyrexia/ low grade fever	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	14OCT2020	2/6	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1168 11681198	INFEC	Sinusitis/ SINUS INFECTION	1	27SEP2020	5/8	1	No	O	NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1168 11681207	INFEC	Hordeolum/ Sty left eye	2	14NOV2020	30/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1168 11681210	GENRL	Chills/ chills	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ body aches	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681213	GENRL	Pyrexia/ fever	1	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Chills/ chills	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
		Pain/ body aches	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
	NERV	Pyrexia/ fever	2	15OCT2020	1/3	2	Yes		NA	R (17OCT2020)	N/N
		Headache/ headache	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ muscle ache	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1168 11681217	GENRL	Injection site erythema/ redness at injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N
		Injection site pruritus/ itching at the injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1168 11681219	MUSC	Injection site swelling/ swelling at the injection site	2	27OCT2020	2/8	1	Yes		NA	R (03NOV2020)	N/N
		Axillary mass/ Lump in L armpit	2	30OCT2020	2/6	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1168 11681231	GENRL	Pain in extremity/ pain in L upper arm	2	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
		Injection site pain/ INJECTION SITE PAIN	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1169 11691001	GENRL	Injection site pain/ Pain at Injection Site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y
	NERV	Headache/ Headache	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C4591001 1169 11691002	GENRL	Injection site induration/ Red induration at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Injection site warmth/ Warmth at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Malaise/ General Malaise	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691007	RESP	Oropharyngeal pain/ Sore Throat	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	INFEC	Skin infection/ Skin Infection Right Wrist	2	16DEC2020	85/9	1	No	O	NA/TCN	R (24DEC2020)	N/N
	GENRL	Fatigue/ Fatigue	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	3	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site Pain#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1169 11691010	NERV	Headache/ Headache#	4	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Swollen Right Axillary lymph node	1	03SEP2020	1/40	1	Yes		NA	R (12OCT2020)	N/Y
16-55/ C4591001 1169 11691011	GENRL	Injection site pain/ Injection Site pain	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/Y
	MUSC	Arthralgia/ Painful Left Knee	1	08SEP2020	6/4	1	No	O	NA/TC	R (11SEP2020)	N/N
		Joint swelling/ swelling Left knee	1	08SEP2020	6/4	1	No	O	NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691012	GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	21/3	1	No	O	NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Arm pain at Injection Site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Sensation of foreign body/ Globus Sensation of the throat	1	06SEP2020	3/19	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1169 11691017	GENRL	Injection site pain/ Arm pain at Injection Site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Mild Soreness at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Mild Injection Site pain#	3	08JAN2021	4/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1169 11691018	GENRL	Injection site pain/ arm pain at injection site#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001		Injection site pain/ Injection Site Pain#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pain/ Generalized Body Aches#	4	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Pain in extremity/ Left Arm pain	2	30SEP2020	1/2	2	Yes		NA/TCN	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691019	GENRL	Chills/ Chills	2	01OCT2020	2/1	1	Yes	NA		R (01OCT2020)	N/N
16-55/ C4591001 1169 11691020	GENRL	Injection site pain/ Tenderness at injection site	1	08SEP2020	1/2	1	Yes	NA		R (09SEP2020)	N/N
		Injection site swelling/ Swelling at injection site	1	08SEP2020	1/2	1	Yes	NA		R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes	NA		R (03OCT2020)	N/N
		Injection site pain/ Soreness at Injection Site	2	02OCT2020	2/3	1	Yes	NA		R (04OCT2020)	N/N
	NERV	Mental impairment/ Mental Fogginess	2	02OCT2020	2/2	1	Yes	NA		R (03OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	03OCT2020	3/1	1	Yes	NA		R (03OCT2020)	N/N
16-55/ C4591001 1169 11691021	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/3	1	Yes	NA/TC		R (01FEB2021)	N/N
		Injection site pain/ Injection Site pain#	3	30JAN2021	2/3	1	Yes	NA/TC		R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site pain#	4	18FEB2021	1/3	1	Yes	NA/TC		R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes	NA		R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691022	GENRL	Injection site pain/ Mild Injection Site Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Injection site pain/ Mild injection site pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691023	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Pain at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site swelling/ Mild swelling at Injection site	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1169 11691024	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
		Injection site swelling/ 2 cm swelling at injection site	1	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Moderate pain at injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691025	NERV	Somnolence/ Drowsiness#	3	04JAN2021	1/1	2	Yes		NA	R (04JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691026	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	5/2	1	No	O	NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ arm soreness at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	INJ&P	Foot fracture/ Fractured left foot#	3	18JAN2021	14/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1169 11691027	MUSC	Arthralgia/ Generalized joint aches#	4	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691029	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Tenderness at Injection Site	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	1	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691030	GENRL	Fatigue/ Fatigue	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Tenderness at Injection site	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	MUSC	Pain in extremity/ pain in left arm	1	10SEP2020	1/4	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Moderate Pain at Injection Site	2	01OCT2020	1/4	2	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Mild pain at Injection Site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1169 11691033	GENRL	Injection site bruising/ Bruise at Injection Site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Soreness at Injection Site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site erythema/ Redness at injection site#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1169 11691036	GENRL	Injection site pain/ Tenderness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1169 11691038	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	2	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	INFEC	Rhinitis/ Rhinitis#	3	08JAN2021	2/2	2	No	O	NA/TC	R (09JAN2021)	N/N
	METAB	Decreased appetite/ Decreased Appetite#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	3	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
		Vomiting/ Vomiting#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691040	GENRL	Fatigue/ fatigue#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/3	2	Yes		NA/TC	R (30JAN2021)	N/N
	GASTR	Nausea/ Nausea	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Pain/ Body Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
	MUSC	Arthralgia/ Joint Aches	2	03OCT2020	2/2	2	Yes		NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1169 11691041	GENRL	Injection site pain/ Injection Site Soreness	1	11SEP2020	1/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1169 11691043	GENRL	Malaise/ General malaise	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		Injection site pain/ injection site soreness	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
		Malaise/ malaise	2	03OCT2020	2/3	1	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	Pyrexia/ Fever of 100.7	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691044	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
	GENRL	Chills/ Chills#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Injection site pain/ Mild injection site pain# Arthralgia/ Generalized Joint Aches#	3	08JAN2021	1/3	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1169 11691046	MUSC	Myalgia/ Muscle Aches#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	2	05JAN2021	92/3	2	Yes		NA	R (07JAN2021)	N/N
	BLOOD	Pain/ Generalized Body Aches# Lymph node pain/ Tender Supraclavicular Lymph Node#	2	05JAN2021	92/3	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	07JAN2021	3/5	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Pain/ Generalized body aches#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691047		Injection site pain/ Tenderness at injection site	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1169 11691049	GENRL	Injection site pain/ Painful Right Arm Injection Site	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1169 11691053	MUSC	Myalgia/ Generalized Muscle Aches#	4	26JAN2021	2/2	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1169 11691055	BLOOD	Lymphadenopathy/ Enlarged Left Axillary and subclavicular lymph nodes#	3	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691056	NERV	Headache/ Mild Headache#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection Site	2	08OCT2020	1/4	2	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever of 99.9	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	SKIN	Onycholysis/ Toenail Onycholysis x3	2	14DEC2020	68/33	2	No	O	NA	R (15JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Enlarged Bilateral Inguinal Lymph Nodes	2	16DEC2020	70/22	2	No	O	NA	R (06JAN2021)	N/N
	GENRL	Peripheral swelling/ Bilateral Lower extremity swelling	2	16DEC2020	70/63	2	No	O	NA/TC	R (16FEB2021)	N/N
	CARD	Tachycardia/ Tachycardia#	2	31DEC2020	85/C	2	No	O	NA/TC	N	N/N
	NERV	Tremor/ Tremors#	2	31DEC2020	85/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1169 11691057	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Generalized Body Aches	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691058	GENRL	Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Chills/ chills#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Pyrexia/ fever 100.2 F#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Headache/ headache#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
NERV	Headache/ Headache#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N	
16-55/ C4591001 1169 11691059	MUSC	Pain in extremity/ Left Arm Pain	1	18SEP2020	2/6	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1169 11691062	GASTR	Nausea/ Nausea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Generalized Body Aches	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Pain in extremity/ Sore Left Arm	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001	INJ&P	Fall/ Fall	2	21DEC2020	77/1	2	No	O	NA	R (21DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1169 11691063		Ligament sprain/ Right ankle sprain	2	21DEC2020	77/68	2	No	O	NA/TCN	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	2/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1169 11691065	GENRL	Injection site pain/ injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Joint range of motion decreased/ mild range of motion deficit left arm	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ mild pain at injection site	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
	MUSC	Joint range of motion decreased/ Limited range of motion in left arm	2	09OCT2020	1/3	1	Yes		NA/TC/TCN	R (11OCT2020)	N/N
16-55/ C4591001 1169 11691067	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	INFEC	Urinary tract infection/ Urinary Tract Infection	2	15OCT2020	7/13	2	No	O	NA/TC	R (27OCT2020)	N/N
	SKIN	Pruritus/ Pruritis	2	29OCT2020	21/13	2	No	O	NA/TC	R (10NOV2020)	N/N
		Urticaria/ Hives- Entire Body	2	29OCT2020	21/13	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1169 11691072	GENRL	Injection site pain/ Pain at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1169 11691073†	GENRL	Injection site pain/ Tenderness at injection site	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
		Chills/ Chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	8/1	1	No	O	NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pyrexia/ Fever#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	Arthralgia/ Generalized Joint Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	Myalgia/ Generalized Muscle Pain#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701003	GENRL	Fatigue/ Fatigue	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ Body Aches	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	27/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1170 11701006	GENRL	Fatigue/ Fatigue	1	19AUG2020	8/1	1	Yes		NA	R (19AUG2020)	N/N
16-55/ C4591001 1170 11701013	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	NOV2020	55/C		No	O	NA/W		N/N
16-55/ C4591001 1170 11701015	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection at pain site#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ General Muscle pain#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701016	GENRL	Chills/ chills#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
		Pyrexia/ fever#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1170 11701018	GENRL	Injection site pain/ Pain at Injection Site#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1170 11701020	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1170 11701021	GENRL	Injection site pain/ Pain at Injection Site	1	18AUG2020	2/5	1	Yes		NA	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	2/2	1	Yes		NA	R (19AUG2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701022	MUSC	Myalgia/ Generalized Muscle Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	GENRL	Pain/ Exercise Induced Body Soreness	1	06SEP2020	21/2	1	No	O	NA/TC	R (07SEP2020)	N/N	
16-55/ C4591001 1170 11701024	NERV	Headache/ Headache	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N	
	GENRL	Fatigue/ fatigue	1	23AUG2020	7/2	2	Yes		NA	R (24AUG2020)	N/N	
16-55/ C4591001 1170 11701029	GENRL	Injection site pain/ pain at injection site#	3	15DEC2020	1/3	1	Yes		NA	R (17DEC2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N	
	NERV	Headache/ Headache#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N	
	GENRL	Injection site erythema/ Injection Site Redness	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N	
			Injection site pain/ Injection Site Pain	1	18AUG2020	1/4	1	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	18AUG2020	1/2	1	Yes		NA/TC	R (19AUG2020)	N/N	
GENRL	Pyrexia/ Fever	1	19AUG2020	2/1	1	Yes		NA	R (19AUG2020)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chest pain/ Chest Pain	2	10SEP2020	2/2	1	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1170 11701031	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ headache#	4	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1170 11701034	GENRL	Fatigue/ Fatigue	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	12SEP2020	4/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1170 11701035	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Generalized Muscle Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
		Vomiting/ Vomiting#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Malaise/ Malaise#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1170 11701036	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1170 11701037	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1170 11701038	GENRL	Injection site pain/ Pain at Injection Site	2	09SEP2020	1/4	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701040	GENRL	Chills/ Chills#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Fatigue/ Fatigue#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Injection site pain/ Pain at Injection site#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
		Pyrexia/ Fever#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
	MUSC	Myalgia/ General Muscle Pain#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	3	30DEC2020	1/1	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Asthenia/ Generalized Weakness#	4	21JAN2021	1/C	1	No	O	NA	RG	N/N
		Fatigue/ Fatigue#	4	21JAN2021	1/8	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	21JAN2021	1/C	1	Yes		NA	RG	N/N
		Myalgia/ Generalized Muscle Pain#	4	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701041	GENRL	Injection site pain/ Pain at injection site	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701042	MUSC	Myalgia/ Muscle pain	1	20AUG2020	2/3	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
		Injection site erythema/ Redness at injection site	2	11SEP2020	2/6	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	11SEP2020	2/6	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Sacroiliac joint pain	2	14SEP2020	5/C	1	No	O	NA	RG	N/N
		Back pain/ Lower Back Pain	2	14SEP2020	5/C	1	No	O	NA	RG	N/N
		Muscular weakness/ Bilateral Lower Extremity Weakness	2	14SEP2020	5/C	1	No	O	NA	RG	N/N
		Myalgia/ Bilateral Lower Extremity Myalgia	2	14SEP2020	5/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/	1	Yes		NA	R	N/N
	NERV	Headache/ Headache	1	20AUG2020	1/	2	Yes		NA	R	N/N
GASTR	Diarrhoea/ Diarrhea#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	
GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701043		Injection site pain/ Injection Site Pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
		Pyrexia/ Fever#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	NERV	Headache/ Headache#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	05FEB2021	1/30	1	Yes		NA	R (06MAR2021)	N/N
		Pyrexia/ fever#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ headache#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701044	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	SKIN	Rash pruritic/ Itchy Pink Rash (bilateral forearms, upper back, top of head at forehead and scalp)	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1170 11701045	GENRL	Fatigue/ Fatigue	1	20AUG2020	1/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Injection site erythema/ Redness at injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Injection site swelling/ Swelling at injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
		Pyrexia/ Fever	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1170 11701047	GENRL	Injection site pain/ Injection Site Pain	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701049	GENRL	Fatigue/ Fatuge	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Fatigue/ Fatigue	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701052	GENRL	Injection site pain/ Injection Site Soreness#	3	17DEC2020	2/1	2	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site erythema/ Injection Site Redness#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701054	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	2/3	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1170 11701055	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701057	GENRL	Injection site pain/ Injection Site Pain	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
		Pyrexia/ Fever	1	21AUG2020	1/2	2	Yes		NA	R (22AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701059	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1170 11701060	GENRL	Injection site pain/ Injection Site Pain#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1170 11701063	GENRL	Injection site pain/ Pain at Injection Site	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1170 11701064	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1170 11701065	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701069	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Myalgia/ Myalgias	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Fatigue/ Fatigue	1	25AUG2020	2/3	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1170 11701072		Injection site pain/ Injection Site Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ Generalize Muscle Pain#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1170 11701073	NERV	Headache/ Headache#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	2/4	1	Yes		NA	R (29AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701074	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	3	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Chills/ Chills#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	16-55/ C4591001 1170 11701075	GENRL	Fatigue/ Fatigue	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)
	Injection site pain/ Injection Site Soreness	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N	
	Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701079	NERV	Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1170 11701085	MUSC	Myalgia/ Muscle Pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	26AUG2020	1/3	2	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701086	GENRL	Chills/ Chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1170 11701087	GENRL	Injection site erythema/ Injection Site Redness	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1170 11701089	GENRL	Pyrexia/ Fever	1	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1170 11701091	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	17SEP2020	2/8	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701092	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1170 11701093	GENRL	Injection site pain/ Pain at Injection Site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
		Injection site swelling/ Swelling at Injection Site	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1170 11701094	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701095	GENRL	Chills/ Chills#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
		Myalgia/ Generalized Muscle Pain#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Headache/ Headache#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701096	GENRL	Chills/ chills#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgias	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701097	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	06JAN2021	1/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	07JAN2021	2/4	2	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701098	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1170 11701099	GENRL	Injection site pain/ Pain at injection site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1170 11701101	GENRL	Injection site pain/ Pain at Injection Site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701102	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1170 11701103	GASTR	Nausea/ Nausea	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701104	NERV	Headache/ Headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1170 11701105	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	2/4	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1170 11701106	GENRL	Fatigue/ Fatigue	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Arthralgia/ Generalized Joint Pain	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Myalgia/ Myalgias	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)
16-55/ C4591001 1170 11701106	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at Injection Site	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701107	MUSC	Pyrexia/ Fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Arthralgia/ Joint Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		Chills/ Chills#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Malaise/ Malaise#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1170 11701108	NERV	Pain/ Body Aches#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Headache/ Headache	1	01SEP2020	6/2	1	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701111	GENRL	Pyrexia/ Fever#	3	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	27AUG2020	1/3	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	28AUG2020	2/2	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1170 11701112	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1170 11701115	IMMUN	Drug hypersensitivity/ Allergic Reaction to Lisinopril	1	15SEP2020	19/2	3	No	O	NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site swelling/ Injection Site Swelling	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1170 11701116	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/2	1	Yes		NA	R (29AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701117	MUSC	Myalgia/ Muscle Pain Generalized	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701119	GENRL	Headache/ Headache#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
16-55/ C4591001 1170 11701120	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	1	28AUG2020	1/2	2	Yes		NA/TC	R (29AUG2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701121		Injection site swelling/ Injection Site Swelling	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	INJ&P	Fall/ Fall#	4	22JAN2021	3/1	2	No	O	NA	R (22JAN2021)	N/N
16-55/ C4591001 1170 11701122		Lower limb fracture/ Right Lower Extremity Fracture#	4	22JAN2021	3/C	3	No	O	NA/TCN	RG	Y/N
	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Injection Pain Site	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701123	MUSC	Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Myalgia/ Muscle Pain	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Headache/ Headache	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
		Decreased appetite/ Poor Appetite	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
MUSC	Myalgia/ Myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N	
NERV	Hypoaesthesia/ Numbness In Toes	2	21SEP2020	6/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1170 11701125	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1170 11701126	GENRL	Chills/ Chills	1	28AUG2020	1/1	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701127	GENRL	Injection site pain/ Injection Site Pain	1	28AUG2020	1/8	1	Yes		NA	R (04SEP2020)	N/N
		Chills/ Chills	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	1/8	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ Fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
		Injection site pain/ pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1170 11701128	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ Fatigue	2	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	19SEP2020	2/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		MUSC	Myalgia/ Myalgias	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701129	GENRL	Injection site pain/ Injection Pain Site	2	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1170 11701131	GENRL	Chills/ Chills	1	31AUG2020	1/1	1	Yes		NA	R (31AUG2020)	N/N
		Injection site pain/ Injection Site Pain	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1170 11701136	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701137	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701138	BLOOD	Lymph node pain/ Right Axillary Lymph Node Tenderness#	4	08JAN2021	3/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	1	31AUG2020	1/8	1	Yes		NA	R (07SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	2	Yes		NA/TC	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	01SEP2020	2/1	2	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	3/6	2	Yes		NA	R (07SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
NERV	Headache/ Headache	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N	
16-55/ C4591001 1170 11701139	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701143		Injection site pain/ pain at injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GASTR	Nausea/ nausea#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	Injection site erythema/ Injection Site Redness	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
	Injection site pain/ Injection Site Pain	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701144	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GASTR	Gingival pain/ Gum Tingling Pain	1	04SEP2020	5/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INFEC	Sinusitis/ Sinus Infection	2	02OCT2020	12/8	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1170 11701145	GENRL	Injection site pain/ Injection Site Pain	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Pain in extremity/ Arm Pain	2	22SEP2020	2/4	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1170 11701146	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701149	GENRL	Fatigue/ Fatigue#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ Headache#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ injection at pain site#	4	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ headaches#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1170 11701150	GENRL	Fatigue/ Fatigue#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
		Injection site pain/ Injection Site Pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	18DEC2020	1/4	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
		Pyrexia/ Fever#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701151	NERV	Headache/ Headache#	4	08JAN2021	1/4	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701152		Pyrexia/ Fever	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
	NERV	Headache/ headache#	3	23DEC2020	2/3	1	Yes		NA	R (25DEC2020)	N/N
16-55/ C4591001 1170 11701153	GENRL	Fatigue/ Fatigue#	4	18JAN2021	7/4	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701154 16-55/ C4591001 1170 11701156	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
1170 11701156 16-55/ C4591001 1170 11701158	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
1170 11701158 16-55/ C4591001 1170 11701159	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
1170 11701159 16-55/ C4591001 1170 11701163	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
1170 11701159 16-55/ C4591001 1170 11701163	GENRL	Fatigue/ Fatigue	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
1170 11701163 16-55/ C4591001 1170 11701163	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
1170 11701163 16-55/ C4591001 1170 11701163	GENRL	Injection site pain/ Injection Site Pain	2	22SEP2020	1/1	1	Yes		NA	R (22SEP2020)	N/N
1170 11701163 16-55/ C4591001 1170 11701163	EYE	Blepharitis/ Blepharitis of the left eye	1	15SEP2020	15/70	1	No	O	NA/TC	R (23NOV2020)	N/N
1170 11701163 16-55/ C4591001 1170 11701163	GENRL	Chills/ Chills#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
1170 11701163 16-55/ C4591001 1170 11701163	GENRL	Injection site pain/ Injection Site Soreness#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701165	GENRL	Pyrexia/ Fever#	3	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Chills/ Chills#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Fatigue/ Fatigue#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pruritus/ Injection Site Itching#	4	06FEB2021	6/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
Injection site pain/ Pain at injection site		2	24SEP2020	1/5	1	Yes		NA	R (28SEP2020)	N/N	
MUSC		Arthralgia/ Joint Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Myalgia/ Muscle Pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701166	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1170 11701167	GENRL	Injection site pain/ Injection Site Pain	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
		Pyrexia/ Fever	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1170 11701174	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701178	MUSC	Injection site pain/ Injection Site Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
		Injection site pain/ Injection Site Soreness	1	03SEP2020	2/4	2	Yes		NA/TC	R (06SEP2020)	N/N
		Arthralgia/ General Joint Pain	1	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Myalgia/ Myalgias	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
		Headache/ Headache	1	03SEP2020	2/4	1	Yes		NA/TC	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/44	2	Yes		NA/TC	R (06NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	24SEP2020	2/25	2	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
	EYE	Vision blurred/ Blurry Vision	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N
	VASC	Hypertension/ High Blood Pressure	2	30SEP2020	8/38	1	No	O	NA/TC	R (06NOV2020)	N/N
GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701179	GENRL	Injection site pain/ Injection Site Pain	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
		Malaise/ Malaise	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1170 11701180	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701181	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
	GENRL	Chills/ chills#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
16-55/ C4591001 1170 11701182	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Pyrexia/ Fever	2	23SEP2020	1/3	2	Yes		NA/TC	R (25SEP2020)	N/N
		Myalgia/ General Muscle Pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1170 11701183	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701187	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1170 11701190	GENRL	Fatigue/ Fatigue	1	03SEP2020	1/2	2	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1170 11701191	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Soreness#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1170 11701192	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701193		Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Malaise/ Malaise	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1170 11701195	GENRL	Chills/ Chills#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
		Fatigue/ Fatigue#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ Fever#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1170 11701196	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701199	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1170 11701203	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701204	GENRL	Injection site pain/ Injection Site Pain	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1170 11701205	GENRL	Chills/ Chills	1	05SEP2020	3/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1170 11701206	GENRL	Injection site pain/ Injection Site Pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701207	GENRL	Injection site erythema/ Injection site Redness	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Pain at injection Site	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1170 11701208	GENRL	Injection site pain/ Pain at injection site#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1170 11701209	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1170 11701210	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701211	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701213	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/6	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	29SEP2020	1/5	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701215	GENRL	Injection site pain/ Injection Site Pain	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701221	NERV	Headache/ Headache	2	01OCT2020	3/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1170 11701222	NERV	Dysgeusia/ Metallic Taste	1	22SEP2020	15/8	1	No	O	NA	R (29SEP2020)	N/N
	NERV	Headache/ Headache	1	25SEP2020	18/1	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1170 11701223	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701225	GENRL	Pyrexia/ Fever	2	02OCT2020	4/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701226	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1170 11701227	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701228	GENRL	Injection site pain/ Injection Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701229	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701230	GENRL	Chills/ Chills	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1170 11701232	GENRL	Chills/ Chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ Fatigue	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1170 11701233	NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701234	GENRL	Injection site pain/ Injection Site Pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1170 11701235	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	11/4	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache	1	12SEP2020	4/8	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N
16-55/ C4591001 1170 11701236	NERV	Headache/ Headache#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Chills/ Chills#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701237		Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	30SEP2020	1/2	3	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1170 11701241	NERV	Headache/ Headache	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1170 11701243	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	3	11FEB2021	22/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1170 11701244	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701245	GENRL	Myalgia/ Generalized Muscle Pain	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Chills/ Chills	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
		Chills/ Chills	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)	N/N
		Injection site erythema/ Redness at injection site	2	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
		MUSC	Myalgia/ Muscle Pain	2	02OCT2020	1/1	1	Yes		NA	R (02OCT2020)
16-55/ C4591001 1170 11701249	GENRL	Chills/ Chills#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
		Fatigue/ Fatigue#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701250	GENRL	Chills/ Chills#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1170 11701252	GENRL	Injection site pain/ Injection Site Pain	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1170 11701253	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701256	GENRL	Injection site pain/ Pain at injection site#	3	15DEC2020	1/2	1	Yes		NA	R (16DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Myalgia/ Myalgias#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701257		Injection site pain/ Pain at injection site	2	30SEP2020	1/37	2	Yes		NA	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
		Myalgia/ Muscle Pain	2	30SEP2020	1/4	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701258	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701259	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1170 11701260	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/4	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701261	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	2/4	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1170 11701262	GENRL	Injection site pain/ Pain at injection site#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1170 11701263	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1170 11701264	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1170 11701268	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701269	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Myalgia/ Muscle Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site erythema/ Redness at Injection Site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N	
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701271	GASTR	Nausea/ Nausea#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001		Vomiting/ Vomiting#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
1170 11701274	GENRL	Chills/ Chills#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/8	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Fever#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GASTR	Abdominal pain/ Abdominal Cramps#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
		Diarrhoea/ Diarrhea#	4	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
1170 11701279											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701280	GENRL	Pyrexia/ Fever	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Chills/ Chills#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
		Injection site erythema/ Injection Site Redness#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
		Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
		Pyrexia/ Fever#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Injection Site Soreness#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	16-55/ C4591001 1170 11701281	GENRL	Injection site pain/ Injection Site Sore (Left Arm)	1	11SEP2020	2/3	2	Yes		NA	R (13SEP2020)
	GASTR	Diarrhoea/ Diarrhea	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701283	NERV	Headache/ Headache	1	12SEP2020	3/4	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Injection site erythema/ Injection Site Redness	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
		Myalgia/ Muscle pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
16-55/ C4591001 1170 11701285	NERV	Headache/ Headache#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1170 11701286	GENRL	Injection site pain/ Injection Site Pain	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	14JAN2021	1/3	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701287	GENRL	Fatigue/ Fatigue#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1170 11701289	NERV	Headache/ Headache	1	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Chills/ Chills#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
		Fatigue/ Fatigue#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701290	GENRL	Injection site pain/ Pain at injection site	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1170 11701291	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Injection site pain/ Left Arm Injection Site Pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pain/ Body Aches	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701293	GENRL	Fatigue/ Fatigue	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1170 11701297	NERV	Headache/ Headache#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1170 11701298	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1170 11701300	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701303	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain Generalized	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Pain at Injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1170 11701304	GENRL	Injection site pain/ Pain at Injection Site	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1170 11701306	GENRL	Injection site pain/ Pain at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	2/1	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701307	GENRL	Fatigue/ Fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Muscular weakness/ Left arm weakness#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	16/3	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Pain in extremity/ Left Arm Pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1170 11701308	GENRL	Injection site pain/ Injection Site Pain	1	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701312	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes	NA	NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	15SEP2020	2/1	1	Yes	NA	NA	R (15SEP2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	2/2	1	Yes	NA	NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/2	1	Yes	NA	NA	R (29JAN2021)	N/N
16-55/ C4591001 1170 11701313	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	1/3	1	Yes	NA	NA	R (16SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	14SEP2020	1/3	1	Yes	NA	NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	15SEP2020	2/1	1	Yes	NA	NA	R (15SEP2020)	N/N
		Fatigue/ Fatigue	1	15SEP2020	2/1	1	Yes	NA	NA	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	05OCT2020	1/2	1	Yes	NA	NA	R (06OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	05OCT2020	1/4	1	Yes	NA	NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes	NA	NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes	NA	NA	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701314	GENRL	Injection site pain/ Pain at injection site#	3	15JAN2021	1/4	1	Yes		NA	R (18JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Chills/ Chills#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1170 11701316	GASTR	Nausea/ Nausea	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ Fever	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1170 11701317	GASTR	Dysphagia/ Difficulty Swallowing	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701318	GENRL	Eructation/ Burping	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Pain at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ Fever#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/N
	GENRL	Chills/ chills#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ fatigue#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ fever#	4	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ Fatigue	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		Injection site erythema/ Injection Site Redness	1	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Pain Injection Site	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
		Pyrexia/ Fever	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
MUSC	Arthralgia/ Generalized Joint Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701319	NERV	Myalgia/ Muscle Pain	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
		Headache/ Headache	1	18SEP2020	4/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/33	1	Yes		NA	R (07NOV2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Injection site erythema/ Redness at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site swelling/ Swelling at Injection Site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Arthralgia/ Joint Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Myalgia/ Muscle Pain	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Headache/ Headache	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N
			Paraesthesia/ Tingling in left and right hand#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701320	GENRL	Injection site pain/ Pain at injection site#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N
	INFEC	Ear infection/ Ear Infection#	3	03JAN2021	18/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	16SEP2020	2/3	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Pyrexia/ Fever#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701321	MUSC	Injection site pain/ Pain at injection site#	4	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Myalgia/ General Muscle Pain#	4	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1170 11701322	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Chills/ Chills	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Fatigue/ Fatigue	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	15SEP2020	1/5	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701323	GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	12/2	1	No	O	NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1170 11701324	GENRL	Chills/ Chills#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
		Pyrexia/ Fever#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701325†	MUSC	Myalgia/ Myalgias#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ headache#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701337	GENRL	Injection site pain/ Pain at Injection Site	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
1170 11701338	MUSC	Myalgia/ General Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at Injection Site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701340	NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	19SEP2020	3/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1170 11701341	GENRL	Injection site pain/ Pain at injection site#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage of right eye#	3	18DEC2020	3/21	1	No	O	NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701342	PSYCH	Attention deficit hyperactivity disorder/ Attention Deficit Hyperactivity Disorder	2	OCT2020	1/C	1	No	O	NA/TC	RG	N/N
	GENRL	Chills/ Chills#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701343	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	18SEP2020	2/3	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	08OCT2020	1/15	1	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Injection site pain/ Injection at Pain Site	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GASTR	Vomiting/ vomiting	2	10OCT2020	3/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1170 11701346	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	2/3	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1170 11701348	GENRL	Injection site pain/ Injection Site Pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1170 11701352†	GENRL	Chills/ Chills	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701355†	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N	
	MUSC	Myalgia/ Muscle Pain	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28DEC2020	1/3	1	Yes		NA	R (30DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
		Fatigue/ Fatigue#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	NERV	Headache/ Headache#	4	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N	
	16-55/ C4591001 1170 11701358	GENRL	Injection site pain/ Injection Site Pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Muscle spasms/ Muscle Spasms	1	07OCT2020	17/34	1	Yes		NA	R (09NOV2020)	N/N	
	NERV	Dizziness/ Dizziness	2	16OCT2020	5/5	1	No	O	NA	R (20OCT2020)	N/N	
	EYE	Glaucoma/ Glaucoma	2	NOV2020	21/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1170 11701359	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701360	GENRL	Injection site pain/ Pain at injection site#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
1170 11701362	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
	MUSC	Myalgia/ General Muscle Pain	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001	INJ&P	Maternal exposure during breast feeding/ EXPOSURE DURING BREASTFEEDING	1	22SEP2020	1/C	1	No	O	NA	N	N/N
1170 11701365	GASTR	Diarrhoea/ Diarrhea	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701372	NERV	Headache/ Headache Pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
		Fatigue/ Fatigue#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
		Injection site pain/ Injection site pain#	3	16DEC2020	1/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Finger#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Hand#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling on Wrist#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701373	GENRL	Injection site pain/ Injection Site Pain	1	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701375	GENRL	Chills/ Chills	2	16OCT2020	2/1	1	Yes	NA	NA	R (16OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	2/1	1	Yes	NA	NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	2/3	1	Yes	NA	NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills#	3	17DEC2020	1/3	1	Yes	NA	NA	R (19DEC2020)	N/N
		Injection site pain/ pain at injection site#	3	17DEC2020	1/3	1	Yes	NA	NA	R (19DEC2020)	N/N
		Injection site swelling/ Swelling at injection site#	3	17DEC2020	1/3	1	Yes	NA	NA	R (19DEC2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	17DEC2020	1/3	1	Yes	NA	NA	R (19DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/3	1	Yes	NA	NA	R (10JAN2021)	N/N
		Injection site pain/ Pain at injection site#	4	08JAN2021	1/4	1	Yes	NA	NA	R (11JAN2021)	N/N
		Injection site swelling/ Injection site swelling#	4	08JAN2021	1/4	1	Yes	NA	NA	R (11JAN2021)	N/N
	NERV	Dizziness/ Dizziness#	4	08JAN2021	1/4	1	Yes	NA	NA	R (11JAN2021)	N/N
		Headache/ headache#	4	08JAN2021	1/4	1	Yes	NA	NA	R (11JAN2021)	N/N
GENRL	Chills/ Chills#	4	09JAN2021	2/3	1	Yes	NA	NA	R (11JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701376	MUSC	Pyrexia/ Fever#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
		Myalgia/ Myalgias#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	VASC	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
Hypertension/ Hypertension		2	25NOV2020	16/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1170 11701378	GENRL	Chills/ Chills	2	10NOV2020	1/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1170 11701379	NERV	Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	22JAN2021	1/4	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1170 11701380	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701381	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701382		Injection site pain/ Pain at injection site.	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701382	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/4	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1170 11701383	GENRL	Injection site pain/ Injection Site Pain	1	20OCT2020	1/3	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701383		Injection site swelling/ Injection Site Swelling	1	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Dysgeusia/ Metallic Taste in Mouth	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701384	GENRL	Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1170 11701384	GENRL	Chills/ Chills	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701385†	MUSC	Fatigue/ Fatigue	2	10NOV2020	1/8	1	Yes		NA	R (17NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
		Myalgia/ Myalgias	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	1/3	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1170 11701387	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1170 11701387	GENRL	Injection site pain/ Pain at injection site#	3	22DEC2020	1/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701388	GENRL	Pyrexia/ Fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
		Chills/ Chills	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain in Injection Site	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Injection site swelling/ Injection Site Swelling	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
		Myalgia/ Generalized Muscle Pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Dysgeusia/ Strange taste in mouth	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
Pyrexia/ Fever		2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N	
Myalgia/ General Muscle Pain		2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N	
GENRL		Fatigue/ Fatigue	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701390		Injection site pain/ Pain at Injection Site	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
	MUSC	Muscle spasms/ Back Spasm	2	15NOV2020	7/2	2	No	O	NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1170 11701391	GENRL	Injection site pain/ Pain at injection site#	3	15DEC2020	1/2	1	Yes		NA	R (16DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701392	GENRL	Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701393		Pyrexia/ Fever	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	CARD	Palpitations/ Palpitations	2	15NOV2020	5/2	1	No	O	NA/TC	R (16NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15NOV2020	5/2	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1170 11701394†	PSYCH	Anxiety/ Anxiety	2	15NOV2020	5/2	1	No	O	NA	R (16NOV2020)	N/N
	GENRL	Chills/ Chills#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Fatigue/ Fatigue#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1170 11701395	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701396	MUSC	Myalgia/ Muscle Pain	1	21OCT2020	1/2	1	Yes	NA	NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/2	1	Yes	NA	NA	R (12NOV2020)	N/N
16-55/ C4591001 1170 11701397	GENRL	Injection site pain/ Injection Site Pain	2	11NOV2020	1/1	1	Yes	NA	NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	2/1	1	Yes	NA	NA	R (29JAN2021)	N/N
16-55/ C4591001 1170 11701398	GENRL	Fatigue/ Fatigue	1	21OCT2020	1/2	1	Yes	NA	NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	21OCT2020	1/4	1	Yes	NA	NA	R (24OCT2020)	N/N
16-55/ C4591001 1170 11701399	GENRL	Injection site pain/ Injection Site Pain#	3	22JAN2021	1/2	1	Yes	NA	NA	R (23JAN2021)	N/N
16-55/ C4591001 1170 11701400	GENRL	Injection site pain/ Pain at injection site	1	21OCT2020	1/3	1	Yes	NA	NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes	NA	NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	3/2	1	Yes	NA	NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701403		Pyrexia/ Fever	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
	VASC	Flushing/ Facial Flushing	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Muscle twitching/ Muscle Twitching	2	11NOV2020	1/2	1	No	O	NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	18JAN2021	1/4	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	19JAN2021	2/2	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
	NERV	Headache/ Headache#	3	19JAN2021	2/1	1	Yes		NA	R (19JAN2021)	N/N
GENRL	Fatigue/ fatigue#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701404	MUSC	Pyrexia/ fever#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
		Myalgia/ General Muscle Pain#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
		Headache/ headache#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL		Chills/ Chills	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	MUSC		Injection site pain/ Injection Site Pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
			Myalgia/ Myalgias	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	GENRL		Fatigue/ Fatigue	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
	MUSC		Injection site erythema/ Injection Site Redness	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
			Injection site swelling/ Injection Site Swelling	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
			Pyrexia/ Fever	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
			Arthralgia/ Generalized Joint Pain	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)	N/N
		NERV		Headache/ Headache	1	22OCT2020	2/3	1	Yes		NA/TC	R (24OCT2020)
GENRL			Injection site pain/ Injection Site Pain	2	23NOV2020	1/4	1	Yes		NA	R (26NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701405	GENRL	Chills/ Chills	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
		Fatigue/ Fatigue	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
	NERV	Headache/ Headache	2	24NOV2020	2/2	1	Yes		NA	R (25NOV2020)	N/N
16-55/ C4591001 1170 11701406	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
		Injection site swelling/ Injection Site Swelling#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
GENRL	Fatigue/ fatigue#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701407	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701408†		Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701408†	NERV	Headache/ Headache	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701411		Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701411	MUSC	Arthralgia/ Generalized Joint Pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Myalgia/ Muscle Pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701411	NERV	Headache/ Headache	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	28DEC2020	1/2	1	Yes		NA	R (29DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1170 11701412	GENRL	Injection site pain/ Pain at Injection Site	1	21OCT2020	1/4	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1170 11701413	GENRL	Chills/ Chills	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1170 11701414	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ Fatigue#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ Fever#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701416	MUSC	Arthralgia/ Generalized Joint Pain#	4	15JAN2021	2/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site erythema/ Redness at injection site	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Fatigue/ Fatigue#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	18JAN2021	1/5	1	Yes		NA	R (22JAN2021)	N/N
		Pyrexia/ Fever#	3	18JAN2021	1/	1	Yes		NA	R	N/N
16-55/ C4591001 1170 11701418	MUSC	Arthralgia/ Generalized Joint Pain#	3	18JAN2021	1/2	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701420	GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	1/5	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1170 11701421	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701422†	GENRL	Injection site pain/ Pain @ injection site	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C4591001 1170 11701423	GENRL	Injection site pain/ Pain at injection site	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	14JAN2021	1/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site.	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701424	GENRL	Chills/ Chills	2	10NOV2020	1/1	1	Yes	NA	NA	R (10NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/1	1	Yes	NA	NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/1	1	Yes	NA	NA	R (11NOV2020)	N/N
16-55/ C4591001 1170 11701425	GENRL	Injection site pain/ Pain at Injection#	3	15DEC2020	1/3	1	Yes	NA	NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	05JAN2021	2/1	1	Yes	NA	NA	R (05JAN2021)	N/N
		Fatigue/ Fatigue#	4	05JAN2021	2/1	1	Yes	NA	NA	R (05JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	4	05JAN2021	2/1	2	Yes	NA	NA	R (05JAN2021)	N/N
		Pyrexia/ Fever#	4	05JAN2021	2/1	2	Yes	NA	NA	R (05JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	05JAN2021	2/1	1	Yes	NA	NA	R (05JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	2/1	2	Yes	NA	NA	R (05JAN2021)	N/N
16-55/ C4591001 1170 11701426	GENRL	Chills/ Chills	1	22OCT2020	1/2	1	Yes	NA	NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701428	MUSC	Myalgia/ General Muscle Pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GASTR	Nausea/ Nausea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	Myalgia/ Myalgias	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701429	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection at pain site#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1170 11701430	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site erythema/ Injection Site Redness	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	11NOV2020	1/7	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1170 11701431		Injection site pain/ Injection Pain	2	11NOV2020	1/7	2	Yes		NA	R (17NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1170 11701431	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701432	GENRL	Injection site pain/ Pain injection site	2	13NOV2020	1/5	1	Yes		NA/TC	R (17NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/2	1	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701433	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Muscle Pain	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701434	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Fatigue/ fatigue#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ fever#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701435	MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/8	2	Yes		NA	R (17NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1170 11701436	GENRL	Injection site pain/ Injection Site Pain	2	12NOV2020	1/1	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1170 11701437	GENRL	Injection site erythema/ Injection Site Redness	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ Injection Site Pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Injection site swelling/ Injection Site Swelling	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
	MUSC	Arthralgia/ Joint Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701438		Injection site erythema/ Injection Site Redness#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ Fatigue#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1170 11701439	GENRL	Chills/ Chills#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N
		Fatigue/ Fatigue#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N
		Myalgia/ Myalgias#	3	16DEC2020	2/2	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Chills/ Chills#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
		Pyrexia/ Fever#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
	MUSC	Arthralgia/ Joint Pain#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701440	GENRL	Myalgia/ Myalgias#	4	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
		Fatigue/ Fatigue#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Injection site pain/ Injection Site Pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
		Injection site swelling/ Injection Site Swelling#	3	17DEC2020	2/4	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	2/1	1	Yes		NA	R (17DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	NERV	Injection site swelling/ Injection Site Swelling#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701442	GENRL	Headache/ Headache#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Chills/ Chills	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	13NOV2020	2/2	2	Yes		NA	R (14NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701443	MUSC	Myalgia/ Myalgias	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Pain Injection Site	2	12NOV2020	1/4	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1170 11701444	MUSC	Myalgia/ Muscle Pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Malaise/ Malaise	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701445	MUSC	Myalgia/ Myalgias	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/3	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	MUSC	Myalgia/ Myalgias#	3	17DEC2020	2/2	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1170 11701446	GENRL	Pyrexia/ Fever#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N
	GENRL	Pyrexia/ Fever#	3	18DEC2020	1/1	1	Yes		NA	R (18DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701447	GENRL	Pyrexia/ fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Chills/ Chills	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1170 11701449	MUSC	Fatigue/ Fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Myalgia/ Generalized Muscle Pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ Pain at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1170 11701450	GENRL	Injection site pain/ Injection Site Pain#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
		Lymph node pain/ Left Axillary Lymph node Pain	1	12NOV2020	18/2	1	No	O	NA	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	13NOV2020	1/1	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701451	GENRL	Injection site pain/ Pain at injection site	1	26OCT2020	1/5	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1170 11701452	GENRL	Injection site swelling/ Injection Site Swelling	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Vomiting/ Vomiting	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	1/3	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	13NOV2020	1/5	2	Yes		NA	R (17NOV2020)	N/N
		Injection site swelling/ Injection Site Swelling	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
		Pyrexia/ Fever	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
	SKIN	Night sweats/ Night Sweats	2	14NOV2020	2/2	2	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1170 11701453	GENRL	Injection site pain/ Injection Site Pain#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	REPRO	Sexual dysfunction/ Sexual Dysfunction#	3	20DEC2020	3/5	1	No	O	NA	R (24DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701455	GENRL	Fatigue/ Fatigue#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/1	1	Yes		NA	R (15JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	16JAN2021	2/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Chills/ Chills#	4	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	04FEB2021	2/34	1	Yes		NA	R (09MAR2021)	N/N
16-55/ C4591001 1170 11701456†	GENRL	Injection site erythema/ Redness at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
		Injection site swelling/ Swelling at injection site	1	02NOV2020	8/1	1	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1170 11701457†	GENRL	Chills/ Chills	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
		Fatigue/ Fatigue	2	16NOV2020	1/7	1	Yes		NA	R (22NOV2020)	N/N
		Injection site pain/ Injection site pain	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
		Pyrexia/ Fever	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N
	MUSC	Myalgia/ General Muscle pain	2	16NOV2020	1/5	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701458	GENRL	Injection site pain/ Injection Site Pain#	3	17DEC2020	1/5	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Chills/ Chills#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
		Fatigue/ Fatigue#	3	18DEC2020	2/3	1	Yes		NA/TC	R (20DEC2020)	N/N
	NERV	Headache/ Headache#	3	18DEC2020	2/3	1	Yes		NA	R (20DEC2020)	N/N
	INFEC	Localised infection/ Right Pinky Infection#	3	25DEC2020	9/34	2	No	O	NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1170 11701460	GENRL	Injection site pain/ Pain at Injection Site	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1170 11701461	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1170 11701463†	GENRL	Chills/ Chills	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701464	MUSC	Myalgia/ Myalgias	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1170 11701465	NERV	Headache/ Headache#	4	23FEB2021	2/7	2	Yes		NA	R (01MAR2021)	N/N
	GENRL	Fatigue/ Fatigue	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701466	GENRL	Pyrexia/ Fever	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N	
		Fatigue/ Fatigue	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
		Pyrexia/ Fever	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N	
	GENRL		Injection site pain/ Pain at injection site#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
	GENRL		Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
			Fatigue/ Fatigue#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
			Injection site pain/ Injection Site Pain#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL		Injection site pain/ Pain at injection site	1	26OCT2020	1/4	1	Yes		NA	R (29OCT2020)	N/N
	GENRL		Chills/ Chills	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
			Fatigue/ Fatigue	1	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	MUSC		Myalgia/ Muscle Pain	1	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL		Chills/ Chills	2	16NOV2020	1/3	2	Yes		NA/TC	R (18NOV2020)	N/N
GENRL		Fatigue/ Fatigue	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701467	MUSC	Injection site pain/ Injection Site Pain	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
		Myalgia/ Myalgias	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
	MUSC	Fatigue/ Fatigue	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	2/2	2	Yes		NA/TC	R (18NOV2020)	N/N
		Myalgia/ Myalgias	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N
NERV	Headache/ Headache	2	17NOV2020	2/2	1	Yes		NA/TC	R (18NOV2020)	N/N	
16-55/ C4591001 1170 11701468	GENRL	Injection site pain/ Pain at injection site#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1170 11701469	GASTR	Diarrhoea/ Diarrhea	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701470	MUSC	Injection site pain/ Pain Injection Site	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Arthralgia/ generalized joint pain	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
		Myalgia/ Muscle Pain	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ General Muscle Pain#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
NERV	Dizziness/ Dizziness#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	
		Headache/ Headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection Site	1	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701471	GENRL	Fatigue/ Fatigue	2	18NOV2020	1/3	1	Yes	NA		R (20NOV2020)	N/N
	MUSC	Arthralgia/ generalized joint pain	2	18NOV2020	1/3	1	Yes	NA		R (20NOV2020)	N/N
		Myalgia/ Muscle Pain	2	18NOV2020	1/3	1	Yes	NA		R (20NOV2020)	N/N
	NERV	Headache/ Headache	2	18NOV2020	1/5	1	Yes	NA/TC		R (22NOV2020)	N/N
16-55/ C4591001 1170 11701472	GENRL	Chills/ Chills	1	27OCT2020	1/2	1	Yes	NA		R (28OCT2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain	1	27OCT2020	1/2	1	Yes	NA		R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	06JAN2021	1/2	1	Yes	NA		R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes	NA		R (26JAN2021)	N/N
		Fatigue/ Fatigue#	4	25JAN2021	1/2	1	Yes	NA		R (26JAN2021)	N/N
16-55/ C4591001 1170 11701473	GENRL	Injection site pain/ Pain at Injection Site	1	28OCT2020	2/2	1	Yes	NA		R (29OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	19NOV2020	2/2	2	Yes	NA		R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701474†	NERV	Malaise/ Malaise	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
		Pyrexia/ Fever	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
		Headache/ Headache	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17NOV2020	1/1	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Pain#	3	28DEC2020	1/5	1	Yes		NA	R (01JAN2021)	N/N
	NERV	Headache/ Headache#	3	28DEC2020	1/5	1	Yes		NA	R (01JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	29DEC2020	2/2	1	Yes		NA	R (30DEC2020)	N/N
		Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	MUSC	Injection site pain/ Pain at injection site#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
Myalgia/ Muscle Pain#		4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N	
NERV		Headache/ Headache#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ Injection Site Redness	1	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1170 11701475		Injection site pain/ Injection Site Pain	1	27OCT2020	1/2	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		Fatigue/ Fatigue	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain	2	17NOV2020	1/3	2	Yes		NA/TC	R (19NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	MUSC	Myalgia/ Myalgias	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
	NERV	Headache/ Headache	2	17NOV2020	1/3	1	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1170 11701476	MUSC	Myalgia/ Generalized Muscle Pain	1	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
		Fatigue/ Fatigue	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ Injection Site Pain	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ Fever	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701477	MUSC	Myalgia/ Myalgias	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1170 11701478		Injection site pain/ Injection site pain	2	18NOV2020	1/3	1	Yes		NA	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	05FEB2021	2/4	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1170 11701482	MUSC	Myalgia/ Muscle Pain	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
		Malaise/ Malaise	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701483	GASTR	Diarrhoea/ Diarrhea	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	GENRL	Chills/ Chills	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
		Pyrexia/ Fever	1	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	29OCT2020	2/3	2	Yes		NA	R (31OCT2020)	N/N
	MUSC	Back pain/ Back Pain	2	22NOV2020	5/2	1	No	O	NA/TC	R (23NOV2020)	N/N
	GENRL	Chills/ Chills	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
		Fatigue/ Fatigue	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
		Injection site pain/ Pain at Injection Site	1	28OCT2020	1/4	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
	Injection site pain/ Injection Site Pain	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N	
	Malaise/ Malaise	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701484	MUSC	Myalgia/ Myalgias	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	20NOV2020	2/2	2	Yes		NA	R (21NOV2020)	N/N
	GENRL	Injection site erythema/ Redness at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Chills/ Chills#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
		Pyrexia/ Fever#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1170 11701485	MUSC	Myalgia/ Myalgias#	4	14JAN2021	2/3	1	Yes		NA	R (16JAN2021)	N/N
	GENRL	Pyrexia/ Fever	1	29OCT2020	2/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Chills/ Chills	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
	Injection site pain/ Pain injection site	2	24NOV2020	1/3	1	Yes		NA	R (26NOV2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701486	MUSC	Malaise/ Malaise	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
		Pyrexia/ Fever	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
		Myalgia/ Myalgias	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
		Headache/ Headache	2	24NOV2020	1/4	1	Yes		NA/TC	R (27NOV2020)	N/N
	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	22DEC2020	1/1	1	Yes		NA	R (22DEC2020)	N/N
Chills/ Chills#		4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001 1170 11701488	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
		Injection site swelling/ Swelling at injection site	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
GENRL	Chills/ Chills	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1170 11701489	MUSC	Fatigue/ Fatigue	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
		Pyrexia/ Fever	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
		Arthralgia/ generalized joint pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
		Myalgia/ Muscle pain	2	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Pain injection Site	2	19NOV2020	3/10	1	Yes		NA	R (28NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	15JAN2021	1/5	1	Yes		NA	R (19JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	05FEB2021	2/4	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Pyrexia/ fever#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
		Myalgia/ general muscle pain#	4	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	16-55/ C4591001 1170 11701490	GENRL	Injection site pain/ Pain at Injection Site	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)
	NERV	Headache/ Headache	1	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701491	MUSC	Injection site pain/ Pain at Injection site	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N	
		Pyrexia/ Fever	2	19NOV2020	1/3	1	Yes		NA	R (21NOV2020)	N/N	
		Myalgia/ Muscle pain	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N	
		NERV	Headache/ Headache	2	19NOV2020	1/1	1	Yes		NA	R (19NOV2020)	N/N
	NERV	Headache/ Headache	1	29OCT2020	1/1	1	Yes		NA	R (29OCT2020)	N/N	
	NERV	Headache/ Headache	2	20NOV2020	1/1	1	Yes		NA	R (20NOV2020)	N/N	
	16-55/ C4591001 1170 11701492	GENRL	Fatigue/ Fatigue	1	30OCT2020	2/17	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
	MUSC	Myalgia/ Generalized Muscle Pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
	GENRL	Chills/ Chills#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N	
16-55/ C4591001 1170 11701493	GENRL	Fatigue/ Fatigue#	3	31DEC2020	2/1	1	Yes		NA	R (31DEC2020)	N/N	
		Injection site pain/ Injection Site Pain	1	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Fatigue/ Fatigue	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Injection site pain/ Pain at Injection Site	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N
16-55/ C4591001 1170 11701494	NERV	Headache/ Headache	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1170 11701499	GENRL	Fatigue/ Fatigue#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
		Injection site swelling/ Swelling at injection site#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ Chills#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ Fever#	4	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1170 11701500	GENRL	Injection site erythema/ Injection site redness	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1170 11701501	NERV	Injection site pain/ injection site pain	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Injection site swelling/ Injection site swelling	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Pyrexia/ Fever	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Headache/ Headache	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		GENRL	Fatigue/ Fatigue	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
			Injection site pain/ Injection Site Pain	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N
	MUSC	Pyrexia/ Fever	2	20NOV2020	1/3	1	Yes		NA	R (22NOV2020)	N/N	
		Myalgia/ Generalized Muscle Pain	2	20NOV2020	1/1	1	Yes		NA	R (20NOV2020)	N/N	
	NERV	Headache/ Headaches	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
	NERV	Pyrexia/ Fever	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N	
		Headache/ Headache	1	01NOV2020	3/19	1	Yes		NA	R (19NOV2020)	N/N	
GENRL		Injection site pain/ Injection Site Pain	2	20NOV2020	1/2	1	Yes		NA	R (21NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N
		Pyrexia/ Fever	2	21NOV2020	2/1	1	Yes		NA	R (21NOV2020)	N/N
	NERV	Headache/ Headache	2	21NOV2020	2/2	1	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1171 11711014	GENRL	Injection site pain/ Arm pain ( at the injection site )	1	02SEP2020	21/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1171 11711021	INFEC	Subcutaneous abscess/ Skin abscess (wrist)	2	14SEP2020	5/6	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1171 11711023	SKIN	Urticaria/ Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas#	3	10FEB2021	2/7	2	Yes		P/TC	R (16FEB2021)	N/N
	SKIN	Angioedema/ Angioedema - Forehead#	3	11FEB2021	3/6	1	Yes		P/TC	R (16FEB2021)	N/N
16-55/ C4591001 1171 11711026	MUSC	Neck pain/ Neck Pain	2	30SEP2020	28/17	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1171 11711027	INJ&P	Muscle strain/ Lower back strain	2	18SEP2020	15/11	2	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	14AUG2020	1/8	1	No	O	NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1171 11711033 16-55/ C4591001	EAR	Vertigo/ Vertigo (Unknown cause)	2	09OCT2020	36/8	2	No	O	NA/TC	R (16OCT2020)	N/N
1171 11711034 16-55/ C4591001	RESP	Nasal congestion/ Nasal Congestion	2	10OCT2020	39/6	2	No	O	NA/TC	R (15OCT2020)	N/N
1171 11711039 16-55/ C4591001	GENRL	Chills/ Chills	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
1171 11711050 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
1171 11711055 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N
1171 11711055 16-55/ C4591001	GENRL	Chills/ Chills	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
1171 11711055 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
1171 11711060 16-55/ C4591001	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711065	GENRL	Injection site pain/ Soreness around injection site	2	09SEP2020	1/4	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1171 11711067	INV	Heart rate increased/ Elevated pulse rate	1	20AUG2020	3/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1171 11711069	GENRL	Chills/ Chills	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1171 11711073	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/1	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1171 11711085	GENRL	Pain/ Body Aches (Generalized)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1171 11711088	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1171 11711091 16-55/ C4591001 1171 11711093	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Arthralgia/ LEFT SHOULDER PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
		Neck pain/ WORSENING OF NECK PAIN	1	31AUG2020	12/12	2	No	O	NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711128	GENRL	Fatigue/ Fatigue	1	28AUG2020	3/5	1	Yes		NA	R (01SEP2020)	N/N
	NERV	Headache/ Headache	1	29AUG2020	4/4	1	Yes		NA	R (01SEP2020)	N/N
16-55/ C4591001 1171 11711130	GASTR	Nausea/ Nausea	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Pain [Left Arm Deltoid]	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711137	GENRL	Injection site pain/ Soreness around injection site	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1171 11711146	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1171 11711151	GENRL	Injection site erythema/ Redness to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
		Injection site swelling/ Swelling to Injection Site	1	31AUG2020	1/6	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1171 11711154	GENRL	Fatigue/ Fatigue	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ Muscle Pain	1	02SEP2020	3/4	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1171 11711158	GENRL	Injection site erythema/ Erythema to injection site	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ Injection Site Pain	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
	NERV	Dizziness/ Dizziness	1	31AUG2020	1/4	1	No	O	NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711175	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1171 11711191	GENRL	Injection site pain/ Pain around injection site	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/N
	SKIN	Alopecia/ Hair loss	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1171 11711200	GENRL	Injection site pain/ Arm Pain (at the injection site)	1	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711203	GENRL	Pyrexia/ Fever	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711209	GENRL	Injection site pain/ Soreness around injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1171 11711211	GENRL	Injection site pain/ INJECTION SITE PAIN	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	CARD	Tachycardia/ Tachycardia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1171 11711216	GASTR	Diarrhoea/ Diarrhea#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Pain in extremity/ Left Arm Aching#	2	22FEB2021	148/3	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1171 11711223	NERV	Headache/ Headache	1	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1171 11711225	MUSC	Pain in extremity/ Pain in Arm [Left]	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1171 11711236	GENRL	Injection site erythema/ Redness around injection site	1	11SEP2020	1/6	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection site pain	1	11SEP2020	1/5	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1171 11711241	GENRL	Chills/ Chills#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711242	NERV	Dizziness/ Dizziness#	4	19JAN2021	2/3	1	Yes		NA	R (21JAN2021)	N/N
		Headache/ Headache#	4	19JAN2021	2/3	1	Yes		NA/TCN	R (21JAN2021)	N/N
	GENRL	Chills/ Chills	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever	1	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1171 11711246	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site erythema/ Erythema at injection site	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ Soreness at Injection Site	1	11SEP2020	1/6	2	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1171 11711249		Pain/ Body aches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches, generalized	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711251	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle Ache	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1171 11711252	GENRL	Chills/ Chills	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1171 11711260	GENRL	Injection site pain/ Arm pain ( at the injection site )	1	16SEP2020	1/2	1	Yes		NA/TCN	R (17SEP2020)	N/N
16-55/ C4591001 1171 11711266	GENRL	Injection site pain/ Left Arm pain ( at the injection site )	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1171 11711271	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N
		Pain/ Body aches	1	18SEP2020	1/3	1	Yes		NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1171 11711274	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Soreness around injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1171 11711281	GENRL	Injection site pain/ Soreness around injection site	1	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1171 11711293	INFEC	Tinea infection/ Ring worm infection	2	05NOV2020	24/15	2	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1171 11711294	GENRL	Injection site pain/ Soreness at Injection Site	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pain/ Body aches, generalized	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001	NEOPL	Malignant melanoma/ right forearm melanoma	2	01OCT2020	11/8	1	No	O	NA/TCN	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741003 16-55/ C4591001	GENRL	Pain/ Generalized Aches and pain#	3	18DEC2020	1/2	1	Yes	NA	NA	R (19DEC2020)	N/N
1174 11741006 16-55/ C4591001	CARD	Tachycardia/ Tachycardia	1	02SEP2020	2/2	1	Yes	NA	NA	R (03SEP2020)	N/N
1174 11741011	GENRL	Fatigue/ Fatigue	1	02SEP2020	2/2	1	Yes	NA	NA	R (03SEP2020)	N/N
		Pyrexia/ Fever	1	02SEP2020	2/2	1	Yes	NA	NA	R (03SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	02SEP2020	2/2	1	Yes	NA	NA	R (03SEP2020)	N/N
	NERV	Headache/ Headache	1	02SEP2020	2/2	1	Yes	NA	NA	R (03SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
		Nausea/ Nausea	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
		Pain/ Aching	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes	NA	NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741015	GASTR	Nausea/ Nausea#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1174 11741020	MUSC	Pain in extremity/ Left arm soreness#	3	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1174 11741026	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain/ Body aches#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Arthralgia/ Generalized joint pain#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain in extremity/ Soreness in the right arm#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1174 11741027	MUSC	Periarthritis/ Adhesive Capsulitis left shoulder	1	04SEP2020	1/99	1	Yes		NA	R (11DEC2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm soreness#	4	16FEB2021	1/2	1	Yes		NA/TCN	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741030	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes	NA/TCN	R	(17FEB2021)	N/N
		Fatigue/ Fatigue#	4	17FEB2021	2/1	1	Yes	NA/TCN	R	(17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes	NA/TCN	R	(17FEB2021)	N/N
16-55/ C4591001 1174 11741031	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes	NA/TCN	R	(27SEP2020)	N/N
		Pyrexia/ Fever	2	26SEP2020	2/2	1	Yes	NA/TCN	R	(27SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26SEP2020	2/2	1	Yes	NA/TCN	R	(27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes	NA/TCN	R	(27SEP2020)	N/N
16-55/ C4591001 1174 11741032	GENRL	Chills/ Chills#	4	26FEB2021	1/2	1	Yes	NA/TCN	R	(27FEB2021)	N/N
		Pyrexia/ Fever#	4	26FEB2021	1/2	1	Yes	NA/TCN	R	(27FEB2021)	N/N
	NERV	Headache/ Headache#	4	26FEB2021	1/2	1	Yes	NA/TCN	R	(27FEB2021)	N/N
16-55/ C4591001 1174 11741034	GENRL	Chills/ Chills#	3	08JAN2021	2/2	1	Yes	NA/TC	R	(09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741038	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pain/ Generalized aches and pain#	3	08JAN2021	2/3	1	Yes		NA/TC	R (10JAN2021)	N/N
		Fatigue/ Fatigue	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1174 11741045	MUSC	Pyrexia/ Feverish	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1174 11741046	MUSC	Pain in extremity/ Right arm soreness#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	MUSC	Pain in extremity/ Right arm soreness#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1174 11741049	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Pain/ Generalized aches and pain	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1174 11741050	GENRL	Fatigue/ Fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
	MUSC	Pain in extremity/ Soreness in the left arm#	3	19DEC2020	2/1	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1174 11741051	GENRL	Fatigue/ Fatigue#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ Low grade fever#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1174 11741053	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	3	21JAN2021	1/2	1	Yes		NA/TCN	R (22JAN2021)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm soreness#	4	13FEB2021	2/2	1	Yes		NA/TCN	R (14FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741055	MUSC	Pain in extremity/ Left arm soreness#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1174 11741056	GENRL	Pyrexia/ Fever	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1174 11741057	MUSC	Myalgia/ Myalgia	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1174 11741057	INJ&P	Ligament rupture/ Torn ACL Left Knee	2	04JAN2021	78/C	1	No	O	NA	N	N/N
16-55/ C4591001 1174 11741058	GENRL	Chills/ Chills#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
		Pain/ Generalized aches#	4	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1174 11741058	GENRL	Chills/ Chills	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	MUSC	Pain in extremity/ Right arm soreness	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001	MUSC	Pain in extremity/ Left arm soreness#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1174 11741060 16-55/ C4591001	MUSC	Arthritis/ Arthritis in the right hand#	4	29JAN2021	17/C	1	No	O	NA/TCN	RG	N/N
1174 11741063 16-55/ C4591001	GENRL	Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA/TCN	R (19SEP2020)	N/N
1174 11741065	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/2	1	Yes		NA/TCN	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/2	1	Yes		NA/TCN	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
1174 11741071	MUSC	Pain in extremity/ Left arm soreness	1	30SEP2020	3/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
1174 11741072		Vomiting/ Vomiting#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Pain in extremity/ Left arm soreness#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1177 11771001	NERV	Headache/ HEADACHE	2	16OCT2020	45/1	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1177 11771030	NERV	Dizziness/ Dizziness	1	27AUG2020	15/4	2	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1177 11771050	GENRL	Fatigue/ FATIGUE	1	18AUG2020	2/29	1	No	O	NA	R (15SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ FEVER	2	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1177 11771051	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	2/4	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1177 11771066	GENRL	Injection site pain/ Injection Site Pain	1	18AUG2020	1/2	1	Yes		NA	R (19AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771078	GASTR	Diarrhoea/ DIARRHEA	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1177 11771096	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1177 11771105	GENRL	Chills/ CHILLS	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Injection site pain/ PAIN AT INJECTION SITE (LEFT ARM)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Pain/ BODY ACHES	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ FEVER	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1177 11771114	GASTR	Diarrhoea/ DIARRHEA	1	25AUG2020	5/2	1	No	O	NA	R (26AUG2020)	N/N
	INFEC	Tooth infection/ TOOTH INFECTION	2	08OCT2020	28/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1177 11771117	GENRL	Pain/ Generalized Body Aches	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1177 11771118	INFEC	Suspected COVID-19/ Potential COVID-19 Symptoms#	4	01MAR2021	8/4	1	No	O	NA	R (04MAR2021)	N/N	
16-55/ C4591001 1177 11771119	MUSC	Back pain/ BACK PAIN, INTERMITTENT	2	30SEP2020	17/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1177 11771134	EYE	Glaucoma/ Glaucoma, OD#	2	26JAN2021	134/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1177 11771155	INFEC	Otitis externa/ EXTERNAL OTITIS, LEFT EAR	1	09SEP2020	15/10	2	No	O	NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1177 11771156	GENRL	Injection site pain/ Injection Site Pain	2	17SEP2020	2/24	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1177 11771159	GENRL	Pain/ WORSENING BODY ACHES	2	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N	
	INFEC	Sinusitis/ SINUS INFECTION	2	03OCT2020	19/14	2	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1177 11771160	GASTR	Nausea/ NAUSEA	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ GENERALIZED BODY ACHES	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1177 11771162	GENRL	Injection site pain/ Injection Site Pain	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1177 11771166	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1177 11771167	GENRL	Pyrexia/ FEVER	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1177 11771170	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1177 11771172	GENRL	Injection site pain/ Injection Site Pain#	4	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1177 11771182	GENRL	Pain/ BODY ACHES	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ FEVER	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771186	GENRL	Pain/ Generalized Body Aches	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1177 11771197	GENRL	Pain/ Generalized Body Aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	19SEP2020	2/1	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1177 11771198	GENRL	Pain/ Generalized Body Aches#	3	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1177 11771219	GASTR	Abdominal pain upper/ Stomach Pain	1	08SEP2020	9/1	2	No	O	NA/TC	R (08SEP2020)	N/N
16-55/ C4591001 1177 11771222	GASTR	Nausea/ NAUSEA	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pain/ BODY ACHES	2	21SEP2020	1/3	3	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	21SEP2020	1/3	2	Yes		NA	R (23SEP2020)	N/N
	PREG	Abortion spontaneous/ Abortion Spontaneous#	2	23DEC2020	94/1		No	O	NA	R (23DEC2020)	Y/N
16-55/ C4591001	GENRL	Pain/ Generalized Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771224 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	1/4	1	Yes		NA	R (05SEP2020)	N/N
1177 11771241	GENRL	Chills/ Chills	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
		Pain/ Generalized Body Aches	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N
1177 11771242 16-55/ C4591001	MUSC	Myalgia/ Muscle Pain, Left Arm	1	03SEP2020	2/8	1	Yes		NA	R (10SEP2020)	N/N
1177 11771254 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
1177 11771283 16-55/ C4591001	MUSC	Muscle spasms/ MUSCLE CRAMP, LEFT SIDE OF BODY	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N
1177 11771297	NERV	Paraesthesia/ TINGLING SENSATION, LEFT ARM	1	10SEP2020	6/1	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771310	GENRL	Fatigue/ FATIGUE	1	08SEP2020	1/2	3	Yes		NA	R (09SEP2020)	N/N
		Pyrexia/ FEVER	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN	1	08SEP2020	1/5	2	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	01OCT2020	3/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1177 11771322	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1177 11771323	MUSC	Arthralgia/ Left Shoulder Pain	2	09OCT2020	10/28	1	No	O	NA	R (05NOV2020)	N/N
16-55/ C4591001 1177 11771330	GENRL	Injection site pain/ Injection Site Pain	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1177 11771331	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1177 11771355	GENRL	Chills/ Chills#	4	05MAR2021	1/3	3	Yes		NA/TC	R (07MAR2021)	N/N
		Pain/ Body Aches#	4	05MAR2021	1/3	3	Yes		NA/TC	R (07MAR2021)	N/N
	NERV	Dizziness/ Dizziness#	3	05MAR2021	22/C	2	Yes		NA/TC	RG	N/N
		Headache/ Headache#	4	05MAR2021	1/3	1	Yes		NA/TC	R (07MAR2021)	N/N
16-55/ C4591001 1177 11771361	GENRL	Pyrexia/ FEVER	1	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1177 11771368	GENRL	Pain/ Body Aches#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1177 11771393	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1177 11771418	INFEC	Herpes zoster/ Shingles	1	11OCT2020	20/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain, Left Deltoid	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771429	GENRL	Fatigue/ Fatigue	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
		Pain/ Generalized Body Aches	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1177 11771441	INFEC	Urinary tract infection/ Urinary Tract Infection	2	26JAN2021	103/10	1	No	O	NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1177 11771443	INJ&P	Hand fracture/ Fracture: 5th Metacarpal, Right	2	05FEB2021	113/34	1	No	O	NA	R (10MAR2021)	N/N
16-55/ C4591001 1177 11771445	GENRL	Pain/ Generalized Body Aches	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches, Neck and Shoulders	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1177 11771465	GASTR	Vomiting/ Vomiting#	4	01MAR2021	1/2	1	Yes		NA	R (02MAR2021)	N/N
16-55/ C4591001	SKIN	Rash/ Generalized Rash#	3	20DEC2020	3/4	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771475 16-55/ C4591001	GENRL	Pain/ Body Aches#	4	23FEB2021	2/5	1	Yes		NA/TC	R (27FEB2021)	N/N
1177 11771484 16-55/ C4591001	GENRL	Chills/ Chills	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
1177 11771501 16-55/ C4591001	GENRL	Injection site pain/ INJECTION SITE PAIN	1	14OCT2020	1/4	1	Yes		NA	R (17OCT2020)	N/N
1177 11771510 16-55/ C4591001	GENRL	Chills/ Chills	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
1177 11771515 16-55/ C4591001	NERV	Headache/ Headache	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
1177 11771520 16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	2	03DEC2020	28/C	1	No	O	NA/TC	RG	N/N
1177 11771539 16-55/ C4591001	GENRL	Chest pain/ Chest Pain	1	20OCT2020	1/12	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C4591001	GENRL	Pain/ Body Aches#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1177 11771551		Pyrexia/ Fever#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	NERV	Headache/ Headache#	3	29DEC2020	1/4	1	Yes		NA	R (01JAN2021)	N/N
16-55/ C4591001 1178 11781019	GENRL	Injection site pain/ Injection Site Soreness	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
		Fatigue/ fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1178 11781029	GENRL	Injection site pain/ soreness, left arm at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Pain/ Achiness	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1178 11781030	GENRL	Injection site pain/ Soreness at injection site.	1	27AUG2020	1/3	1	Yes		NA/TC	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781036	GENRL	Fatigue/ fatigue	2	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	INJ&P	Road traffic accident/ Motor Vehicle Accident	1	14SEP2020	19/1	1	No	O	NA	R (14SEP2020)	N/N
	MUSC	Neck pain/ Neck pain	1	14SEP2020	19/3	1	No	O	NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	13JAN2021	1/2	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	3	13JAN2021	1/2	2	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	INV	Body temperature increased/ elevated temperature#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ generalized myalgia#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1178 11781040	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/3	2	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Soreness at Injection Site#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
		Injection site pain/ tenderness at injection site#	4	26FEB2021	2/2	1	Yes		NA/TC	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781041	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1178 11781043	GENRL	Injection site pain/ Injection site soreness	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
	NERV	Headache/ Headache	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1178 11781044	GENRL	Injection site pain/ Pain at injection site.	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1178 11781051	MUSC	Bursitis/ Bursitis exacerbation left shoulder	2	09OCT2020	19/32	2	No	O	NA/TCN	R (09NOV2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	NERV	Headache/ headache#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1178 11781052	GENRL	Fatigue/ fatigue	1	02SEP2020	3/2	2	Yes		NA	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781054	NERV	Injection site pain/ Injection Site Muscle Soreness	1	02SEP2020	3/7	1	Yes		NA	R (08SEP2020)	N/N
		Headache/ Headache	1	02SEP2020	3/2	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Pyrexia/ Fever	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		Myalgia/ Myalgia	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	2	Yes		NA	R (23SEP2020)	N/N
	MUSC	Arthralgia/ Diffuse Arthralgia	2	23SEP2020	3/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	24DEC2020	2/2	1	Yes		NA	R (25DEC2020)	N/N
	16-55/ C4591001 1178 11781055	GENRL	Injection site pain/ Pain at injection site	1	31AUG2020	1/2	1	Yes		NA/TC	R (01SEP2020)
GENRL		Injection site pain/ pain at injection site	2	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N
GENRL		Chills/ chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781058	NERV	Syncope/ syncope	1	18SEP2020	18/1	1	No	O	NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1178 11781061	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ injection site soreness	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Myalgia/ myalgias	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	NERV	Headache/ headache	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ partner exposure during pregnancy	1	02OCT2020	32/C		No	O	NA	UNK	N/N
	MUSC	Bone pain/ sternum pain	2	15OCT2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1178 11781067	GENRL	Injection site pain/ Pain at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
		Injection site pain/ Tenderness at injection site.	2	22SEP2020	2/4	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781069		Injection site pain/ Left deltoid injection site soreness	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Body aches (generalized muscle aches)	2	22SEP2020	1/5	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1178 11781070	GENRL	Fatigue/ Fatigue#	3	17DEC2020	1/2	1	Yes		NA	R (18DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1178 11781072	EYE	Visual impairment/ visual disturbance#	3	02FEB2021	8/3	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ headache#	3	02FEB2021	8/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Musculoskeletal stiffness/ stiff neck#	3	03FEB2021	9/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1178 11781073	GENRL	Pyrexia/ fever	2	23SEP2020	2/4	1	Yes		NA/TC	R (26SEP2020)	N/N
	BLOOD	Lymphadenopathy/ bilateral axillary lymphadenopathy	2	25SEP2020	4/3	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001	SKIN	Rash/ left shoulder blade rash	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781074	INJ&P	Skin laceration/ right arch cut	1	05SEP2020	4/45	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1178 11781077	GENRL	Injection site pain/ left arm soreness (injection site)#	2	27JAN2021	127/3	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1178 11781082	GENRL	Fatigue/ fatigue#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ injection site tenderness#	3	18JAN2021	1/6	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	INV	Body temperature increased/ increased temp#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1178 11781084	GENRL	Injection site pain/ pain at injection site	1	02SEP2020	1/4	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site erythema/ Redness at injection site	2	24SEP2020	2/7	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781087	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/3	1	Yes		NA/TC	R (26SEP2020)	N/N
		Injection site pain/ soreness at injection site#	3	28JAN2021	2/4	1	Yes		NA	R (31JAN2021)	N/N
		Headache/ headache#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ soreness at injection site#	4	22FEB2021	1/C	1	Yes		NA	N	N/N
		Myalgia/ Myalgia#	4	23FEB2021	2/C	1	Yes		NA	N	N/N
16-55/ C4591001 1178 11781089	GENRL	Headache/ headache#	4	23FEB2021	2/C	1	Yes		NA	N	N/N
		Injection site pain/ injection site pain	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
		Thirst/ increased sense of thirst	1	12SEP2020	10/C	1	No	O	NA	N	N/N
16-55/ C4591001 1178 11781092	GENRL	Pyrexia/ fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
		Fatigue/ fatigue#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
		Body temperature increased/ increased temperature#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781095	MUSC	Myalgia/ generalized myalgia#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/4	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	08SEP2020	6/3	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1178 11781096	MUSC	Myalgia/ muscle aches	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ fatigue#	4	11FEB2021	2/1	2	Yes		NA	R (11FEB2021)	N/N
		Pyrexia/ fever#	4	11FEB2021	2/2	3	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1178 11781097	NERV	Headache/ headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	SKIN	Rash/ Rash, inner left arm, left fingers, right flank	1	14SEP2020	11/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781098	GENRL	Injection site pain/ pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1178 11781100	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1178 11781104	RESP	Pulmonary embolism/ Pulmonary embolism	2	20OCT2020	28/102	2	No	O	NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1178 11781106	GENRL	Injection site pain/ injection site soreness#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1178 11781107	GENRL	Injection site erythema/ injection site redness	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ injection site muscle soreness	1	04SEP2020	1/3	2	Yes		NA	R (06SEP2020)	N/N
		Injection site warmth/ injection site warmth	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Chills/ chills	1	05SEP2020	2/1	1	Yes		NA/TC	R (05SEP2020)	N/N
	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781110 16-55/ C4591001	GENRL	Injection site pain/ Arm soreness - Right (injection site)	1	08SEP2020	1/2	1	Yes		NA/TCN	R (09SEP2020)	N/N
1178 11781113	GENRL	Chills/ chills	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ injection site soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ generalized body ache	2	29SEP2020	2/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1178 11781114	GENRL	Pyrexia/ fever#	4	02FEB2021	2/2	2	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ myalgias#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	4	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1178 11781120	GENRL	Injection site pain/ soreness at injection site#	3	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1178 11781121	GENRL	Fatigue/ Fatigue	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Injection site pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781128	GENRL	Fatigue/ fatigue	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ left deltoid injection site soreness	2	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Feeling hot/ feeling of warmth - generalized	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Injection site muscle soreness	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ Myalgias	1	10SEP2020	2/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	2	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1178 11781130		Fatigue/ Fatigue	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
		Injection site pain/ pain at injection site	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781133	GENRL	Injection site pain/ Injection site soreness	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pain/ generalized body ache	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ Left deltoid soreness, injection site	1	09SEP2020	1/4	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ headache	1	29SEP2020	21/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	2/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Malaise/ generalized malaise	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1178 11781135	GENRL	Injection site pain/ Pain at injection site	1	10SEP2020	2/1	1	Yes		NA/TC	R (10SEP2020)	N/N
	SKIN	Night sweats/ Night sweats	1	11SEP2020	3/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	30SEP2020	1/15	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1178 11781137	GENRL	Injection site pain/ Tenderness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1178 11781145	GENRL	Injection site pain/ Soreness at injection site*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781149	NERV	Headache/ Headache	1	23SEP2020	14/1	1	No	O	NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site myalgia	1	11SEP2020	1/4	1	Yes		NA	R (14SEP2020)	N/N
	INJ&P	Skin laceration/ laceration, left index finger	2	22OCT2020	23/12	2	No	O	NA	R (02NOV2020)	N/N
	GENRL	Injection site pain/ Left arm soreness (injection site)#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1178 11781150	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1178 11781153		Pain/ Body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Upper arm myalgia, left#	3	17DEC2020	1/4	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ low grade temperature	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781161 16-55/ C4591001	GENRL	Injection site pain/ tenderness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
1178 11781162 16-55/ C4591001	GENRL	Injection site pain/ Soreness at injection site	1	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
1178 11781163	GENRL	Malaise/ General malaise	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1178 11781168	GENRL	Injection site pain/ Injection site tenderness	1	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1178 11781170	GENRL	Injection site pain/ pain at injection site	2	14OCT2020	1/1	1	Yes		NA	R (14OCT2020)	N/Y
	INFEC	Bacterial vaginosis/ bacterial vaginosis	1	14OCT2020	31/31	2	No	O	NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/Y
	NERV	Migraine/ migraine#	3	26JAN2021	1/1	2	No	O	NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pain in extremity/ upper and lower left arm tenderness#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1178 11781171	GENRL	Injection site pain/ Injection site tenderness#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/Y
16-55/ C4591001 1178 11781175	GENRL	Fatigue/ fatigue	1	15SEP2020	1/4	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headache	1	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ chills	1	16SEP2020	2/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Chills/ chills	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ myalgias	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781179	GENRL	Chills/ rigors	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1178 11781181	GENRL	Injection site pain/ Injection site tenderness - Right arm	1	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1178 11781182	GASTR	Nausea/ Intermittent nausea	2	10OCT2020	6/29	1	No	O	NA	R (07NOV2020)	N/N
16-55/ C4591001 1178 11781183	GENRL	Chills/ chills	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
		Fatigue/ fatigue	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pruritus/ Itchiness at injection site	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781185	GENRL	Injection site pain/ injection site tenderness	1	16SEP2020	1/2	1	Yes	NA	R (17SEP2020)	N/N	
1178 11781186	GENRL	Fatigue/ fatigue	1	19SEP2020	4/2	1	Yes	NA	R (20SEP2020)	N/N	
	MUSC	Myalgia/ generalized myalgia	2	09OCT2020	4/3	1	Yes	NA/TC	R (11OCT2020)	N/N	
	GENRL	Injection site pain/ injection site soreness#	3	21JAN2021	1/2	1	Yes	NA/TC	R (22JAN2021)	N/Y	
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness - Left deltoid*		16SEP2020	1/4	1	Yes	NA	R (19SEP2020)	N/N	
1178 11781187	GENRL	Injection site erythema/ Erythema at injection site	1	17SEP2020	2/1	1	Yes	NA	R (17SEP2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site	2	07OCT2020	1/3	1	Yes	NA	R (09OCT2020)	N/N	
	GASTR	Nausea/ nausea	2	08OCT2020	2/2	1	Yes	NA	R (09OCT2020)	N/N	
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes	NA	R (09OCT2020)	N/N	
16-55/ C4591001	GENRL	Chills/ chills	1	16SEP2020	1/2	1	Yes	NA	R (17SEP2020)	N/N	
1178 11781188		Fatigue/ fatigue	1	16SEP2020	1/4	2	Yes	NA	R (19SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781189		Injection site pain/ left arm pain at injection site	1	16SEP2020	1/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Fatigue/ Fatigue	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	SKIN	Ingrowing nail/ ingrown toenail (left big toe)#	3	02JAN2021	17/10	2	No	O	NA/TC	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	Malaise/ Malaise#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ Headache#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1178 11781194	GENRL	Injection site pain/ soreness at injection#	3	22DEC2020	2/3	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781197	GENRL	Fatigue/ Fatigue	1	17SEP2020	2/5	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1178 11781198	GENRL	Fatigue/ fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ Diffuse myalgias	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1178 11781208	GENRL	Fatigue/ increased fatigue	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1178 11781210	GENRL	Injection site pain/ Left deltoid soreness at injection site	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/Y
	GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/4	1	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781211 16-55/ C4591001 1178 11781214	GENRL	Chills/ chills, intermittent	2	09OCT2020	1/5	1	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Fatigue/ increased fatigue	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
	METAB	Decreased appetite/ decreased appetite	2	11OCT2020	3/3	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Chills/ chills#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Fatigue/ fatigue#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	21JAN2021	1/3	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	INV	Body temperature increased/ elevated temperature#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1178 11781217	GENRL	Injection site pain/ Injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1178 11781218	MUSC	Arthralgia/ Left knee pain	2	20OCT2020	9/28	2	No	O	NA/TC/TCN	R (16NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781219	INV	Body temperature increased/ increased temp#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1178 11781221	GENRL	Injection site pain/ injection site tenderness	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1178 11781221	GENRL	Pain/ generalized body ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ head ache	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1178 11781223	GENRL	Injection site pain/ burning at injection site#	3	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	INJ&P	Clavicle fracture/ right clavicle fracture	1	03OCT2020	13/C	1	No	O	NA/TC/TCN	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781224	GENRL	Injection site pain/ soreness at injection site	1	21SEP2020	1/4	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	INFEC	Pharyngitis streptococcal/ Strep throat	1	28SEP2020	8/11	1	No	O	NA	R (08OCT2020)	N/N
	SKIN	Livedo reticularis/ livedo reticularis intermittent	1	28SEP2020	8/9	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1178 11781226	GENRL	Chills/ Chills#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N
		Fatigue/ fatigue#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N
		Pain/ Body aches#	3	19DEC2020	3/3	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Chills/ chills#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	2/2	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1178 11781227	GENRL	Malaise/ malaise	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1178 11781228	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781230	GENRL	Injection site pain/ Tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	15OCT2020	3/3	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1178 11781233	GENRL	Injection site pain/ soreness at injection site, left deltoid	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Malaise/ generalized malaise	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1178 11781234	GENRL	Injection site pain/ injection site soreness#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1178 11781237	GENRL	Injection site pain/ tenderness at injection site	1	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1178 11781239	GENRL	Fatigue/ fatigue#	3	11FEB2021	1/1	2	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ injection site soreness#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781244	GENRL	Injection site pain/ Pain at injection site.	1	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Pain in extremity/ Left intermittent forearm pain.	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Malaise/ malaise	2	13OCT2020	1/4	1	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ myalgias	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	1/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1178 11781245	GENRL	Injection site pain/ pain at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1178 11781247	GENRL	Fatigue/ fatigue#	3	07JAN2021	1/4	1	Yes		NA	R (10JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ headache#	3	07JAN2021	1/4	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781248	GENRL	Chills/ chills	2	16OCT2020	1/3	1	Yes	NA	R (18OCT2020)	N/N	
		Fatigue/ fatigue	2	16OCT2020	1/3	1	Yes	NA	R (18OCT2020)	N/N	
		Pyrexia/ fever	2	16OCT2020	1/3	1	Yes	NA/TC	R (18OCT2020)	N/N	
	NERV	Headache/ headache	2	16OCT2020	1/3	1	Yes	NA	R (18OCT2020)	N/N	
16-55/ C4591001 1178 11781249	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	1	Yes	NA	R (17OCT2020)	N/N	
	MUSC	Myalgia/ myalgias	2	16OCT2020	2/2	1	Yes	NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 1178 11781251	GENRL	Injection site pain/ soreness, left arm beyond injection site	1	24SEP2020	1/2	1	Yes	NA	R (25SEP2020)	N/N	
	GENRL	Chills/ chills#	3	25FEB2021	1/2	1	Yes	NA	R (26FEB2021)	N/N	
		Injection site pain/ soreness at injection site#	3	25FEB2021	1/6	1	Yes	NA/TC	R (02MAR2021)	N/N	
16-55/ C4591001 1178 11781253	NERV	Headache/ Headache	1	24SEP2020	1/2	1	Yes	NA/TC	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	2/2	1	Yes	NA	R (26SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ Body ache	1	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Chills/ chills	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
		Myalgia/ mayalgias	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1178 11781254	GENRL	Injection site pain/ Soreness at injection site	1	25SEP2020	2/1	2	Yes		NA/TCN	R (25SEP2020)	N/N
16-55/ C4591001 1178 11781257	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N
	BLOOD	Lymphadenopathy/ left axillary adenopathy with cortical thickening#	3	27JAN2021	6/C	1	Yes		NA	N	N/N
		Lymphadenopathy/ right axillary adenopathy with cortical thickening#	3	27JAN2021	6/C	1	Yes		NA	N	N/N
	BLOOD	Anaemia/ anemia#	4	25FEB2021	16/C	1	No	O	NA	N	N/N
	INJ&P	Seroma/ seroma (left axilla)#	4	26FEB2021	17/C	2	No	O	NA	N	N/N
16-55/ C4591001 1178 11781258	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1178 11781260	GENRL	Fatigue/ fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N	
	GENRL	Injection site pain/ tenderness at injection site#	4	13JAN2021	1/4	1	Yes		NA	R (16JAN2021)	N/N	
	GENRL	Fatigue/ fatigue#	4	14JAN2021	2/2	3	Yes		NA	R (15JAN2021)	N/N	
	MUSC	Myalgia/ myalgia#	4	14JAN2021	2/2	2	Yes		NA/TC	R (15JAN2021)	N/N	
	MUSC	Musculoskeletal stiffness/ left shoulder stiffness#	4	10FEB2021	29/C	1	No	O	NA/TC	N	N/N	
	GENRL	Chills/ chills#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N	
			Fatigue/ fatigue#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N
			Malaise/ malaise#	3	19DEC2020	2/2	1	Yes		NA	R (20DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N	
			Myalgia/ myalgias#	3	19DEC2020	2/2	1	Yes		NA/TC	R (20DEC2020)	N/N
	GENRL	Chills/ rigor#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N	
			Pyrexia/ pyrexia#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	3	Yes		NA/TC	R (08JAN2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781262	GENRL	Pain/ body aches#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	SKIN	Night sweats/ night sweats#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1178 11781263	GENRL	Chills/ Chills	1	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Injection site pain	1	28SEP2020	1/3	2	Yes		NA	R (30SEP2020)	N/N
	RESP	Upper-airway cough syndrome/ post nasal drip	1	01OCT2020	4/23	1	No	O	NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ fever	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ headache	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	RESP	Upper-airway cough syndrome/ post nasal drip	2	30DEC2020	72/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1178 11781266	GENRL	Injection site pain/ pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781267	MUSC	Myalgia/ myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1178 11781268	GENRL	Fatigue/ Fatigue	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ chills	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	21OCT2020	2/12	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	2/12	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1178 11781269	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781270	PSYCH	Insomnia/ insomnia#	4	13JAN2021	2/1	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Vessel puncture site bruise/ Bruising at the site for blood draw	1	30SEP2020	2/10	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/Y
	GENRL	Injection site pain/ Soreness at injection site	2	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgias	2	21OCT2020	2/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	21OCT2020	2/2	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1178 11781271	GENRL	Injection site pain/ injection site soreness	1	29SEP2020	1/6	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	19OCT2020	1/4	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1178 11781275	GENRL	Injection site erythema/ erythema at injection site#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781279	GENRL	Injection site pain/ soreness at injection site, right deltoid	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1178 11781284	GENRL	Injection site bruising/ Bruising at injection site	1	06OCT2020	1/15	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
		Fatigue/ fatigue#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1178 11781285	GENRL	Injection site pain/ Tenderness at injection site	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pain/ Body aches	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ Chills	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781288	GENRL	Pain/ Generalized body aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection pain	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgias	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1178 11781290	GENRL	Injection site pain/ tenderness at injection site	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1178 11781291	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ Chills	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001		Fatigue/ Fatigue	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	INFEC	Sinusitis/ Sinus infection	2	25NOV2020	28/7	1	No	O	NA/TC	R (01DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1178 11781295	MUSC	Pain in extremity/ Arm pain, entire left arm#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	MUSC	Myalgia/ Left upper arm myalgia#	4	05JAN2021	1/7	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	2/1	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ Myalgias#	4	06JAN2021	2/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1178 11781296	INFEC	Gonorrhoea/ gonorrhea	2	04NOV2020	2/9	2	No	O	NA/TC	R (12NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	4	24FEB2021	1/2	2	Yes		NA	R (25FEB2021)	N/N
		Injection site pain/ soreness at injection site#	4	24FEB2021	1/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1178 11781300	INFEC	Hordeolum/ Left eye stye	1	19OCT2020	6/23	2	No	O	NA/TC	R (10NOV2020)	N/N
	GASTR	Nausea/ nausea#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Pain/ body aches#	3	21DEC2020	1/4	1	Yes		NA/TC	R (24DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
	GENRL	Chills/ chills#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
		Pain/ body ache#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
		Pyrexia/ fever#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/3	3	Yes		NA	R (14JAN2021)	N/N
	BLOOD	Lymphadenopathy/ left axillary lymphadenopathy#	4	13JAN2021	2/8	1	Yes		NA	R (20JAN2021)	N/N
	SKIN	Lichen sclerosus/ lichen sclerosus#	4	19JAN2021	8/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1178 11781309	GENRL	Chills/ chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ soreness at injection site	1	21OCT2020	2/5	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ myalgias	1	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ pain at injection site	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1178 11781310	MUSC	Myalgia/ generalized muscle ache	2	12NOV2020	1/3	1	Yes		NA/TC	R (14NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Axillary pain/ left axillary pain	2	13NOV2020	2/3	2	Yes		NA	R (15NOV2020)	N/N
		Fatigue/ fatigue	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N
		Injection site pain/ pain at injection site	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1178 11781312	MUSC	Myalgia/ body aches/myalgia	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	13NOV2020	2/1	2	Yes		NA	R (13NOV2020)	N/N
	GENRL	Injection site pain/ injection site tenderness#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ fever#	4	22FEB2021	1/3	2	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	22FEB2021	1/3	3	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1179 11791002	GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1179 11791030	GENRL	Injection site pain/ Injection Site Soreness#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ Headache#	3	26FEB2021	2/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1179 11791058	GENRL	Chills/ CHILLS#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
		Pain/ BODY ACHES#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1179 11791066	MUSC	Pain in extremity/ Arm Soreness#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1179 11791079	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1179 11791091		Injection site pain/ Injection Site Soreness#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1179 11791101	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pain/ Body Aches#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1179 11791107	GENRL	Chills/ Chills#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1179 11791109	GENRL	Injection site pain/ Injection Site Soreness#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1179 11791118	GENRL	Influenza like illness/ FLU LIKE SYMPTOMS#	3	21DEC2020	3/2	1	Yes		NA	R (22DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1179 11791126	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1179 11791130	GENRL	Injection site pain/ Injection Site Soreness#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1179 11791136	GENRL	Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ Fever#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1179 11791158	GASTR	Diarrhoea/ Mild Diarrhea	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
		Nausea/ Nausea	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
		Vomiting/ Vomiting	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
	NERV	Headache/ Headache	2	16NOV2020	1/2	1	Yes		NA/TC	R (17NOV2020)	N/N
16-55/ C4591001 1179 11791162	NERV	Headache/ Headache	2	19NOV2020	1/2	1	Yes		NA/TC	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1185 11851032	MUSC	Myalgia/ myalgia#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Somnolence/ drowsiness#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1185 11851048	GENRL	Chills/ Chills#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ headache#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1185 11851050	MUSC	Intervertebral disc protrusion/ vertebral slipped disc cervicobrachial C5/C6#	2	13FEB2021	88/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1185 11851054	INJ&P	Arthropod bite/ tick bite right lower leg	1	11NOV2020	14/1	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C4591001 1185 11851055	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	02NOV2020	5/C		No	O	NA	UNK	N/N
16-55/ C4591001 1185 11851060	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Somnolence/ Drowsiness#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1185 11851064	GENRL	Fatigue/ Fatigue#	3	09FEB2021	1/8	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1194 11941004	GENRL	Injection site pain/ Pain at injection site#	3	11JAN2021	1/3	2	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1194 11941014	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1194 11941016	GENRL	Fatigue/ Fatigue#	3	27JAN2021	3/4	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	27JAN2021	3/25	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1194 11941024	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/6	2	Yes		NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/2	1	Yes		NA	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941026	NERV	Headache/ Headache#	4	17FEB2021	15/4	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1194 11941030	RESP	Asthma/ Worsening of Asthma	2	07NOV2020	1/5	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1194 11941032	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/5	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache (intermittent)#	3	26JAN2021	2/14	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1194 11941033	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathia (axillar left)#	4	04FEB2021	3/3	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1194 11941041	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1194 11941045	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain injection site#	3	29JAN2021	1/4	2	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941046 16-55/ C4591001 1194 11941047	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	2/4	2	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	15FEB2021	1/5	2	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1194 11941048	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	1/1	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/4	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1194 11941054	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1194 11941058	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/4	2	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/9	2	Yes		NA	R (11FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Swelling lymph node (axillar right)#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1194 11941067	MUSC	Arthralgia/ Pain at thumb base joint#	4	04FEB2021	3/8	2	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	15JAN2021	1/6	3	Yes		NA	R (20JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	15JAN2021	1/6	2	Yes		NA	R (20JAN2021)	N/N
		Injection site swelling/ Swelling at injection pain#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
	NERV	Headache/ Headache#	3	16JAN2021	2/3	2	Yes		NA	R (18JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	05FEB2021	1/7	2	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	08FEB2021	11/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	15JAN2021	1/2	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1194 11941080											
16-55/ C4591001 1194 11941081											
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941086	NERV	Headache/ Headache#	3	29JAN2021	2/2	2	Yes	NA	NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	19FEB2021	2/3	2	Yes	NA	NA	R (21FEB2021)	N/N
16-55/ C4591001 1194 11941087	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/2	2	Yes	NA	NA	R (29JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	28JAN2021	1/3	2	Yes	NA	NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941089	GENRL	Injection site pain/ Pain at injection site#	2	28JAN2021	78/3	2	Yes	NA	NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	2	29JAN2021	79/2	2	Yes	NA	NA	R (30JAN2021)	N/N
16-55/ C4591001 1194 11941090	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/2	2	Yes	NA	NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	16FEB2021	1/3	2	Yes	NA	NA	R (18FEB2021)	N/N
16-55/ C4591001 1194 11941092	GENRL	Injection site pain/ Pain at the injection site#	3	27JAN2021	2/3	2	Yes	NA	NA	R (29JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	26JAN2021	1/3	2	Yes	NA	NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1194 11941098 16-55/ C4591001 1194 11941100	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
	GASTR	Abdominal pain upper/ Stomach ache#	4	21FEB2021	5/C	2	Yes		NA	N	N/N
16-55/ C4591001 1194 11941103	GENRL	Injection site pain/ Pain at injection site#	3	13JAN2021	2/4	1	Yes		NA	R (16JAN2021)	N/N
16-55/ C4591001 1194 11941106	GENRL	Injection site pain/ Pain at the injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1195 11951003	MUSC	Spondylolisthesis/ Spondylolisthesis L4/5#	2	05FEB2021	93/33	2	No	O	NA	R (09MAR2021)	Y/N
	NERV	Headache/ Headache#	4	10MAR2021	1/3	2	Yes		NA	R (12MAR2021)	N/N
	EAR	Vertigo/ Vertigo#	4	11MAR2021	2/2	1	Yes		NA	R (12MAR2021)	N/N
	GASTR	Nausea/ Nausea#	4	11MAR2021	2/1	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	10MAR2021	1/2	2	Yes		NA	R (11MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1195 11951004	NERV	Headache/ Headache#	4	11MAR2021	2/1	2	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
1195 11951008	MUSC	Pain in extremity/ limb pain#	4	10FEB2021	2/2	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Anal prolapse/ anal prolapse#	4	18FEB2021	10/10	3	No	O	NA	R (27FEB2021)	Y/N
	GASTR	Anal fistula/ anal fistula#	4	25FEB2021	17/1	2	Yes		NA	R (25FEB2021)	N/N
	INFEC	Abscess/ Abscess#	4	27FEB2021	19/1	2	No	O	NA	R (27FEB2021)	N/N
16-55/ C4591001	NERV	Sciatica/ Lumboischialgia	1	02NOV2020	19/7	1	No	O	NA/TCN	R (08NOV2020)	N/N
1195 11951009	MUSC	Spondylolisthesis/ worsening of Spondylolisthesis	2	19DEC2020	47/29	3	No	O	NA/TC	R (16JAN2021)	Y/N
1195 11951017	VASC	Hypertension/ worsening Hypertension#	2	20JAN2021	77/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GASTR	Gastritis/ acute Gastritis#	3	30JAN2021	10/7	2	No	O	NA/TC	R (05FEB2021)	N/N
1195 11951018											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951020	PSYCH	Sleep disorder/ Sleep disorder#	3	05FEB2021	16/11	1	No	O	NA	R (15FEB2021)	N/N
	INJ&P	Contusion/ Contusion thorax right#	3	11FEB2021	17/C	3	No	O	NA	RG	N/N
16-55/ C4591001 1195 11951023		Fall/ Fall#	3	11FEB2021	17/1	3	No	O	NA	R (11FEB2021)	N/N
	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	16NOV2020	13/5	1	No	O	NA/TC/TCN	R (20NOV2020)	Y/N
	MUSC	Intervertebral disc protrusion/ worsening herniated disc cervical vertebra#	3	29JAN2021	1/C	3	No	O	NA	RG	N/N
	GASTR	Diarrhoea/ Diarrhoea#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
		Vomiting/ Vomiting#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site erythema/ Redness injection site#	4	21FEB2021	3/7	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1195 11951027	MUSC	Back pain/ lower back pain	2	18NOV2020	13/6	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001	NERV	Sciatica/ Lumboischialgia	1	19OCT2020	4/39	1	No	O	NA	R (26NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1195 11951030 16-55/ C4591001 1195 11951041	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1195 11951053	GENRL	Chills/ Chills#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Pain injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1195 11951064	GENRL	Chills/ Chills#	4	12MAR2021	1/C	2	Yes		NA	N	N/N
	MUSC	Myalgia/ muscle pain#	4	12MAR2021	1/C	2	Yes		NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951066	GENRL	Chills/ Chills#	3	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1195 11951070	GENRL	Injection site pain/ Pain injection side#	3	27JAN2021	2/4	2	Yes		NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1195 11951075	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1195 11951076	GENRL	Chills/ Chills#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1195 11951100	GASTR	Vomiting/ Emesis	1	18OCT2020	1/1	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1195 11951117	MUSC	Back pain/ Lumbago	2	03DEC2020	27/5	1	No	O	NA/TC	R (07DEC2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951134	GENRL	Injection site erythema/ Redness injection site#	3	18FEB2021	1/5	1	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site swelling/ Swelling injection site#	3	18FEB2021	1/5	1	Yes		NA/TC	R (22FEB2021)	N/N
	SKIN	Urticaria/ intermittent generalized Urticaria#	3	21FEB2021	4/1	2	Yes		NA	R (21FEB2021)	N/N
	SKIN	Urticaria/ Urticaria Arm left#	3	22FEB2021	5/9	3	Yes		NA/TC	R (02MAR2021)	N/N
	GENRL	Injection site erythema/ Redness injection site#	4	11MAR2021	1/C	2	Yes		NA/TC	N	N/N
		Injection site swelling/ Swelling injection site#	4	11MAR2021	1/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1195 11951135	INJ&P	Epicondylitis/ Epicondylitis humeri radialis right	2	30NOV2020	20/56	1	No	O	NA	R (24JAN2021)	N/N
16-55/ C4591001 1195 11951136	GENRL	Injection site pain/ pain on the injection site#	3	08FEB2021	1/4	2	Yes		NA	R (11FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache#	4	02MAR2021	2/3	2	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1195 11951141	MUSC	Intervertebral disc protrusion/ herniated disc thoracic spine	1	21OCT2020	2/C	2	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1195 11951148	MUSC	Osteochondrosis/ Osteochondrosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N
		Scoliosis/ Scoliosis	1	02NOV2020	14/C	1	No	O	NA	N	N/N
	MUSC	Intervertebral disc protrusion/ herniated disc cervical spine	1	09NOV2020	21/C	1	No	O	NA	RG	N/N
	MUSC	Spinal disorder/ cervical spine syndrome	1	02NOV2020	14/45	1	No	O	NA/TC	R (16DEC2020)	N/N
	GENRL	Injection site pain/ pain injection site#	3	09FEB2021	2/7	2	Yes		NA	R (15FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	24FEB2021	17/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	VASC	Hypertension/ hypertension	1	01NOV2020	18/18	2	No	O	NA/TC	R (18NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ headache#	4	19FEB2021	1/2	2	Yes		NA/TC	R (20FEB2021)	N/N
GENRL	Peripheral swelling/ arm swelling#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N	
MUSC	Myalgia/ muscle pain#	4	20FEB2021	2/2	2	Yes		NA/TC	R (21FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1197 11971015	MUSC	Tendon pain/ Worsening of Achillodynia	2	22NOV2020	17/55	2	No	O	NA/TC/TCN	R (15JAN2021)	N/N
16-55/ C4591001 1197 11971017	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1197 11971019	NERV	Dizziness/ lightheadedness	1	22OCT2020	7/1	2	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1197 11971020	GASTR	Gastritis/ Gastritis#	3	07FEB2021	17/6	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	5/2	2	No	O	NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1197 11971026	GENRL	Injection site pain/ pain at injection site left arm#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	26FEB2021	1/4	1	Yes		NA	R (01MAR2021)	N/N
	NERV	Headache/ headache#	4	27FEB2021	2/3	1	Yes		NA	R (01MAR2021)	N/N
16-55/ C4591001 1197 11971028	PSYCH	Depression/ depression	2	12NOV2020	9/51	1	No	O	NA/TCN	R (01JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1197 11971031	MUSC	Tenosynovitis/ Tenosynovitis right forearm	2	15JAN2021	71/C	2	No	O	NA/TC	N	N/N	
	NERV	Headache/ headache#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N	
16-55/ C4591001 1197 11971035	MUSC	Pain in extremity/ pain at arm#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N	
	NERV	Headache/ headache#	3	31JAN2021	3/1	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N	
	GENRL	Injection site pain/ pain at injection site left arm#	4	19FEB2021	2/5	1	Yes		NA	R (23FEB2021)	N/N	
16-55/ C4591001 1197 11971039	VASC	Hypertension/ worsening hypertension	1	01NOV2020	16/C	2	No	O	NA/TC	N	N/N	
	GENRL	Fatigue/ Fatigue#	2	08FEB2021	94/C	2	Yes		NA	N	N/N	
	PSYCH	Adjustment disorder/ Adapt Problems#	2	08FEB2021	94/C	2	No	O	NA	N	N/N	
	SOCCI	Job dissatisfaction/ Place of Employment Problems#	2	08FEB2021	94/C	2	No	O	NA	N	N/N	
16-55/ C4591001 1197 11971040	GENRL	Fatigue/ fatigue#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1197 11971041	MUSC	Myalgia/ muscle pain arm#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	01FEB2021	4/4	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Pain in extremity/ arm pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ headache#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Back pain/ worsening back pain	2	19NOV2020	13/13	2	No	O	NA/TC	R (01DEC2020)	N/N
	GENRL	Injection site pain/ pain at injection site let arm#	3	03FEB2021	1/2	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	27FEB2021	2/1	2	Yes		NA/TC	R (27FEB2021)	N/N
16-55/ C4591001 1197 11971064	MUSC	Myalgia/ muscle pain#	4	27FEB2021	2/2	2	Yes		NA/TC	R (28FEB2021)	N/N
	NERV	Headache/ headache#	4	27FEB2021	2/2	2	Yes		NA/TC	R (28FEB2021)	N/N
	INFEC	Epididymitis/ Epididymitis right#	2	02FEB2021	89/C	2	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Musclepain#	3	05FEB2021	1/3	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	26FEB2021	1/2	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1197 11971068	NERV	Carpal tunnel syndrome/ Carpal Tunnel Syndrome Right Hand#	2	15FEB2021	102/C	2	No	O	NA/TCN	N	N/N
16-55/ C4591001 1197 11971069	GENRL	Chills/ Chills#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Pyrexia/ fever#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
	GENRL	Pyrexia/ fever#	4	26FEB2021	1/2	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1197 11971088	GENRL	Injection site pain/ Musclepain under the injection Point#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
		Malaise/ Indisposed#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection siede#	4	24FEB2021	1/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pain/ generalized pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1197 11971093	GENRL	Fatigue/ fatigue#	3	22JAN2021	1/10	1	Yes		NA	R (31JAN2021)	N/N
		Pyrexia/ fever (38.5C)#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Pain in extremity/ pain left arm#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ shivering#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ chills#	4	13FEB2021	1/2	2	Yes		NA	R (14FEB2021)	N/N
		Fatigue/ fatigue#	4	13FEB2021	1/3	2	Yes		NA	R (15FEB2021)	N/N
		Pyrexia/ fever#	4	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	1/3	2	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1197 11971094	MUSC	Back pain/ back pain	2	20NOV2020	14/9	2	No	O	NA/TC	R (28NOV2020)	N/N
	GENRL	Injection site pain/ pain art injection site#	3	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1197 11971096	NERV	Migraine/ worsening migraine	1	21OCT2020	3/3	2	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1203 12031004	REPRO	Dysmenorrhoea/ menstrual pain	1	04NOV2020	20/1	2	No	O	NA/TC	R (04NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	03MAR2021	1/5	2	Yes		NA/TC	R (07MAR2021)	N/N
	GENRL	Fatigue/ fatigue#	3	04MAR2021	2/2	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1203 12031005	NERV	Headache/ headache	2	01DEC2020	26/1	2	No	O	NA/TC	R (01DEC2020)	N/N
	GASTR	Umbilical hernia/ hernia umbilicalis	2	08JAN2021	64/48	2	No	O	NA/TC	R (24FEB2021)	N/N
	GENRL	Vaccination site reaction/ local vaccination reaction#	3	01MAR2021	1/3	2	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1203 12031015	NERV	Headache/ headache	1	28OCT2020	10/5	3	No	O	NA/TC	R (01NOV2020)	N/N
	NERV	Headache/ headache	1	05NOV2020	18/1	2	No	O	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1203 12031020	GENRL	Injection site pain/ tenderness at injection site#	3	10FEB2021	1/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1203 12031020	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1203 12031026	NERV	Headache/ headache	1	07NOV2020	19/1	2	No	O	NA/TC	R (07NOV2020)	N/N
	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	NERV	Headache/ systemic vaccination reaction headache#	3	01MAR2021	1/1	2	Yes		NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1203 12031031	SKIN	Urticaria/ urticaria upper and lower body	1	22OCT2020	3/7	2	No	O	NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	11FEB2021	2/3	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1203 12031032	GENRL	Injection site pain/ tenderness at injection site#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	SKIN	Hyperhidrosis/ sweating#	3	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001	NERV	Disturbance in attention/ concentration deficite	1	21OCT2020	1/8	2	Yes		NA	R (28OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1203 12031033	NERV	Disturbance in attention/ concentration deficite	2	11NOV2020	1/11	2	Yes		NA	R (21NOV2020)	N/N
	NERV	Aphasia/ dysphasia	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Dizziness/ dizziness	2	13NOV2020	3/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1203 12031034	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1203 12031037	INFEC	Rhinitis/ rhinitis	1	02NOV2020	13/15	1	No	O	NA/TC	R (16NOV2020)	N/N
	INFEC	Oral herpes/ herpes labialis	1	07NOV2020	18/10	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1203 12031044	INFEC	Cystitis/ cystitis	1	30OCT2020	10/5	2	Yes		NA/TC	R (03NOV2020)	N/N
	NERV	Headache/ headache	1	04NOV2020	15/1	2	No	O	NA/TC	R (04NOV2020)	N/N
	GASTR	Odynophagia/ pain when swallowing	1	05NOV2020	16/4	1	No	O	NA	R (08NOV2020)	N/N
	INFEC	Cystitis/ cystitis	2	21NOV2020	11/5	2	Yes		NA/TC	R (25NOV2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/4	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1203 12031047	GENRL	Injection site pain/ tenderness at injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Malaise/ Malaise#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	MUSC	Arthralgia/ Arthralgia#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	GENRL	Pyrexia/ Fever#	4	04MAR2021	2/2	1	Yes		NA/TC	R (05MAR2021)	N/N
16-55/ C4591001 1203 12031048	GENRL	Injection site pain/ pain at injection site#	3	10FEB2021	1/6	2	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1203 12031051	INFEC	Pustule/ pustulas frontal head and cheeks	1	26OCT2020	4/6	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1203 12031056	INJ&P	Lip injury/ laceration Right upper lip	2	14NOV2020	2/13	2	No	O	NA/TC/TCN	R (26NOV2020)	N/N
		Tooth fracture/ tooth fracture	2	14NOV2020	2/49	1	No	O	NA	R (01JAN2021)	N/N
16-55/ C4591001 1203 12031058	INFEC	Rhinitis/ rhinitis	1	06NOV2020	15/10	2	No	O	NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1203 12031059	NERV	Headache/ headache#	3	08FEB2021	1/2	2	Yes		NA	R (09FEB2021)	N/N	
	GENRL	Malaise/ malaise#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	GENRL	Medical device pain/ toothache afte totth brace implantation#	2	13JAN2021	62/17	2	No	O	NA/TC	R (29JAN2021)	N/N	
	SURG	Orthodontic procedure/ implantation of permanent tooth brace#	2	13JAN2021	62/1	1	No	O	NA	R (13JAN2021)	N/N	
	GASTR	Diarrhoea/ diarrhea#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N	
	GENRL		Nausea/ nausea#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
			Fatigue/ fatigue#	4	10FEB2021	1/2	3	Yes		NA	R (11FEB2021)	N/N
			Pyrexia/ fever up to 39.8 degree#	4	10FEB2021	1/2	3	Yes		NA/TC	R (11FEB2021)	N/N
NERV	Headache/ headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N		
16-55/ C4591001 1203 12031064	GASTR	Nausea/ nausea	2	17NOV2020	2/3	2	Yes		NA	R (19NOV2020)	N/N	
	NERV	Dizziness/ dizziness	2	18NOV2020	3/4	2	Yes		NA	R (21NOV2020)	N/N	
	NERV	Headache/ headache	2	30NOV2020	15/1	2	No	O	NA/TC	R (30NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1203 12031066	NERV	Dizziness/ dizziness	2	13DEC2020	28/1	2	No	O	NA	R (13DEC2020)	N/N
	GASTR	Flatulence/ meteorism	2	17NOV2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1203 12031067	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N
		Malaise/ malaise#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1203 12031069	INFEC	Cystitis/ cystitis	2	28NOV2020	13/3	2	No	O	NA/TC	R (30NOV2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ vaginal mycosis	2	30NOV2020	15/9	2	No	O	NA/TC	R (08DEC2020)	N/N
16-55/ C4591001 1204 12041001	GENRL	Injection site pain/ pain at injection site#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Malaise/ malaise#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
		Arthralgia/ joint pain#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ headache due to Vaccination#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
GENRL	Injection site pain/ Injection Site Pain	1	24AUG2020	1/3	1	Yes		NA/TC	R (26AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041005		Pyrexia/ Fever	1	24AUG2020	1/2	1	Yes		NA/TC	R (25AUG2020)	N/N
	GASTR	Dyspepsia/ Heart Burn	1	12SEP2020	20/2	2	No	O	NA/TC	R (13SEP2020)	N/N
	GASTR	Retching/ gagging lasting 5-10 seconds, with second episode today	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N
	IMMUN	Hypersensitivity/ allergies, normal per patient.	1	06SEP2020	13/2	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C4591001 1204 12041006	GENRL	Malaise/ body malaise#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1204 12041008		Pyrexia/ Fever 102 F#	4	05JAN2021	1/3	2	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Pyrexia/ Fever	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Grade 1 Myalgias	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1204 12041009	MUSC	Myalgia/ Muscle aches	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041010	NERV	Pyrexia/ Mild fever	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
		Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA	R (27AUG2020)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1204 12041012	GENRL	Chills/ chills#	3	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ chills	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1204 12041013	MUSC	Myalgia/ Muscle aches	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1204 12041015	GENRL	Injection site pain/ Muscle pain at injection site	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Chills/ Chills	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041017	GENRL	Chills/ Chills	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041018	MUSC	Pyrexia/ Fever	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
		Back pain/ Back soreness	2	04OCT2020	7/2	1	Yes		NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1204 12041020	GENRL	Injection site pain/ Pain at the Injection Site	1	31AUG2020	1/3	2	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain (injection site)#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1204 12041021	GENRL	Fatigue/ moderate to strong fatigue after the injection lasting days	1	01SEP2020	2/6	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1204 12041023	BLOOD	Lymphadenopathy/ swollen lymph node gland on neck	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Subjective Fever	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		Chills/ chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ left arm pain (injection site)#	3	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041025 16-55/ C4591001 1204 12041026	MUSC	Arthralgia/ Sore Left Shoulder	1	01SEP2020	1/3	1	Yes		NA	R (03SEP2020)	N/N
	GASTR	Nausea/ nausea	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/8	1	Yes		NA	R (29SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Headache/ Severe headache	2	22SEP2020	1/25	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1204 12041029	NERV	Dizziness/ Dizziness	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1204 12041030	GASTR	Diarrhoea/ non-bloody diarrhea x2 - his fiance who is not participating in the study also experience diarrhea	1	08SEP2020	7/1	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1204 12041039	GENRL	Chills/ chills	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041040	SKIN	Hyperhidrosis/ sweats	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Chills	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	25SEP2020	22/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever, 101#	4	28JAN2021	1/4	2	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1204 12041043	EAR	Ear pain/ Right ear pain#	4	29JAN2021	2/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Dizziness/ Dizziness	1	18SEP2020	15/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ left arm pain (vac #2 injection site)	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Dizziness/ dizziness	2	29SEP2020	5/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041047	GASTR	Nausea/ Nausea#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041049	GENRL	Pyrexia/ Fever#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Pyrexia/ low grade fever	1	09SEP2020	2/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever, maximum temp of 100.3 F	2	29SEP2020	1/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041055	MUSC	Pain in extremity/ left arm pain	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041058	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041059	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041064	MUSC	Pain in extremity/ left arm pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041066	GENRL	Injection site pain/ left arm soreness (injection site)#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
		Pyrexia/ Low grade fever (100.7F)#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1204 12041067	GENRL	Injection site pain/ injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1204 12041071	GENRL	Pyrexia/ Fever: Temp 101 F	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ right arm pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ mild diarrhea	1	11SEP2020	3/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041072	MUSC	Arthralgia/ left shoulder pain	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	INJ&P	Animal bite/ Cat bite, left index finger#	3	28FEB2021	17/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1204 12041073	NERV	Migraine/ Migraine	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1204 12041075	GENRL	Pyrexia/ Low grade fever, 102	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever, 100	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1204 12041077	GENRL	Influenza like illness/ Flu-like symptoms	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Vomiting/ Vomiting	2	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
		Pain/ Generalized body aches	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041078	NERV	Pyrexia/ fever 101.2	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
		Migraine/ Migraine	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen lymph nodes neck area (left side )#	4	05FEB2021	2/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1204 12041080	GENRL	Chills/ chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ fatigue	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Injection site pain (post administration of injection #2)	2	30SEP2020	1/6	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1204 12041082	INV	Body temperature increased/ elevated temperature, 100.1	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1204 12041086	GENRL	Chills/ Chills	1	12SEP2020	3/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Muscle aches	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041091	GENRL	Pyrexia/ low grade fever, max temp of 100 F	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1204 12041093	MUSC	Pain in extremity/ left arm pain (post vaccine #2)	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Chills/ chills	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
		Fatigue/ fatigue	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1204 12041095	VASC	Hot flush/ Feeling of hot flushes	1	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1204 12041097	GENRL	Fatigue/ Fatigue	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1204 12041100	GENRL	Injection site pain/ right arm soreness (injection site)#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1204 12041107	GENRL	Injection site pain/ pain at injection site	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041108	NERV	Headache/ headache	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness at injection site#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1204 12041110	MUSC	Myalgia/ Myalgia#	4	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ chills#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Back pain/ back pain#	4	07JAN2021	2/2	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1204 12041111	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1204 12041112	MUSC	Pain in extremity/ Pain left arm	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1204 12041116	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ Chills#	3	23DEC2020	1/2	1	Yes		NA	R (24DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041120	INFEC	Fungal skin infection/ fungal infection small toe right foot#	4	28JAN2021	23/14	2	No	O	NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1204 12041121	GENRL	Injection site pain/ left upper arm pain (injection site)	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Pyrexia/ Low grade fever 100.3 F	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Back pain/ mild back pain	1	20SEP2020	3/15	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1204 12041123	GENRL	Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Injection site pain/ left arm soreness (vac #2 injection site)	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1204 12041124	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
		Nausea/ Nausea	1	28SEP2020	11/8	1	No	CD	NA	R (05OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Feeling hot/feverish	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041125	GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1204 12041128	GENRL	Fatigue/ fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Pain/ body aches	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Pain in extremity/ whole left arm pain	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1204 12041129	MUSC	Myalgia/ Generalized myalgia#	4	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	4	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1204 12041131	MUSC	Pain in extremity/ Right Arm Pain#	3	09FEB2021	1/3	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1204 12041133	GENRL	Chills/ Chills	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041136	GENRL	Injection site pain/ left arm soreness (vac#2 injection site)	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1204 12041137	GASTR	Nausea/ Nausea#	4	06JAN2021	1/3	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Chills/ Chills#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
		Malaise/ Body Malaise#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1204 12041138	MUSC	Arthralgia/ opposite shoulder pain intermittent	1	22SEP2020	2/2	1	No	O	NA	R (23SEP2020)	N/N
		Myalgia/ muscle pain - abdominal	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12OCT2020	1/3	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	2	12OCT2020	1/3	1	Yes		NA/TC	R (14OCT2020)	N/N
	METAB	Polydipsia/ Polydipsia	2	12OCT2020	1/4	2	Yes		NA	R (15OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Swollen submandibular lymph nodes	2	13OCT2020	2/3	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Pyrexia/ Low grade fever, 99.0	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041139	GENRL	Injection site pain/ Pain left arm at injection site	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ Fever (100.4)	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1204 12041144	GASTR	Hypoaesthesia oral/ tongue numbness	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	24SEP2020	3/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1204 12041145	GENRL	Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Injection site pain/ Injection site pain	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Low grade fever 100.3 F	1	23SEP2020	1/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Fever; max temp of 102 F	2	14OCT2020	1/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1204 12041147	GENRL	Injection site pain/ Muscle tenderness on injection site	1	23SEP2020	1/7	1	Yes		NA	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041150	GENRL   NERV	Fatigue/ Fatigue	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Headache/ Headache	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1204 12041153	GENRL	Chills/ Chills	1	30SEP2020	8/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1204 12041154†	GENRL	Fatigue/ tired	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1204 12041155	GENRL  NERV	Fatigue/ fatigue	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Headache/ headache	1	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1204 12041167	GENRL	Injection site pain/ Muscle tenderness at injection site	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ left arm soreness (vac #2 injection site)	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041170	MUSC	Myalgia/ Muscle aches	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever (100.4)	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1204 12041176†	GENRL	Pyrexia/ Subjective low grade fever	2	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1204 12041178	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	2	21OCT2020	1/6	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Pyrexia/ Low grade fever, 100.6	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1204 12041182†	GENRL	Chills/ chills	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N
		Malaise/ malaise	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	04NOV2020	7/2	1	Yes		NA	R (05NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041184	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/4	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1204 12041186	METAB	Dehydration/ dehydration	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N
	NERV	Syncope/ syncope	2	31OCT2020	9/2	3	No	O	NA	R (01NOV2020)	N/N
16-55/ C4591001 1204 12041187	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1204 12041188†	GENRL	Pyrexia/ Low grade fever, 100.4	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	NERV	Headache/ Headaches	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/3	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1204 12041191	RESP	Dyspnoea/ mild shortness of breath	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041192	SKIN	Pruritus/ itching left arm	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
		Pruritus/ itching left leg	1	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
		Pyrexia/ Low grade fever, 100.4	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	27OCT2020	2/2	1	Yes		NA	R (28OCT2020)	N/N
	SKIN	Rash/ Rash on the back of neck	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Chills/ Chills	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	08OCT2020	3/4	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N
GENRL	Chills/ Chills	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N	
16-55/ C4591001 1204 12041194†	GENRL	Fatigue/ Fatigue	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041195	NERV	Headache/ Headache	1	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1204 12041199	INJ&P	Procedural pain/ Pain from hair transplant procedure	2	10NOV2020	12/5	2	No	O	NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1204 12041202	NERV	Headache/ Headaches#	4	26JAN2021	1/3	2	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1204 12041203	GENRL	Fatigue/ Fatigue	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain (vac#2 site)	2	29OCT2020	1/4	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ headache	2	29OCT2020	1/4	1	Yes		NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1204 12041205	GENRL	Pyrexia/ Low grade fever, 100.2	2	30OCT2020	2/1	1	Yes		NA/TC	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041208	MUSC	Myalgia/ Muscle aches	2	30OCT2020	2/2	1	Yes		NA/TC	R (31OCT2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	4	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1204 12041209	GENRL	Fatigue/ fatigue#	4	05JAN2021	2/1	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1204 12041210†		Injection site pain/ Muscle tenderness at injection site	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
		Malaise/ Malaise	2	29OCT2020	1/5	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Myalgia/ Muscle aches	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Tenderness at injection site#	3	21JAN2021	2/C	1	Yes		NA	RG	N/N
		Injection site rash/ Localized rash at injection site s/p revaccination#	3	21JAN2021	2/C	2	Yes		NA/TC	RG	N/N
	SKIN	Rash/ Localized rash on left shoulder s/p revaccination#	3	21JAN2021	2/C	2	Yes		NA/TC	RG	N/N
	GENRL	Chills/ chills	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041214		Malaise/ body malaise	1	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	03NOV2020	2/2	1	Yes		NA	R (04NOV2020)	N/N
		Pain/ Body aches	2	03NOV2020	2/2	1	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1204 12041220	GASTR	Abdominal discomfort/ stomach discomfort	1	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain	2	02NOV2020	1/2	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1204 12041222	NERV	Headache/ Headache	1	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	03NOV2020	2/1	1	Yes		NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1204 12041227	GENRL	Injection site pain/ left arm soreness (vac #1 injection site)	1	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041233†	MUSC	Pyrexia/ Low grade fever, 100.4	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
		Myalgia/ Muscle aches	2	03NOV2020	1/3	2	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Injection site pain/ left arm soreness (injection site)#	3	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1204 12041234	GENRL	Fatigue/ Fatigue	1	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001	BLOOD	Injection site pain/ Muscle tenderness at injection site	1	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
		Lymphadenopathy/ Swollen, tender left axillary lymph node	1	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Muscle tenderness at injection site	2	04NOV2020	1/3	1	Yes		NA/TC	R (06NOV2020)	N/N
	BLOOD	Lymphadenopathy/ Right axillary lymph node swelling	2	05NOV2020	2/7	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	2/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Pyrexia/ Low grade fever, 100.7	2	05NOV2020	2/2	1	Yes		NA/TC	R (06NOV2020)	N/N
		Headache/ Headache	2	05NOV2020	2/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1204 12041236	GENRL	Injection site pain/ left arm soreness (vac #1 injection site)	1	15OCT2020	1/3	1	Yes	NA	NA	R (17OCT2020)	N/N
1204 12041237	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes	NA	NA	R (07NOV2020)	N/N
		Injection site pain/ Injection site pain	2	05NOV2020	1/3	1	Yes	NA	NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	2/3	1	Yes	NA	NA	R (08NOV2020)	N/N
16-55/ C4591001 1204 12041239	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	15OCT2020	1/3	1	Yes	NA	NA	R (17OCT2020)	N/N
16-55/ C4591001 1204 12041240	NERV	Headache/ Headache	1	16OCT2020	2/2	1	Yes	NA/TC	NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1204 12041242	GENRL	Injection site pain/ Left Arm Soreness (vac #2 site)	2	05NOV2020	1/2	1	Yes	NA	NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	2/1	1	Yes	NA	NA	R (06NOV2020)	N/N
		Pyrexia/ Low Grade Fever (100.4)	2	06NOV2020	2/1	1	Yes	NA/TC	NA/TC	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041248	NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Pyrexia/ low grade fever 100.4F#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	SKIN	Rash/ rashes at the back of bilateral knees#	4	13JAN2021	2/11	2	Yes		NA/TC	R (23JAN2021)	N/N
16-55/ C4591001 1204 12041253		Rash/ rashes in the chest#	4	13JAN2021	2/11	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ fatigue	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1204 12041255	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041259	GENRL	Pyrexia/ low grade fever; temp 100 F	1	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
		Pyrexia/ Low Grade Fever	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1204 12041260	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/4	1	Yes		NA	R (19OCT2020)	N/N
		Pyrexia/ fever - 101.0	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1204 12041262	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1204 12041262	GENRL	Injection site pain/ left arm soreness at injection site#	3	06JAN2021	1/3	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1204 12041263	GENRL	Injection site pain/ injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041267	GENRL	Fatigue/ Fatigue	2	09NOV2020	1/4	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
	GASTR	Vomiting/ Vomiting	2	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Chills/ Chills	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1204 12041268		Malaise/ Malaise	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N
		Pain/ Body aches	2	17NOV2020	2/3	2	Yes		NA/TC	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Left Arm Soreness (Vaccination #1 Injection Site	1	21OCT2020	2/3	1	Yes		NA	R (23OCT2020)	N/N
		Malaise/ Body Malaise	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	Injection site pain/ Left Arm Soreness (vac #2 site)	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N	
	Pain/ Body Aches	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041269	GENRL  NERV	Injection site pruritus/ Itchiness in the injection site	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		Headache/ Headache	2	10NOV2020	1/1	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1204 12041272	GENRL	Injection site pain/ left arm soreness (injection site)#	3	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Malaise/ body malaise#	3	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1204 12041273	GENRL	Injection site pain/ left arm soreness (injection site)#	3	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1204 12041274	GENRL	Injection site pain/ Muscle tenderness at injection site	1	21OCT2020	1/3	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1204 12041275	GENRL	Injection site pain/ left arm soreness (vac#1 injection site)	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ headache	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Chills/ chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ low grade fever, 101.0	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041276	NERV	Headache/ headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1204 12041280		Pain/ Body Aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
	INJ&P	Exposure during pregnancy/ Drug Exposure During Pregnancy	1	21OCT2020	1/20	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1204 12041283	SURG	Abortion induced/ Medication abortion	1	09NOV2020	20/1	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
	NERV	Headache/ Headache	1	24OCT2020	2/1	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Muscle Tenderness at the injection site	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Low Grade Fever 101.2	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1204 12041285	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
		Injection site pain/ Muscle tenderness at injection site	2	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
16-55/ C4591001 1204 12041287	MUSC	Myalgia/ myalgia	1	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	25OCT2020	3/2	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1204 12041293	GENRL	Pyrexia/ fever	2	14NOV2020	2/1	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1204 12041294	MUSC	Myalgia/ muscle aches	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1205 12051004	GENRL	Pyrexia/ fever#	3	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ muscle pain on injection area#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1205 12051014	GENRL	Injection site pain/ muscle pain on injection area#	4	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1205 12051028	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N
16-55/ C4591001 1205 12051065	GENRL	Pyrexia/ Fever#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1205 12051066	MUSC	Myalgia/ muscle pain#	3	06JAN2021	3/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1205 12051074	GENRL	Injection site pain/ muscle pain on injection area#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1205 12051075	INFEC	Anal abscess/ Anal Abscess	2	04JAN2021	35/3	2	No	O	NA/TC/TCN	R (06JAN2021)	Y/N
16-55/ C4591001 1205 12051077	NEOPL	Lipoma/ Encapsulated Lipoma	2	11JAN2021	41/10	2	No	O	NA/TC	R (20JAN2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071002	RESP	Nasal septum deviation/ Nasal Septum Deviation	2	11JAN2021	41/10	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N
	RESP	Rhinorrhoea/ runny nose#	2	28FEB2021	108/3	1	No	O	NA	R (02MAR2021)	N/N
16-55/ C4591001 1207 12071005	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1207 12071010	GENRL	Fatigue/ fatigue#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	20JAN2021	1/2	1	Yes		NA/TCN	R (21JAN2021)	N/N
16-55/ C4591001 1207 12071014	GENRL	Pyrexia/ fever 38.3#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Tremor/ Body Shaking#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
			Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)
	SKIN	Hyperhidrosis/ SWEATING#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071018	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1207 12071021	GENRL	Fatigue/ FATIGUE#	3	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/4	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1207 12071025	GENRL	Injection site pain/ pain at injection site#	3	20JAN2021	1/6	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pyrexia/ fever#	3	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1207 12071026	MUSC	Pain in extremity/ LEFT ARM PAIN#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ redness at injection site#	3	05JAN2021	1/4	1	Yes		NA	R (08JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1207 12071028		Injection site swelling/ Swelling at injection site#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Tremor/ body shaking#	4	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001	INV	Blood pressure increased/ INCREASE BLOOD PRESSURE#	3	19JAN2021	8/2	1	No	O	NA	R (20JAN2021)	N/N
1207 12071032	NERV	Headache/ HEADACHE#	3	19JAN2021	8/2	1	No	O	NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	02FEB2021	1/4	2	Yes		NA/TC	R (05FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N
	NERV	Headache/ headache#	4	02FEB2021	1/4	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ REDNESS AT INJECTION SITE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
1207 12071033	MUSC	Pain in extremity/ ARMACHE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ FATIGUE#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
1207 12071038											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071042	GENRL	Injection site pain/ pain at injection site#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1207 12071044	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Pyrexia/ fever#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1207 12071047	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ chill#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pyrexia/ fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Arthralgia/ joint ache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1207 12071048	GENRL	Injection site pain/ pain at injection site#	3	30DEC2020	1/4	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	18JAN2021	1/3	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071050	GENRL	Chills/ chill#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint pain#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	INJ&P	Road traffic accident/ Motor vehicle Accident	2	24DEC2020	30/1	1	No	O	NA/TC	R (24DEC2020)	N/N
		Scar/ scar behind the knee	2	24DEC2020	30/17	1	No	O	NA	R (09JAN2021)	N/N
		Scar/ scar on hand	2	24DEC2020	30/16	1	No	O	NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1207 12071051	GENRL	Injection site pain/ Pain at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001 1207 12071053	GENRL	Injection site pain/ pain at injection site#	4	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	11JAN2021	1/2	1	Yes		NA/TC	R (12JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1207 12071054		Injection site pain/ pain at injection site#	4	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	MUSC	Arthralgia/ RIGHT LATERALITY SHOULDERACHE	2	03JAN2021	40/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071059	GENRL	Injection site hypersensitivity/ sensitivity at injection site#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ pain at injection site#	3	20JAN2021	1/5	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ headache#	4	09FEB2021	1/3	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	16-55/ C4591001 1207 12071065	MUSC	Pain in extremity/ Left thumbache	2	28DEC2020	32/3	1	No	O	NA/TC	R (30DEC2020)
GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	30DEC2020	1/3	1	Yes		NA	R (01JAN2021)	N/N	
GENRL	Fatigue/ fatigue#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1207 12071067	MUSC	Arthralgia/ generalized Joint pain#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Myalgia/ muscle pain#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	30DEC2020	1/4	1	Yes		NA	R (02JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ headache#	4	19JAN2021	2/3	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1208 12081001	GENRL	Fatigue/ Fatigue	1	05NOV2020	15/2	1	No	O	NA	R (06NOV2020)	N/N
16-55/ C4591001 1208 12081002	INJ&P	Hand fracture/ Finger fracture on the left hand#	3	22JAN2021	12/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1208 12081003	INJ&P	Foot fracture/ Broken Toe	2	07DEC2020	25/26	1	No	O	NA/TC	R (01JAN2021)	N/N
16-55/ C4591001 1208 12081010	MUSC	Myalgia/ muscle pain#	3	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1208 12081011 16-55/ C4591001	GASTR	Abdominal pain upper/ Stomachache	2	21DEC2020	29/1	1	No	O	NA/TC	R (21DEC2020)	N/N
1208 12081021 16-55/ C4591001	GASTR	Gingival pain/ ulalgia	2	07DEC2020	15/5	1	No	O	NA/TC	R (11DEC2020)	N/N
1208 12081024 16-55/ C4591001	CARD	Arteriospasm coronary/ Coronary Heart Spasm	2	16DEC2020	21/1	1	No	O	NA	R (16DEC2020)	N/N
1208 12081026 16-55/ C4591001	SKIN	Hand dermatitis/ dermatitis on the right hand	2	30NOV2020	6/	1	No	O	NA/TC	R	N/N
1208 12081038 16-55/ C4591001	INFEC	Urinary tract infection/ urinary tract infections	1	20NOV2020	15/4	1	No	O	NA/TC	R (23NOV2020)	N/N
1208 12081044 16-55/ C4591001	RENAL	Dysuria/ dysuria	2	20JAN2021	69/C	1	No	O	NA/TC	RG	N/N
1209 12091001 16-55/ C4591001	CARD	Angina pectoris/ Stenocardia	2	05FEB2021	85/2	1	No	O	NA/TC/TCN	R (06FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	12NOV2020	21/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1209 12091002	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
1209 12091003	NERV	Headache/ headache#	4	24FEB2021	6/6	1	No	O	NA/TC	R (01MAR2021)	N/N
1209 12091004	VASC	Hypertension/ hypertension#	4	24FEB2021	6/C	1	No	O	NA/TC	RG	N/N
	METAB	Insulin resistance/ insulin resistance#	4	26FEB2021	8/C	1	No	O	NA/TC	RG	N/N
1209 12091001	GENRL	Fatigue/ fatigue#	4	18FEB2021	1/22	1	Yes		NA	R (11MAR2021)	N/N
1209 12091008	PSYCH	Anxiety/ anxiety#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N
	VASC	Hypertension/ hypertension#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N
1209 12091009	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ headache#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1209 12091011	GENRL	Injection site pain/ pain at injection site#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1209 12091013	GENRL	Chest pain/ Chest Pain	1	08NOV2020	7/2	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001 1209 12091020	GASTR	Constipation/ constipation	2	15JAN2021	51/7	1	No	O	NA	R (21JAN2021)	N/N
	GENRL	Chest pain/ chest pain	2	15JAN2021	51/7	1	No	O	NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1210 12101002	INFEC	Nasopharyngitis/ common cold	1	27OCT2020	6/6	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1210 12101010	PSYCH	Anxiety/ anxiety	1	11NOV2020	17/C	1	No	O	NA	N	N/N
16-55/ C4591001 1210 12101015	GENRL	Pyrexia/ fever#	3	28DEC2020	1/2	1	Yes		NA/TC	R (29DEC2020)	N/N
	GENRL	Chills/ chills#	4	19JAN2021	2/2	3	Yes		NA/TC	R (20JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1210 12101023	MUSC	Myalgia/ muscle pain#	4	19JAN2021	2/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	23JAN2021	2/2	2	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1210 12101026	MUSC	Arthralgia/ General joint pain#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	07NOV2020	9/10	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1210 12101029	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	16NOV2020	18/22	3	No	O	NA/TC	R (07DEC2020)	Y/N
	MUSC	Arthralgia/ joint pain	1	04NOV2020	6/2	3	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1210 12101032	BLOOD	Lymphadenopathy/ Axillary lymphadenopathy on the left.#	4	20JAN2021	2/4	2	Yes		NA	R (23JAN2021)	N/N
	INJ&P	Lower limb fracture/ Leg fracture	2	17DEC2020	25/54	3	No	O	NA/TCN	R (08FEB2021)	N/N
16-55/ C4591001 1210 12101037	GASTR	Nausea/ nausea#	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1210 12101048	MUSC	Vomiting/ vomiting#	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)	N/N
		Arthralgia/ generalized joint pain#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N
			NERV	3	30DEC2020	2/2	3	Yes		NA	R (31DEC2020)
16-55/ C4591001 1210 12101048	PSYCH	Anxiety/ anxiety#	4	02FEB2021	15/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1210 12101049	MUSC	Neck pain/ neck pain	1	09NOV2020	6/6	1	No	O	NA	R (14NOV2020)	N/N
16-55/ C4591001 1210 12101056	GENRL	Pyrexia/ fever#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	MUSC	Arthralgia/ general joint pain#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1212 12121006	MUSC	Myalgia/ mild muscle pain	2	18JAN2021	68/4	1	No	O	NA	R (21JAN2021)	N/N
16-55/ C4591001 1212 12121019	GENRL	Injection site pain/ injection pain#	3	12JAN2021	2/2	1	No	O	NA	R (13JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	2	14DEC2020	21/26	1	Yes		NA/TC	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1212 12121020† 16-55/ C4591001 1212 12121024	MUSC	Myalgia/ mild muscle pain#	2	15JAN2021	52/5	1	No	O	NA	R (19JAN2021)	N/N
	CARD	Myocardial infarction/ Heart Attack#	2	03FEB2021	71/1	4	Yes		NA/TC/TCN	R (03FEB2021)	Y/N
16-55/ C4591001 1213 12131003	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	08JAN2021	1/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
	SKIN	Hyperhidrosis/ SWEATING#	4	29JAN2021	1/2	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1213 12131004	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	1/2	3	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1213 12131005	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131006	MUSC	Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	INFEC	Pharyngotonsillitis/ Tonsillopharyngitis	2	02DEC2020	21/10	1	No	O	NA/TC	R (11DEC2020)	N/N
	GENRL	Fatigue/ FATIGUE#	3	21JAN2021	1/3	2	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1213 12131010		Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/3	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ FEVER (38 Celsius)#	4	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N
	MUSC	Arthralgia/ JOINT PAIN#	4	28JAN2021	1/3	2	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131014	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	27JAN2021	1/3	3	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1213 12131015	EYE	Dry eye/ DRY EYE#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/3	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	27JAN2021	1/3	2	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1213 12131018	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131026	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	01FEB2021	1/3	3	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pyrexia/ FEVER#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1213 12131032	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	GENRL	Chills/ CHILLS#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1213 12131034	NERV	Headache/ HEADACHE#	4	12FEB2021	1/2	3	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	12JAN2021	1/2	2	Yes		NA	R (13JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	12JAN2021	1/1	2	Yes		NA	R (12JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
NERV	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ HEADACHE#	4	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131035	GENRL	Fatigue/ FATIGUE#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1213 12131039	GENRL	Fatigue/ FATIGUE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
		Pyrexia/ FEVER#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Back pain/ BACKACHE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
		Myalgia/ MUSCLE PAIN#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	07JAN2021	1/4	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
		Fatigue/ FATIGUE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131040	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	3	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	07JAN2021	1/2	3	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1213 12131043	SKIN	Hyperhidrosis/ SWEATING#	4	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1213 12131044	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	11FEB2021	1/3	3	Yes		NA	R (13FEB2021)	N/N
	GENRL	Chills/ CHILLS#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	21JAN2021	1/2	2	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1213 12131044	GENRL	Fatigue/ FATIGUE#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131055	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Dizziness/ DIZZINESS#	3	08JAN2021	1/1	2	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1213 12131056	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ MUSCLE PAIN#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	NERV	Headache/ HEADACHE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GASTR	Diarrhoea/ DIARRHEA#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ CHILLS#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
		Fatigue/ FATIGUE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
		Injection site pain/ PAIN AT INJECTION SITE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1213 12131057	NERV	Headache/ HEADACHE#	4	29JAN2021	1/3	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	08JAN2021	1/3	2	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	4	26JAN2021	1/5	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1213 12131060	MUSC	Myalgia/ MUSCLE PAIN#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ CHILLS#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1214 12141005	GENRL	Injection site pain/ PAIN AT INJECTION SITE#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ FATIGUE#	4	25JAN2021	1/4	3	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Pyrexia/ FEVER (39.9 centigrade degrees )#	4	25JAN2021	1/1	3	Yes		NA/TC	R (25JAN2021)	N/N
16-55/ C4591001 1214 12141005	GENRL	Fatigue/ Fatigue#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	31DEC2020	1/2	2	Yes		NA	R (01JAN2021)	N/N
	GENRL	Injection site pain/ Injection Pain#	4	19JAN2021	1/4	2	Yes		NA/TC	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141007	MUSC	Pain in extremity/ Arm Pain#	4	19JAN2021	1/4	2	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	29JAN2021	1/4	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1214 12141009	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1214 12141012	NERV	Headache/ Headache#	3	30JAN2021	2/1	3	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/4	3	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141015	NERV	Headache/ Headache#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	24FEB2021	1/4	2	Yes		NA	R (27FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chill#	3	02FEB2021	1/1	3	Yes		NA	R (02FEB2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	02FEB2021	1/3	3	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/1	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1214 12141018	MUSC	Pain in extremity/ Arm Pain#	4	25FEB2021	1/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1214 12141018	MUSC	Intervertebral disc protrusion/ recurrence vertebral disc herniation	1	18NOV2020	17/15	2	No	O	NA/TC/TCN	R (02DEC2020)	Y/N
	RESP	Pulmonary embolism/ pulmonary embolism	2	05DEC2020	13/1	2	No	O	NA/TC	R (05DEC2020)	Y/N
16-55/ C4591001 1214 12141020	INFEC	Bartholin's abscess/ BARTHOLIN'S ABSCESS	1	08NOV2020	7/10	1	No	O	NA/TC/TCN	R (17NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N
	NERV	Headache/ Headache#	3	30DEC2020	1/2	2	Yes		NA/TC	R (31DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
	NERV	Headache/ Headache#	4	19JAN2021	1/3	2	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1214 12141022	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/4	2	Yes		NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141024	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	23FEB2021	2/2	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141025	INFEC	Pyelonephritis/ Pyelonephritis	1	09NOV2020	7/12	1	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 1214 12141027	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/2	3	Yes		NA	R (02FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Pain in extremity/ arm pain#	4	23FEB2021	1/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141030	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	22FEB2021	1/3	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141031	MUSC	Pain in extremity/ Arm Pain#	3	01FEB2021	1/2	3	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/1	2	Yes		NA/TC	R (02FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	2/1	3	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Pain in extremity/ Arm pain#	4	22FEB2021	1/2	2	Yes		NA	R (23FEB2021)	N/N
	GASTR	Vomiting/ Vomiting#	4	23FEB2021	2/1	2	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141036	GENRL	Fatigue/ fatigue#	4	23FEB2021	2/2	3	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	23FEB2021	2/1	3	Yes		NA	R (23FEB2021)	N/N
	GENRL	Chills/ Chill#	2	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	2	24FEB2021	2/1	2	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1214 12141038	NERV	Headache/ Headache#	2	24FEB2021	2/1	2	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	3	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1214 12141039	MUSC	Myalgia/ Muscle Pain#	4	25JAN2021	1/3	3	Yes		NA/TC	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea	1	26NOV2020	21/2	1	No	O	NA	R (27NOV2020)	N/N
	BLOOD	Lymphadenopathy/ lymphadenomegaly in the right submandibular#	2	06JAN2021	41/10	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141040	GENRL	Injection site pain/ pain at the injection site#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	1	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001 1214 12141041	GENRL	Fatigue/ Fatigue#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Joint Pain#	4	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1214 12141041	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/1	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1214 12141044	GENRL	Fatigue/ fatigue#	4	23FEB2021	1/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	23FEB2021	1/4	2	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1214 12141048	GENRL	Injection site pain/ pain at injection site#	4	23FEB2021	1/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	04JAN2021	1/2	2	Yes		NA	R (05JAN2021)	N/N
16-55/ C4591001	INFEC	Pharyngitis/ pharyngitis	2	19DEC2020	19/2	1	No	O	NA	R (20DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1214 12141051	GENRL	Injection site pain/ pain at injection site#	3	05JAN2021	1/3	2	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	3	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	3	05JAN2021	1/3	2	Yes		NA/TC	R (07JAN2021)	N/N
	INFEC	Oral herpes/ Orolabial Herpes (inside the cheek and close to the left lower anterior tooth)#	3	06JAN2021	2/6	1	Yes		NA	R (11JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	BLOOD	Lymphadenitis/ lymphadenitis in the left lower cervical#	4	27JAN2021	2/2	2	Yes		NA	R (28JAN2021)	N/N
	INFEC	Oral herpes/ Orolabial Herpes (close to the left molar teeth on both sides of the cheek and inside of the cheek)#	4	27JAN2021	2/9	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle Pain#	4	27JAN2021	2/3	2	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1214 12141053	MUSC	Pain in extremity/ Arm Pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1214 12141054	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	MUSC	Pain in extremity/ Arm Pain#	4	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1217 12171003	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	SKIN	Seborrheic dermatitis/ seborrheic dermatitis	2	07DEC2020	26/C	1	No	CD	NA/TC/TCN	N	N/N
	GENRL	Injection site pain/ Arm pain (injection pain)#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1217 12171008	NERV	Headache/ headache#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pyrexia/ 37.8C Fever#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Arthralgia/ Joint pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1217 12171011		Myalgia/ Muscle pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ lassitude#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171014	MUSC	Injection site pain/ Injection pain (arm pain)#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
		Myalgia/ muscle pain#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ lassitude#	4	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	SKIN	Rash/ skin rash of neck and upper body#	4	25JAN2021	1/3	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1217 12171015†	GENRL	Injection site pain/ Arm pain (Injection pain)#	2	25JAN2021	70/2	1	Yes		NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1217 12171018	GENRL	Chills/ Chill#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1217 12171018	MUSC	Myalgia/ Muscle pain#	3	04JAN2021	1/4	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1217 12171020	GENRL	Injection site pain/ arm pain (injection pain)#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	INFEC	Tonsillitis/ Tonsillitis#	4	14FEB2021	3/3	1	Yes		NA/TC	R (16FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171023	INFEC	Cystitis/ cystitis	2	29DEC2020	43/10	1	No	O	NA/TC	R (07JAN2021)	N/N
	GENRL	Chills/ Chill#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Injection pain (arm pain)#	4	29JAN2021	1/3	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1217 12171028	GENRL	Injection site pain/ Injection pain (Arm pain)#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Chill#	4	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N
		Fatigue/ Lassitude#	4	28JAN2021	1/4	1	Yes		NA/TC	R (31JAN2021)	N/N
		Pyrexia/ 37.7 Fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1217 12171031	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	30OCT2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1217 12171032	GENRL	Injection site pain/ Injection pain (Arm pain)#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Injection pain(arm pain)#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171035	GENRL	Fatigue/ lassitude#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
		Pyrexia/ 38.5 C Fever#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	07JAN2021	1/3	1	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pyrexia/ 39.0 C Fever#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1217 12171039	EAR	Deafness unilateral/ Acute hearing loss in right ear	2	JAN2021	38/	1	No	O	NA/TC	R (18JAN2021)	N/N
	EAR	Tinnitus/ Tinnitus in right ear	2	08JAN2021	45/11	1	No	O	NA/TC	R (18JAN2021)	N/N
	MUSC	Pain in extremity/ Injection arm pain#	3	03MAR2021	1/4	1	Yes		NA	R (06MAR2021)	N/N
16-55/ C4591001 1217 12171041	GENRL	Injection site pain/ arm pain (injection pain)#	3	20JAN2021	1/3	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pyrexia/ 38 C Fever#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1217 12171044	PSYCH	Anxiety/ Anxiety	1	21NOV2020	18/104	1	No	O	NA/TC	R (04MAR2021)	N/N
16-55/ C4591001 1217 12171048	GENRL	Fatigue/ Lassitude#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
		Myalgia/ Muscle pain#	3	08JAN2021	1/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1217 12171054	GENRL	Injection site pain/ Arm pain (Injection pain)#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
		Pyrexia/ 37.0 C Fever#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	3	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Injection pain (arm pain)#	4	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Lassitude#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1217 12171055		Injection site pain/ Arm pain (Injection pain)#	3	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Fatigue/ Lassitude#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
		Pyrexia/ 38.2 C Fever#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1217 12171061	MUSC	Myalgia/ Muscle pain#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1217 12171062	GENRL	Fatigue/ fatigue#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N
		Injection site pain/ Injection pain (arm pain)#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1218 12181001	GASTR	Abdominal pain/ Abdominal pain	1	03NOV2020	16/4	1	No	O	NA	R (06NOV2020)	N/N
	GASTR	Nausea/ Nausea	1	04NOV2020	17/3	1	No	O	NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	HEPAT	Cholecystitis acute/ Acute cholecystitis#	2	18JAN2021	69/4	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N
16-55/ C4591001 1218 12181004	GENRL	Injection site pain/ Injection site pain	1	10NOV2020	21/4	1	Yes		NA	R (13NOV2020)	N/N
		Injection site swelling/ Injection site swelling	1	10NOV2020	21/4	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1218 12181007	GENRL	Fatigue/ Fatigue/Tiredness	2	18NOV2020	2/2	3	Yes		NA	R (19NOV2020)	N/N
		Injection site pain/ Injection site pain	2	18NOV2020	2/2	2	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ new muscle pain	2	18NOV2020	2/2	1	Yes		NA	R (19NOV2020)	N/N
16-55/ C4591001 1218 12181008	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal	2	11DEC2020	25/4	1	No	O	NA	R (14DEC2020)	N/N
	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal	2	28DEC2020	42/3	1	No	O	NA	R (30DEC2020)	N/N
	GASTR	Gastritis alcoholic/ Alcoholic gastritis#	2	31JAN2021	76/3	1	No	O	NA/TC	R (02FEB2021)	N/N
16-55/ C4591001 1218 12181009	PSYCH	Alcohol withdrawal syndrome/ Alcohol Withdrawal	2	11DEC2020	18/4	1	No	O	NA	R (14DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	02NOV2020	1/5	1	Yes		NA	R (06NOV2020)	N/Y



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1218 12181011	PSYCH	Alcohol abuse/ Alcohol abuse	2	09JAN2021	47/C	1	No	O	NA/TCN	RG	Y/N
16-55/ C4591001 1218 12181012	GENRL	Chills/ Chills#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1218 12181013		Pain/ Body aches#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1218 12181015	NERV	Facial paralysis/ Bell's Palsy - Left#	3	10JAN2021	4/12	1	Yes		NA/TC/TCN	R (21JAN2021)	N/N
16-55/ C4591001 1218 12181016	INFEC	Cellulitis/ Cellulitis	1	19NOV2020	8/8	1	No	O	NA/TC	R (26NOV2020)	N/N
	INJ&P	Animal bite/ dog bite	1	19NOV2020	8/8	1	No	O	NA/TC	R (26NOV2020)	N/N
16-55/ C4591001 1218 12181017	MUSC	Musculoskeletal chest pain/ Musculoskeletal Chest Pain	1	29NOV2020	17/5	1	No	O	NA/TC	R (03DEC2020)	N/N
	INJ&P	Thermal burn/ Left Foot Burn#	2	31DEC2020	28/7	1	No	O	NA/TCN	R (06JAN2021)	N/N
	INJ&P	Skin laceration/ Left Leg Laceration#	2	08JAN2021	36/11	1	No	O	NA/TCN	R (18JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1218 12181023	INJ&P	Thermal burn/ Right forearm burn#	4	01MAR2021	28/C	1	No	O	NA/TCN	N	N/N	
	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal#	4	03MAR2021	30/2	2	No	O	NA/TC	R (04MAR2021)	Y/N	
16-55/ C4591001 1218 12181028	INFEC	Anal abscess/ Perianal abscess	2	26DEC2020	17/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1218 12181034	INJ&P	Fall/ Fall	1	01DEC2020	9/1	1	No	O	NA	R (01DEC2020)	N/N	
	INJ&P	Joint injury/ Left knee injury	1	02DEC2020	10/C	2	No	O	NA/TC/TCN	RG	N/N	
	INJ&P	Contusion/ Left foot contusion#	2	14JAN2021	32/9	1	No	O	NA/TC/TCN	R (22JAN2021)	N/N	
16-55/ C4591001 1218 12181039	INFEC	Otitis media/ right otitis media	1	11DEC2020	12/C	1	No	O	NA/TC	N	N/N	
	INFEC	Conjunctivitis/ Bilateral Conjunctivitis	2	31DEC2020	11/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1218 12181042	GENRL	Chills/ Chills	1	01DEC2020	1/2	1	Yes		NA	R (02DEC2020)	N/N	
	GASTR	Abdominal pain upper/ Stomach Aches	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1218 12181043	GENRL	Nausea/ Nausea	1	02DEC2020	2/3	1	Yes		NA	R (04DEC2020)	N/N
		Pain/ Body Aches	1	02DEC2020	2/1	1	Yes		NA	R (02DEC2020)	N/N
	NERV	Headache/ Headaches	1	02DEC2020	2/3	1	Yes		NA	R (04DEC2020)	N/N
	RESP	Dyspnoea exertional/ winded upon exertion	1	02DEC2020	2/1	1	Yes		NA	R (02DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/Y
	GASTR	Nausea/ Nausea after 2nd injection	2	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
16-55/ C4591001 1218 12181044	GENRL	Injection site pain/ Burning pain at injection site	2	21DEC2020	1/1	1	Yes		NA	R (21DEC2020)	N/Y
	GENRL	Injection site pain/ Injection site muscle aches	2	21DEC2020	1/5	1	Yes		NA	R (25DEC2020)	N/N
	SKIN	Rash pruritic/ itchy rash lower legs	1	04DEC2020	3/7	1	No	O	NA	R (10DEC2020)	N/N
16-55/ C4591001 1218 12181046	EYE	Eye irritation/ Sensation of Irritation of Eye Proper (right eye)#	3	16JAN2021	20/2	1	No	O	NA	R (17JAN2021)	N/N
	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	20DEC2020	19/3	2	No	O	NA/TC	R (22DEC2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NEOPL	Ovarian germ cell teratoma benign/ Mature cystic teratoma left ovary	1	20DEC2020	19/3	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001 1218 12181049	GASTR	Abdominal pain lower/ RLQ abdominal pain#	4	17FEB2021	8/2	1	No	O	NA/TCN	R (18FEB2021)	N/N
	MUSC	Back pain/ right lower back pain#	4	17FEB2021	8/2	1	No	O	NA/TCN	R (18FEB2021)	N/N
16-55/ C4591001 1218 12181050	INJ&P	Ligament sprain/ Sprained ankle-right#	3	27DEC2020	5/7	2	No	O	NA/TC/TCN	R (02JAN2021)	N/N
16-55/ C4591001 1218 12181051	RESP	Asthma/ Asthma exacerbation#	2	16JAN2021	25/3	1	No	O	NA/TC	R (18JAN2021)	Y/N
16-55/ C4591001 1218 12181057	GENRL	Injection site pain/ Injection site pain	1	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/Y
	GASTR	Vomiting/ Vomiting	1	09DEC2020	2/1	1	Yes		NA	R (09DEC2020)	N/N
	GASTR	Oesophageal varices haemorrhage/ Esophageal varices hemorrhage	1	09JAN2021	33/1	4	No	O	NA/TC/TCN	R (09JAN2021)	Y/N
	GASTR	Toothache/ Toothache	1	01FEB2021	56/4	1	No	O	NA/TC/TCN	R (04FEB2021)	N/N
16-55/ C4591001 1219 12191001	GENRL	Injection site reaction/ odd sensation posterior to injection site	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191003	GENRL	Chills/ mild chills	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ fatigue	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
	INFEC	Urinary tract infection/ Urinary tract infection	1	02OCT2020	2/5	1	No	O	NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	20JAN2021	1/1	1	Yes		NA	R (20JAN2021)	N/Y
16-55/ C4591001 1219 12191013	NERV	Headache/ Headache after hiking 22 miles	1	12OCT2020	5/1	1	No	O	NA/TC	R (12OCT2020)	N/N
	GENRL	Injection site pain/ muscle soreness at injection site	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
16-55/ C4591001 1219 12191014	GENRL	Fatigue/ fatigue	2	28OCT2020	2/1	3	Yes		NA	R (28OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle soreness	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ headache	2	28OCT2020	2/1	1	Yes		NA	R (28OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191016	GENRL	Fatigue/ fatigue	1	09OCT2020	1/6	1	No	O	NA	R (14OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	01NOV2020	5/1	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache, waxing and waning	2	01NOV2020	5/10	1	Yes		NA	R (10NOV2020)	N/N
	PSYCH	Depressed mood/ depressed mood	2	20NOV2020	24/46	1	No	O	NA	R (04JAN2021)	N/N
	GENRL	Fatigue/ tiredness#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y
		Injection site pain/ injection site pain#	3	22DEC2020	1/4	1	Yes		NA	R (25DEC2020)	N/Y
	GENRL	Fatigue/ tiredness#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/Y
	Injection site pain/ injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/Y	
16-55/ C4591001 1219 12191017	REPRO	Amenorrhoea/ secondary amenorrhea	2	24DEC2020	53/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1219 12191022	INFEC	Onychomycosis/ onychomycosis	1	29OCT2020	10/C	2	No	O	NA/TC	N	N/N
	METAB	Type 2 diabetes mellitus/ Diabetes Mellitus Type 2	1	29OCT2020	10/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191028	GENRL	Fatigue/ Fatigue	1	30OCT2020	4/7	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Back pain/ Low Back Pain	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N
		Myalgia/ Muscle aches	1	02NOV2020	7/4	1	Yes		NA	R (05NOV2020)	N/N
	INJ&P	Contusion/ left knee contusion	2	16DEC2020	28/10	1	No	O	NA	R (25DEC2020)	N/N
		Fall/ fall	2	16DEC2020	28/1	1	No	O	NA	R (16DEC2020)	N/N
	GENRL	Injection site pain/ injection site soreness#	4	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/Y
16-55/ C4591001 1219 12191030	GENRL	Fatigue/ tiredness	1	29OCT2020	1/6	1	Yes		NA	R (03NOV2020)	N/Y
	NERV	Headache/ slight headache	1	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/Y
	GENRL	Pain/ Body aches	1	30OCT2020	2/2	1	Yes		NA	R (31OCT2020)	N/N
	NERV	Headache/ Headache	1	03NOV2020	6/1	1	Yes		NA	R (03NOV2020)	N/N
	NERV	Headache/ headache	1	11NOV2020	14/9	1	No	O	NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	07DEC2020	1/C	1	Yes		NA	N	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191033	GENRL	Injection site pain/ Soreness at injection site	2	01DEC2020	1/2	1	Yes		NA	R (02DEC2020)	N/N
	MUSC	Arthralgia/ right elbow joint soreness	2	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
	GENRL	Injection site discolouration/ hypopigmented skin patch at prior injection site, right upper arm	2	15DEC2020	15/C	1	Yes		NA	N	N/N
16-55/ C4591001 1219 12191034	GENRL	Injection site pain/ mild soreness at injection site	1	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/Y
	GENRL	Injection site pain/ soreness at injection site	2	01DEC2020	1/3	1	Yes		NA	R (03DEC2020)	N/N
16-55/ C4591001 1219 12191039	INJ&P	Contusion/ contusion to right elbow and back#	3	20JAN2021	15/3	1	No	O	NA/TCN	R (22JAN2021)	N/N
	MUSC	Back pain/ back pain#	3	20JAN2021	15/3	1	No	O	NA/TCN	R (22JAN2021)	N/N
	SKIN	Rash/ rash to right hand#	3	20JAN2021	15/8	1	No	O	NA/TCN	R (27JAN2021)	N/N
16-55/ C4591001 1219 12191040	GENRL	Injection site pain/ injection site soreness	1	17NOV2020	1/2	1	Yes		NA	R (18NOV2020)	N/N
		Pain/ body aches	1	17NOV2020	1/2	2	Yes		NA	R (18NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ injection site soreness	2	07DEC2020	1/2	2	Yes		NA	R (08DEC2020)	N/N
		Pain/ body aches	2	07DEC2020	1/C	2	Yes		NA	N	N/N
16-55/ C4591001 1219 12191044	GENRL	Injection site pain/ injection site pain#	3	02MAR2021	1/4	1	Yes		NA	R (05MAR2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	03MAR2021	2/1	2	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1219 12191047	INJ&P	Burns second degree/ second degree burn, right wrist	1	30NOV2020	6/8	2	No	O	NA/TCN	R (07DEC2020)	N/N
16-55/ C4591001 1219 12191048	NERV	Headache/ headache	1	25NOV2020	1/1	1	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ tiredness#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
		Injection site pain/ injection site pain#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	3	06JAN2021	1/2	1	Yes		NA	R (07JAN2021)	N/N
16-55/ C4591001 1219 12191050	GASTR	Nausea/ nausea#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
	GENRL	Fatigue/ tiredness#	3	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1219 12191056 16-55/ C4591001 1220 12201004 16-55/ C4591001 1220 12201009 16-55/ C4591001 1220 12201013 16-55/ C4591001 1220 12201013	NERV	Dizziness/ dizziness#	3	12JAN2021	1/1	1	Yes		NA	R (12JAN2021)	N/N
		Headache/ headache#	3	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ injection site pain#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	REPRO	Pelvic pain/ pelvic pain	2	01JAN2021	72/30	2	No	O	NA	R (30JAN2021)	N/N
	REPRO	Cervical dysplasia/ mild cervical dysplasia on PAP smear#	2	17FEB2021	119/C	1	No	O	NA/TCN	N	N/N
	INFEC	Ear infection/ Ear Infection (left)	2	10NOV2020	13/37	1	No	O	NA/TC	R (16DEC2020)	N/N
	MUSC	Temporomandibular joint syndrome/ TMJ pain	2	16DEC2020	49/3	1	No	O	NA/TC	R (18DEC2020)	N/N
	GASTR	Nausea/ Nausea#	3	04JAN2021	1/1	1	Yes		NA	R (04JAN2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Fatigue/ fatigue#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Pain/ Body aches#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1220 12201017	GENRL	Injection site pain/ Soreness at injection site left arm	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1220 12201018	NERV	Headache/ headache	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
		Hypoaesthesia/ facial numbness	1	18OCT2020	3/16	1	No	O	NA	R (02NOV2020)	N/N
		Hypoaesthesia/ leg numbness	1	18OCT2020	3/25	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C4591001 1220 12201020	GASTR	Diarrhoea/ diarrhea	1	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	23OCT2020	8/55	3	No	O	NA/TCN	R (16DEC2020)	N/N
	GASTR	Vomiting/ Vomiting	2	07NOV2020	2/1	2	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection site (left deltoid)	2	07NOV2020	2/3	2	Yes		NA	R (09NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201021	NERV	Headache/ Headache	2	07NOV2020	2/1	2	Yes		NA	R (07NOV2020)	N/N
	GENRL	Fatigue/ fatigue#	3	24JAN2021	4/1	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1220 12201022	GENRL	Injection site pain/ soreness at injection site	1	20OCT2020	1/8	1	Yes		NA	R (27OCT2020)	N/Y
16-55/ C4591001 1220 12201026	MUSC	Myalgia/ Muscle aches#	4	19FEB2021	3/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ tiredness	1	27OCT2020	1/1	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1220 12201027	INV	Body temperature increased/ body temperature increased	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N
	NERV	Dysgeusia/ taste in mouth	2	16NOV2020	1/1	1	Yes		NA	R (16NOV2020)	N/N
16-55/ C4591001 1220 12201027	GENRL	Injection site pain/ pain at injection site#	3	04JAN2021	1/1	1	Yes		NA/TC	R (04JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection site (left Deltoid)#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201028	NERV	Headache/ Headache#	4	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	16DEC2020	1/1	1	Yes		NA	R (16DEC2020)	N/N
	MUSC	Myalgia/ Muscle Aches#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	29OCT2020	1/3	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	18NOV2020	1/8	2	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	19NOV2020	2/1	2	Yes		NA	R (19NOV2020)	N/N
	MUSC	Myalgia/ myalgia	2	19NOV2020	2/1	2	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ injection site tenderness	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/3	1	Yes		NA	R (19DEC2020)	N/N
16-55/ C4591001 1220 12201031	GENRL	Injection site pain/ injection site tenderness	1	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1220 12201032	GENRL	Fatigue/ fatigue#	3	18DEC2020	2/2	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201033	GASTR	Nausea/ nausea#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
		Fatigue/ fatigue#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
		Pyrexia/ fever#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Dysgeusia/ metallic taste in mouth#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/Y
		Headache/ headache#	4	05JAN2021	1/1	1	Yes		NA	R (05JAN2021)	N/Y
	GENRL	Pain/ generalized body aches#	4	06JAN2021	2/2	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
GENRL	Fatigue/ fatigue#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
	Injection site pain/ soreness at injection site#	4	11JAN2021	1/2	1	Yes		NA	R (12JAN2021)	N/N	
16-55/ C4591001	GENRL	Injection site erythema/ redness at injection site	1	04NOV2020	2/3	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1220 12201035		Injection site pain/ soreness at injection site	1	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	INFEC	Tooth abscess/ Periodontal Abscess	2	02DEC2020	9/C	1	No	O	NA	N	N/N
16-55/ C4591001 1220 12201037	GENRL	Injection site pain/ soreness at injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	MUSC	Myalgia/ myalgia#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Myalgia/ muscle aches#	4	13JAN2021	2/2	2	Yes		NA/TC	R (14JAN2021)	N/N
16-55/ C4591001 1220 12201039	INJ&P	Foot fracture/ Acute mid foot fracture left foot	2	04JAN2021	34/36	3	No	O	NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ headache#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/Y
16-55/ C4591001 1220 12201041	INJ&P	Soft tissue injury/ soft tissue injury L foot	1	21NOV2020	10/12	2	No	O	NA/TCN	R (02DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/1	1	Yes		NA	R (17DEC2020)	N/N
	NERV	Headache/ headache#	3	17DEC2020	1/1	1	Yes		NA/TC	R (17DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1220 12201042	GASTR	Diarrhoea/ diarrhea#	3	23DEC2020	7/1	1	Yes		NA	R (23DEC2020)	N/N	
	GENRL	Injection site pain/ pain at injection site#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/Y	
	GENRL	Fatigue/ fatigue	1	13NOV2020	1/6	1	Yes		NA	R (18NOV2020)	N/N	
			Injection site pain/ Soreness at injection site left arm	1	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04DEC2020	1/2	1	Yes		NA	R (05DEC2020)	N/N	
	NERV	Headache/ Headache	2	04DEC2020	1/2	1	Yes		NA	R (05DEC2020)	N/N	
16-55/ C4591001 1220 12201043	GENRL	Injection site pain/ Soreness at Injection site	1	14NOV2020	2/3	1	Yes		NA	R (16NOV2020)	N/N	
16-55/ C4591001 1220 12201044	GASTR	Diarrhoea/ Diarrhea	2	08DEC2020	2/1	1	Yes		NA	R (08DEC2020)	N/N	
	GENRL	Injection site pain/ Soreness at injection site	2	08DEC2020	2/2	1	Yes		NA	R (09DEC2020)	N/N	
	NERV	Headache/ headache	2	08DEC2020	2/1	1	Yes		NA	R (08DEC2020)	N/N	
	BLOOD	Lymphadenopathy/ lymphadenopathy#	3	22DEC2020	2/8	2	Yes		NA	R (29DEC2020)	N/N	
	GENRL	Chills/ chills#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201045	GENRL	Pain/ body aches#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N
		Pyrexia/ fever#	3	22DEC2020	2/3	2	Yes		NA	R (24DEC2020)	N/N
		Injection site pain/ Soreness at injection site	1	17NOV2020	2/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	10DEC2020	2/1	1	Yes		NA	R (10DEC2020)	N/N
	INFECTION	Injection site pain/ Soreness at injection site	2	10DEC2020	2/2	1	Yes		NA	R (11DEC2020)	N/N
16-55/ C4591001 1220 12201048	INFECTION	Papilloma viral infection/ Diagnosis of Human Papilloma virus inection	2	15DEC2020	7/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Soreness at injection site left arm	1	17NOV2020	1/3	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection site	2	08DEC2020	2/3	1	Yes		NA	R (10DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	16DEC2020	1/3	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1220 12201050	GENRL	Fatigue/ fatigue#	4	07JAN2021	1/2	3	Yes		NA	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site erythema/ Redness at Injection site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site swelling/ Swelling at Injection Site#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body aches#	4	08JAN2021	2/1	2	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1220 12201051	GENRL	Injection site pain/ soreness at injection site	1	18NOV2020	1/1	1	Yes		NA	R (18NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	18DEC2020	2/1	1	Yes		NA	R (18DEC2020)	N/N
16-55/ C4591001 1220 12201052	GENRL	Injection site pain/ Soreness at injection site	1	19NOV2020	2/1	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Chills/ Chills	2	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/N
		Injection site pain/ Soreness at injection site	2	08DEC2020	1/2	1	Yes		NA	R (09DEC2020)	N/N
	BLOOD	Lymphadenopathy/ Lymphadenopathy Left axillary	2	09DEC2020	2/6	1	Yes		NA	R (14DEC2020)	N/N
	GENRL	Malaise/ Malaise	2	09DEC2020	2/2	2	Yes		NA	R (10DEC2020)	N/N
	NERV	Headache/ headache	2	09DEC2020	2/2	2	Yes		NA	R (10DEC2020)	N/N
16-55/ C4591001 1220 12201053	GENRL	Injection site pain/ soreness at injection site#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue#	4	12JAN2021	2/1	1	Yes		NA	R (12JAN2021)	N/N
16-55/ C4591001 1220 12201057	GENRL	Injection site pain/ soreness at injection site	1	21NOV2020	2/3	1	Yes		NA	R (23NOV2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	12DEC2020	2/1	1	Yes		NA	R (12DEC2020)	N/N
16-55/ C4591001 1220 12201059	GENRL	Fatigue/ fatigue	1	25NOV2020	2/2	1	Yes		NA	R (26NOV2020)	N/N
	GENRL	Chills/ chills#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
		Pyrexia/ fever#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
	MUSC	Myalgia/ myalgias#	2	16DEC2020	1/2	2	Yes		NA	R (17DEC2020)	N/N
16-55/ C4591001 1220 12201061	GASTR	Nausea/ nausea	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N
		Vomiting/ vomiting	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N
	MUSC	Flank pain/ R flank pain	1	01DEC2020	7/1	2	No	O	NA	R (01DEC2020)	N/N
	RENAL	Haematuria/ 1+ hematuria	1	01DEC2020	7/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	17DEC2020	1/2	1	Yes		NA/TC	R (18DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1220 12201063	GENRL	Injection site pain/ soreness at injection site#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
	NERV	Dysgeusia/ Taste in mouth	1	25NOV2020	1/1	1	Yes		NA	R (25NOV2020)	N/Y
	NERV	Dysgeusia/ Metallic taste in mouth#	2	25FEB2021	1/1	1	Yes		NA	R (25FEB2021)	N/Y
	GENRL	Chills/ Chills#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N
		Pain/ Body aches#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1220 12201065		Pyrexia/ Fever#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ headache#	2	26FEB2021	2/2	2	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ headache	1	02DEC2020	1/2	1	Yes		NA	R (03DEC2020)	N/N
	GENRL	Fatigue/ fatigue	1	04DEC2020	3/3	1	Yes		NA	R (06DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/N
16-55/ C4591001 1221 12211003	NERV	Dizziness/ dizziness#	3	01MAR2021	1/1	1	Yes		NA	R (01MAR2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211005	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	5/5	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1221 12211007	INFEC	Abscess jaw/ Abscess in left jaw	1	31OCT2020	16/33	3	No	O	NA/TC/TCN	R (02DEC2020)	N/N
	INFEC	Otitis externa/ Left Otitis Externa	1	06NOV2020	22/13	1	No	O	NA/TC	R (18NOV2020)	N/N
	INJ&P	Exposure to communicable disease/ STD Exposure	1	06NOV2020	22/1	1	No	O	NA/TC	R (06NOV2020)	N/N
	INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/23	3	No	O	NA/TC	R (02DEC2020)	Y/N
16-55/ C4591001 1221 12211013	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1221 12211014	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1221 12211020	MUSC	Pain in extremity/ Right Forearm Pain#	3	20FEB2021	4/C	2	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1221 12211024	GENRL	Injection site pain/ Injection site soreness	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211026	GENRL	Malaise/ Malaise	1	19NOV2020	2/2	1	Yes		NA	R (20NOV2020)	N/N
		Injection site pain/ Injection Site Soreness	2	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/N
	GENRL	Malaise/ Maliase	2	10DEC2020	1/3	1	Yes		NA	R (12DEC2020)	N/N
		Pain/ Body aches	2	11DEC2020	2/2	2	Yes		NA	R (12DEC2020)	N/N
16-55/ C4591001 1221 12211036	GENRL	Chills/ Chills#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
	GENRL	Pain/ Body Aches#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1221 12211037	GENRL	Chills/ Chills	1	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17NOV2020	2/1	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1221 12211037	GENRL	Injection site pain/ Injection site soreness#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GASTR	Vomiting/ Vomiting#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Chills/ Body chills#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Migraine/ Migraine#	3	09MAR2021	20/1	2	No	O	NA	R (09MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211043	GENRL	Chills/ Chills#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ Body Aches#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1221 12211044	GENRL	Injection site pain/ Injection site arm soreness	1	18NOV2020	1/4	1	Yes		NA	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	19NOV2020	2/3	2	Yes		NA	R (21NOV2020)	N/N
	MUSC	Myalgia/ myalgias	1	19NOV2020	2/3	2	Yes		NA	R (21NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09DEC2020	2/1	2	Yes		NA	R (09DEC2020)	N/N
	MUSC	Myalgia/ Achiness (Myalgia)	2	09DEC2020	2/1	2	Yes		NA	R (09DEC2020)	N/N
16-55/ C4591001 1221 12211045	NERV	Headache/ Headache	1	19NOV2020	2/1	1	Yes		NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1221 12211056	GENRL	Injection site pain/ Injection site pain	1	23NOV2020	1/2	1	Yes		NA	R (24NOV2020)	N/N
16-55/ C4591001 1221 12211069	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1221 12211072	NERV	Pain/ Bodyaches#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
		Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Chills/ Chills	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
		Fatigue/ Fatigue	1	02DEC2020	2/2	2	Yes		NA	R (03DEC2020)	N/N
		Injection site pain/ Right Arm injection site soreness	1	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
16-55/ C4591001 1221 12211083	MUSC	Pain in extremity/ Left Arm Soreness	1	04DEC2020	2/1	1	Yes		NA	R (04DEC2020)	N/N
16-55/ C4591001 1221 12211088	INJ&P	Contusion/ Right forearm contusion	2	23JAN2021	27/C	1	No	O	NA/TC	RG	N/N
		Contusion/ Right wrist contusion	2	23JAN2021	27/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1223 12231001	RESP	Epistaxis/ Epistaxis	2	23JAN2021	27/1	1	No	O	NA	R (23JAN2021)	N/N
		GENRL	Injection site pain/ arm pain at injection site#	2	17FEB2021	155/3	1	Yes		NA	R (19FEB2021)
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231005 16-55/ C4591001	GENRL	Fatigue/ fatigue#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
1223 12231008	MUSC	Back pain/ back pain#	4	15JAN2021	2/1	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001	INFEC	Appendicitis/ appendicitis	2	11JAN2021	116/4	4	No	O	NA/TC/TCN	R (14JAN2021)	Y/N
1223 12231014	GENRL	Injection site pain/ injection site pain#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	NERV	Headache/ headache#	3	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ myalgias	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
1223 12231022	RESP	Throat irritation/ scratchy throat	2	28SEP2020	11/5	1	No	O	NA	R (02OCT2020)	N/N
1223 12231024	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	07NOV2020	51/C	1	No	O	NA	UNK	N/N
	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231025 16-55/ C4591001	GENRL	Injection site pain/ mild injection site pain#	3	21DEC2020	2/2	1	Yes		NA	R (22DEC2020)	N/N
1223 12231028 16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	28JAN2021	1/7	1	Yes		NA	R (03FEB2021)	N/N
1223 12231031	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	PSYCH	Abnormal dreams/ Vivid Dreams	1	29AUG2020	1/2	2	Yes		NA	R (30AUG2020)	N/N
1223 12231034	GENRL	Chills/ chills	2	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ myalgias	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	INJ&P	Hip fracture/ fractured hip pain	2	03JAN2021	105/1	1	No	O	NA/TC	R (03JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	3	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
1223 12231035											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231036	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1223 12231045	GENRL	Injection site pain/ pain at injection site#	3	01MAR2021	1/4	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1223 12231050	INFEC	Herpes zoster/ Shingles	2	29SEP2020	8/17	1	No	O	NA/TC	R (15OCT2020)	N/N
	MUSC	Arthralgia/ Knee pain	2	18OCT2020	27/15	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1223 12231051	GENRL	Injection site pain/ injection site pain#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1223 12231055	GENRL	Chills/ chills#	3	08JAN2021	20/2	1	Yes		NA/TC	R (09JAN2021)	N/N
		Fatigue/ fatigue#	3	08JAN2021	20/33	1	Yes		NA	R (09FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgia#	3	08JAN2021	20/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1223 12231057	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231062		Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	INJ&P	Post procedural swelling/ facelift swelling	2	13OCT2020	21/1	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1223 12231066		Procedural pain/ pain from facelift	2	13OCT2020	21/13	2	No	O	NA	R (25OCT2020)	N/N
	GENRL	Pyrexia/ fever#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Pain in extremity/ sore arm#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	NERV	Headache/ headache#	3	18FEB2021	1/2	2	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231073	GASTR	Nausea/ nausea	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	04OCT2020	13/2	2	No	O	NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1223 12231074	INJ&P	Skin laceration/ left inner finger laceration	2	05JAN2021	105/9	2	No	O	NA/TCN	R (13JAN2021)	N/N
16-55/ C4591001 1223 12231075	GENRL	Chills/ chills#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/1	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ intermittent headaches#	4	07JAN2021	2/20	1	Yes		NA	R (26JAN2021)	N/N
	GASTR	Gastrointestinal necrosis/ Bowel necrosis#	4	04FEB2021	30/C	4	No	O	NA/TC/TCN	N	Y/N
	INJ&P	Postoperative ileus/ Postoperative ileus#	4	11FEB2021	37/5	3	No	O	NA/TC	R (15FEB2021)	Y/N
	GASTR	Small intestinal obstruction/ Small Bowel Obstruction#	4	16FEB2021	42/4	3	No	O	NA/TC	R (19FEB2021)	Y/N
16-55/ C4591001 1223 12231077	MUSC	Arthralgia/ joint aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
		Myalgia/ muscle aches	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1223 12231084	GENRL	Injection site pain/ injection site pain#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231086	GENRL	Fatigue/ fatigue#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ injection site pain#	2	19FEB2021	150/2	2	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ headaches#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1223 12231090	GENRL	Peripheral swelling/ left arm swelling	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
	SKIN	Erythema/ Left arm redness	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C4591001 1223 12231094	NERV	Headache/ headache	2	25SEP2020	1/1	2	Yes		NA/TC	R (25SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweats	1	25SEP2020	24/2	2	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1223 12231095	MUSC	Arthralgia/ right elbow pain	2	30SEP2020	6/2	2	No	O	NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231099	GENRL	Fatigue/ fatigue#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231101	GENRL	Pyrexia/ low grade fever#	4	07JAN2021	2/2	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ injection site pain#	4	11JAN2021	1/3	1	Yes		NA	R (13JAN2021)	N/N
	INFEC	Herpes zoster/ shingles, 1 dermatome#	4	12JAN2021	2/21	1	No	O	NA/TC	R (01FEB2021)	N/N
16-55/ C4591001 1223 12231105	GENRL	Injection site pain/ injection site pain#	3	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1223 12231112	GENRL	Fatigue/ fatigue	2	20OCT2020	23/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1223 12231113	GENRL	Injection site pain/ injection site pain#	2	18FEB2021	144/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1223 12231118	GENRL	Chills/ chills	2	29SEP2020	2/1	1	Yes		NA	R (29SEP2020)	N/N
	MUSC	Pain in extremity/ left arm soreness	2	29SEP2020	2/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231121		Fatigue/ fatigue#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1223 12231122	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231133	GENRL	Fatigue/ fatigue#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231135	MUSC	Myalgia/ generalized myalgias#	4	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1223 12231137	MUSC	Pain in extremity/ arm soreness#	3	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1223 12231141	GENRL	Fatigue/ fatigue	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1223 12231141	MUSC	Myalgia/ muscle pain	2	30SEP2020	1/3	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1223 12231141	GENRL	Chills/ chills#	4	09JAN2021	2/1	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1223 12231141		Chills/ rigors#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231145	GASTR	Fatigue/ fatigue#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
		Diarrhoea/ Diarrhea	1	11SEP2020	3/1	2	No	O	NA	R (11SEP2020)	N/N
	NERV	Tension headache/ tension headaches	2	14OCT2020	15/11	2	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1223 12231147	GASTR	Diarrhoea/ loose stools#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Pyrexia/ fever 100.1 F#	4	04FEB2021	1/4	1	Yes		NA/TC/TCN	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	3/4	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1223 12231151	GENRL	Injection site pain/ injection site pain#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1223 12231154	GENRL	Chills/ chills*		10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ fatigue	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ chills#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231157	MUSC	Pyrexia/ fever#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Myalgia/ myalgia#	4	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Pain in extremity/ Exertional Left arm soreness	1	10SEP2020	1/4	3	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/2	3	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1223 12231160	GENRL	Pyrexia/ mild fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Fatigue/ fatigue	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1223 12231161	GENRL	Fatigue/ fatigue	2	07OCT2020	3/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1223 12231166	METAB	Gout/ exacerbation of gout in shoulder	1	04OCT2020	21/C	1	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1223 12231175 16-55/ C4591001 1223 12231181 16-55/ C4591001 1223 12231184 16-55/ C4591001 1223 12231187 16-55/ C4591001 1223 12231192	VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N	
	GENRL	Pyrexia/ fever	2	06OCT2020	2/2	2	Yes		NA/TC	R (07OCT2020)	N/N	
	GENRL	Asthenia/ generalized weakness#	4	09JAN2021	2/3	1	Yes		NA	R (11JAN2021)	N/N	
			Injection site pain/ injection site pain#	4	09JAN2021	2/3	1	Yes		NA/TC	R (11JAN2021)	N/N
	GASTR	Abdominal pain/ abdominal pain#	4	31JAN2021	24/C	3	Yes		NA/TC	RG	N/N	
	BLOOD	Lymphadenopathy/ Submandibular lymphadenopathy#	4	01FEB2021	25/C	2	Yes		NA/TC	RG	N/N	
	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	10OCT2020	5/1	2	Yes		NA	R (10OCT2020)	N/N	
	NERV	Headache/ headache	2	10OCT2020	5/1	2	Yes		NA/TC	R (10OCT2020)	N/N	
	GASTR	Nausea/ nausea	1	19SEP2020	2/1	3	Yes		NA/TCN	R (19SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231197	GENRL	Injection site bruising/ bruising at injection site#	3	28FEB2021	3/11	1	Yes		NA	R (10MAR2021)	N/N
	GENRL	Chills/ CHILLS#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
		Fatigue/ FATIGUE#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1223 12231204	GENRL	Pyrexia/ FEVER#	4	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Chills/ chills	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1223 12231212		Pain/ bodyaches	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Pyrexia/ fever#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1223 12231212	MUSC	Myalgia/ myalgias#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	02MAR2021	2/4	1	Yes		NA	R (05MAR2021)	N/N
16-55/ C4591001 1223 12231213	GENRL	Injection site pain/ injection site pain	1	21OCT2020	22/3	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231220	GENRL	Chills/ chills	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
		Malaise/ malaise	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Arthralgia/ Arthralgia ankles and knees#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea*		01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ right arm soreness	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ headache*		08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ muscle aches	2	03NOV2020	2/1	2	Yes		NA/TC	R (03NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1223 12231236		Pain in extremity/ arm pain	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
	VASC	Flushing/ generalized flushing	2	03NOV2020	2/1	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1223 12231242	GENRL	Fatigue/ fatigue	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Pain in extremity/ left arm soreness	1	14OCT2020	1/4	2	Yes		NA	R (17OCT2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	06NOV2020	1/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1223 12231243	MUSC	Pain in extremity/ arm pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/Y
	GENRL	Pyrexia/ subjective fever#	4	09JAN2021	1/2	1	Yes		NA	RS (10JAN2021)	N/N
	MUSC	Myalgia/ deltoid pain#	4	10JAN2021	2/4	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1223 12231244	GENRL	Pyrexia/ fever	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	MUSC	Pain in extremity/ sore arm post vaccine	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
	INV	Body temperature/ temperature	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1223 12231245	MUSC	Pain in extremity/ arm pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y
	GENRL	Injection site pain/ left arm injection pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1223 12231246	BLOOD	Lymph node pain/ tenderness left axillary lymph node	2	06NOV2020	2/4	1	Yes		NA	R (09NOV2020)	N/N
	NERV	Headache/ headache	1	30OCT2020	16/3	2	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1223 12231247†	NERV	Headache/ headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Injection site pain/ injection site pain#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1223 12231247†	GENRL	Chills/ chills#	4	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	09JAN2021	2/2	1	Yes		NA/TC	R (10JAN2021)	N/N
16-55/ C4591001 1223 12231251	MUSC	Pain in extremity/ left arm pain	1	06NOV2020	22/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1223 12231252	MUSC	Pain in extremity/ left arm pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Malaise/ malaise	2	05NOV2020	2/2	2	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1223 12231253	GENRL	Injection site pain/ pain in injection site	1	12NOV2020	21/4	1	Yes		NA	R (15NOV2020)	N/N
16-55/ C4591001 1223 12231256	MUSC	Pain in extremity/ sore arm#	3	02MAR2021	1/3	1	Yes		NA	R (04MAR2021)	N/N
16-55/ C4591001 1223 12231258	NERV	Headache/ headache#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1224 12241010	EYE	Lacrimation increased/ Watery eyes	2	02SEP2020	2/C	1	No	O	NA	N	N/N
	RESP	Rhinorrhoea/ Runny Nose	2	02SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1224 12241065	GASTR	Diarrhoea/ Diarrhea	1	24AUG2020	1/14	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N
		Pyrexia/ Feverish Chills	1	24AUG2020	1/10	2	Yes		NA	R (02SEP2020)	N/N
	INV	Blood pressure increased/ Increased Blood Pressure	1	24AUG2020	1/18	2	Yes		NA	R (10SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1224 12241079	GENRL	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P	R (10SEP2020)	N/N
		Asthenia/ Weakness	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
	PSYCH	Fatigue/ Fatigue	1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N
Depression/ Depression		1	27AUG2020	3/2	1	No	O	NA	R (28AUG2020)	N/N	
16-55/ C4591001 1224 12241083	CARD	Cardiac disorder/ Left Atrial Abnormality	1	01SEP2020	7/C	1	No	O	NA	N	N/N
16-55/ C4591001 1224 12241114	MUSC	Arthritis/ Arthritis - Left hip	2	01NOV2020	41/93	3	No	O	NA/TC/TCN	R (01FEB2021)	N/N
16-55/ C4591001 1224 12241118	GENRL	Chills/ Chills	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Injection site pain/ Injection Site Pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
	NERV	Pyrexia/ Fever (100.6)	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
		Headache/ Headache	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	ENDO	Thyroid cyst/ Thyroid Nodule/Cyst	2	20OCT2020	29/43	2	No	O	NA/TC/TCN	RS (01DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1224 12241119											
16-55/ C4591001 1224 12241121	GENRL	Feeling abnormal/ Brain Fog	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
		Lethargy/ Lethargy	2	30SEP2020	2/2	2	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1224 12241126	GASTR	Dry mouth/ Dry Mouth	1	02SEP2020	1/1	2	Yes		NA	R (02SEP2020)	N/Y
	GASTR	Dry mouth/ Dry Mouth	2	23SEP2020	1/1	2	Yes		NA	R (23SEP2020)	N/Y
16-55/ C4591001 1224 12241131	GENRL	Pyrexia/ Low Grade Fever	1	08SEP2020	6/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Pyrexia/ Low Grade Fever	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Achy Muscles	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Exhaustion	1	07SEP2020	4/4	2	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1224 12241135 16-55/ C4591001	RESP	Sinus congestion/ Sinus Congestion	1	18SEP2020	15/7	1	No	O	NA	R (24SEP2020)	N/N
1224 12241138 16-55/ C4591001	GENRL	Pyrexia/ Fever - 101.0F	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
1224 12241168	SKIN	Rash/ Rash - bilateral upper arms	2	18DEC2020	9/1	1	Yes		NA/TC	R (18DEC2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
1226 12261002	NERV	Headache/ Headache#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Pyrexia/ fever (38,3 C)#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ headache#	4	10FEB2021	1/3	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N
1226 12261004	GENRL	Injection site pain/ Pain at the injection site#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261005	GENRL	Injection site pain/ pain at the injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1226 12261010	GENRL	Injection site pain/ pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/Y
16-55/ C4591001 1226 12261013	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	12FEB2021	1/2	2	Yes		NA	R (13FEB2021)	N/N
	GENRL	Pyrexia/ fever (38,3 C)#	4	13FEB2021	2/3	2	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1226 12261014	NERV	Tremor/ Tremors	1	06AUG2020	2/2	2	Yes		NA/TC	R (07AUG2020)	N/N
16-55/ C4591001 1226 12261016	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261017	GENRL	Injection site pain/ Pain at the injection site#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.3 C#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261018	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1226 12261019	GENRL	Pain/ Body pain#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ chills#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain#	3	09FEB2021	2/3	2	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261025	GENRL	Chills/ chills#	3	30JAN2021	1/1	1	Yes		NA/TC	R (30JAN2021)	N/N
1226 12261026		Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	20FEB2021	1/1	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001	RESP	Cough/ Dry cough	1	14AUG2020	9/28	1	No	O	NA	R (10SEP2020)	N/N
1226 12261027	NERV	Headache/ Headache	2	28AUG2020	4/1	1	Yes		NA	R (28AUG2020)	N/N
1226 12261030	GENRL	Injection site pain/ pan at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
1226 12261031	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	GENRL	Pain/ body pain#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261032	GENRL	Injection site pain/ pain at injection site#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261037	GENRL	Fatigue/ Fatigue	1	18AUG2020	12/2	1	No	O	NA	R (19AUG2020)	N/N
	MUSC	Myalgia/ Muscular pain	2	28AUG2020	3/2	1	Yes		NA	R (29AUG2020)	N/N
	MUSC	Myalgia/ Muscular pain	2	30AUG2020	5/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
	INFEC	Rhinitis/ Coryza#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261038	NERV	Headache/ headache	2	26NOV2020	91/3	2	Yes		NA/TC	R (28NOV2020)	N/N
16-55/ C4591001 1226 12261041	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	30JAN2021	1/2	2	Yes		NA/TC	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261043	INFEC	Herpes zoster oticus/ Ramsay Hunt Syndrome#	2	25JAN2021	153/21	4	No	O	NA/TC	RS (14FEB2021)	Y/N
16-55/ C4591001 1226 12261044	MUSC	Back pain/ Backache	2	29SEP2020	35/7	1	No	O	NA/TC	R (05OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	2/3	2	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261045	MUSC	Back pain/ Backache	2	11SEP2020	17/9	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261049	GENRL	Pyrexia/ fever (38 C)	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
	NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1226 12261052	GENRL	Fatigue/ fatigue#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261055		Injection site pain/ Pain at the injection site#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N
		Pyrexia/ Fever 38.5 C#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	23FEB2021	2/3	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ headache#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
1226 12261065											
16-55/ C4591001	GENRL	Injection site pain/ PAIN AT INJECTION SITE	2	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
1226 12261067											
	RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/18	3	No	O	NA/TC	R (26NOV2020)	Y/N
	GENRL	Injection site haematoma/ Hematoma at injection site#	3	23JAN2021	2/5	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
		Pain/ Body pain#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
		Pyrexia/ Fever 38.5#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle pain (shoulders and neck, on the right body side)	1	18AUG2020	8/C	2	Yes		P/TC/W	N	N/N
1226 12261072											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261073	INFEC	Rhinitis/ Coryza	1	03SEP2020	24/2	1	Yes		NA	R (04SEP2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1226 12261074	EYE	Blepharitis/ blepharitis	2	28SEP2020	25/3	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261076	INFEC	Urinary tract infection/ Urinary tract infection	1	18AUG2020	8/3	2	No	O	NA/TC	R (20AUG2020)	N/N
16-55/ C4591001 1226 12261082	GASTR	Nausea/ nausea	1	19AUG2020	9/1	1	No	O	NA/TC	R (19AUG2020)	N/N
	MUSC	Torticollis/ torticollis	1	24AUG2020	14/1	1	No	O	NA/TC	R (24AUG2020)	N/N
16-55/ C4591001 1226 12261083	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	2	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261084	GENRL	Pain/ body pain#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261085	GASTR	Diarrhoea/ diarrhea	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	01SEP2020	1/2	2	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
	MUSC	Arthralgia/ arthralgia	2	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1226 12261086	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/4	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ chill#	3	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261087	GENRL	Pyrexia/ Fever 38.4 C#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001	GASTR	Angular cheilitis/ Angular cheilitis	1	20AUG2020	10/22	1	No	O	NA/TC	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261088 16-55/ C4591001 1226 12261093	INJ&P	Ligament rupture/ Left knee ligament rupture	2	18NOV2020	79/C	2	No	O	NA/TC	RG	N/N
		Ligament rupture/ Right knee ligament rupture	2	18NOV2020	79/C	2	No	O	NA/TC	RG	N/N
	GENRL	Chills/ chills#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ fever (38.5C)#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261094	RENAL	Nephrolithiasis/ Worsening of Nephrolithiasis	2	21DEC2020	112/33	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N
	INFEC	Urinary tract infection/ Urinary tract infection	2	29DEC2020	120/8	2	No	O	NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1226 12261100	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	22JAN2021	1/3	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Pyrexia/ Fever 39 C#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261104	GENRL	Fatigue/ Fatigue	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261106	NERV	Headache/ Headache	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N	
	GENRL	Injection site pain/ pain at the injection site#	4	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N	
	GENRL	Asthenia/ asthenia#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N	
	NERV	Headache/ Headache	1	21AUG2020	11/1	1	No	O	NA/TC	R (21AUG2020)	N/N	
	REPRO	Dysmenorrhoea/ Menstrual cramps	1	22AUG2020	12/1	1	No	O	NA/TC	R (22AUG2020)	N/N	
	GENRL	Fatigue/ fatigue	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N	
	MUSC	Arthralgia/ joint pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N	
			Myalgia/ muscle pain	2	02SEP2020	2/2	3	Yes		NA	R (03SEP2020)	N/N
	NERV	Headache/ headache	2	02SEP2020	2/3	3	Yes		NA	R (04SEP2020)	N/N	
16-55/ C4591001 1226 12261110	GENRL	Injection site pain/ pain at the injection site#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	
	INV	Body temperature increased/ increased body temperature#	3	02FEB2021	1/2	2	Yes		NA	R (03FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Dizziness/ dizziness#	3	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
		Headache/ headache#	3	03FEB2021	2/1	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1226 12261111	GENRL	Injection site pain/ pain at the injection site#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261115	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261118	MUSC	Back pain/ back pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
		Neck pain/ neck pain	2	16SEP2020	14/2	1	No	O	NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261120	GENRL	Injection site pain/ pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA/TC	R (01FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	30JAN2021	1/3	2	Yes		NA/TC	R (01FEB2021)	N/N
	GENRL	Pyrexia/ fever (37,9 C)#	3	31JAN2021	2/1	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261121	GENRL	Injection site pain/ Pain at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site pain/ Pain at injection site#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N
		Pyrexia/ Fever (38.3 C)#	4	21FEB2021	2/2	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261123	INV	Body temperature increased/ increase of temperature (37,8 C)#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261124	MUSC	Pain in extremity/ Pain in legs	1	19AUG2020	8/3	2	No	O	NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1226 12261126	MUSC	Back pain/ acute low back pain	1	20AUG2020	9/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ tiredness#	3	02FEB2021	2/3	2	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	02FEB2021	2/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261130	GENRL	Injection site swelling/ Swelling at the injection site#	4	22FEB2021	1/4	2	Yes		NA/TC	R (25FEB2021)	N/N	
		Chills/ Chills#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
		Body temperature increased/ Increased body temperature 37.6 C#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
	MUSC	Arthralgia/ Joint pain#	4	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
		GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	16-55/ C4591001 1226 12261132	GENRL	Chills/ Chills#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
			Fatigue/ Tiredness#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		MUSC	Injection site pain/ Pain at the injection site#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	16-55/ C4591001 1226 12261134	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
			GENRL	Malaise/ Malaise#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)
MUSC		Pyrexia/ Fever 38 C#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
		Myalgia/ Muscle pain#	4	24FEB2021	3/1	1	Yes		NA/TC	R (24FEB2021)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261135	GENRL	Fatigue/ tiredness#	3	31JAN2021	2/2	2	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	2	Yes		NA/TCN	R (01FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261136	GASTR	Haemorrhoids/ Hemorrhoid Worsening	2	26JAN2021	145/2	4	No	O	NA/TC/TCN	R (27JAN2021)	Y/N
16-55/ C4591001 1226 12261137	INJ&P	Fall/ Bicycle fall	2	20SEP2020	18/1	3	No	O	NA/TCN	R (20SEP2020)	N/N
		Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N
16-55/ C4591001 1226 12261139	GASTR	Dental caries/ Dental cavity	1	21AUG2020	10/6	1	No	O	NA/TCN	R (26AUG2020)	N/N
	INFEC	Gingivitis/ gingivitis	1	21AUG2020	10/8	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1226 12261144	NERV	Headache/ Headache	1	27AUG2020	16/1	1	No	O	NA	R (27AUG2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/3	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261147	GENRL	Injection site pain/ Pain at injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Pain/ body pain#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ fever#	4	22FEB2021	1/3	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12261148	GENRL	Injection site pain/ Pain at injection site#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261150	GENRL	Injection site pain/ pain at the injection site#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1226 12261153	GENRL	Injection site pain/ Pain at injection site#	3	30JAN2021	1/4	2	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	30JAN2021	1/4	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1226 12261156	GENRL	Chills/ chills#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
		Fatigue/ fatigue#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261158		Injection site pain/ Pain at the injection site#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pain/ body pain#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1226 12261159	PSYCH	Anxiety disorder/ Anxiety disorder	1	14AUG2020	2/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Tiredness#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	MUSC	Back pain/ Left back pain	2	12OCT2020	40/3	1	No	O	NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261161 16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
1226 12261163 16-55/ C4591001	BLOOD	Lymph node pain/ sore left axillary lymph node	2	07SEP2020	5/15	1	Yes		NA	R (21SEP2020)	N/N
1226 12261164	MUSC	Back pain/ back pain on the left	2	07SEP2020	5/5	1	Yes		NA	R (11SEP2020)	N/N
		Pain in extremity/ left arm pain	2	07SEP2020	5/5	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261167	GENRL	Injection site pain/ pain at the injection site#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Pyrexia/ fever#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12261168	GENRL	Injection site erythema/ Redness at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	18SEP2020	16/1	1	No	O	NA	R (18SEP2020)	N/N
	GENRL	Chills/ chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261172	NERV	Dizziness/ dizziness#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Headache/ headache#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ chills#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	30JAN2021	1/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	INFEC	Herpes zoster cutaneous disseminated/ multidermatomal herpes zoster	2	25OCT2020	53/27	2	No	O	NA/TC	R (20NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12261176	GENRL	Fatigue/ fatigue#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y
		Injection site pain/ pain at the injection site#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y
16-55/ C4591001 1226 12261178	GASTR	Abdominal pain/ abdominal colic	2	30OCT2020	57/1	1	No	O	NA	R (30OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261185	GENRL	Injection site pain/ Pain at the injection site#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1226 12261186	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Somnolence/ Somnolence#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261188	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261189	INFEC	Rhinitis/ coryza	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N
	RESP	Nasal congestion/ nasal congestion	2	26OCT2020	53/6	1	No	O	NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1226 12261190	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement	2	06SEP2020	3/	1	Yes		NA	R	N/N
16-55/ C4591001 1226 12261193	METAB	Glucose tolerance impaired/ Pre-diabetes	2	24NOV2020	82/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261194	INV	Body temperature increased/ Increased body temperature 37.5 C#	4	10FEB2021	1/30	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 1226 12261196	GASTR	Dyspepsia/ dyspepsia	2	01DEC2020	89/6	2	No	CD	NA	R (06DEC2020)	N/N
16-55/ C4591001 1226 12261199	GENRL	Asthenia/ Asthenia#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature (37.7C)#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261200	GENRL	Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Chills/ chills#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	INV	Body temperature increased/ body increased temperature (37.8 C)#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	20FEB2021	1/2	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261203	PSYCH	Panic reaction/ Panic syndrome	1	22AUG2020	9/1	3	No	O	NA/TC	R (22AUG2020)	N/N
	METAB	Glucose tolerance impaired/ prediabetes	2	10SEP2020	7/C	1	No	O	NA/TC	RG	N/N
	MUSC	Arthralgia/ left knee arthralgia	2	29SEP2020	26/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261207	GENRL	Pyrexia/ Fever 38 C#	4	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12261208	GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
		Nausea/ Nausea	2	12SEP2020	5/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain (intermittent)	2	12OCT2020	35/C	2	No	O	NA/TC	RG	N/N
		Nausea/ Nausea (intermittent)	2	12OCT2020	35/27	2	No	O	NA/TC	R (07NOV2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261210	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	10DEC2020	94/C		No	O	NA/TC	UNK	N/N
16-55/ C4591001 1226 12261214	INFEC	Ear infection/ otitis on the left	2	12SEP2020	5/5	1	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261215	GENRL	Injection site erythema/ erythema at the injection site#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ headache#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1226 12261216	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	12FEB2021	2/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261217	GENRL	Pyrexia/ Fever 38 C	2	11SEP2020	4/1	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261220	GENRL	Injection site pain/ Pain at the injection site#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	21FEB2021	2/2	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site oedema/ Edema at the injection site#	3	23JAN2021	1/3	2	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	2	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	03FEB2021	1/13	2	Yes		NA	R (15FEB2021)	N/N
	GENRL	Pain/ body pain#	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/Y
	NERV	Headache/ headache#	3	04FEB2021	1/1	1	Yes		NA/TC	R (04FEB2021)	N/Y
	GENRL	Injection site pain/ Pain at the injection site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261238	MUSC	Pyrexia/ Fever 38 C#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N
		Myalgia/ Myalgia#	4	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261239	GENRL	Injection site pain/ pain at the injection site#	3	31JAN2021	2/2	2	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1226 12261240	GENRL	Fatigue/ Tiredness#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	INV	Body temperature increased/ Body increased temperature#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ headache	2	09NOV2020	62/3	1	No	O	NA	R (11NOV2020)	N/N
16-55/ C4591001 1226 12261241	GENRL	Injection site pain/ pain at the injection site#	4	18FEB2021	1/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
	BLOOD	Lymphadenopathy/ lymphadenomegaly#	4	16FEB2021	2/7	1	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261244	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Pyrexia/ fever (38,3 C- 39,5 C)#	4	12FEB2021	1/3	3	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Asthenia/ asthenia#	4	13FEB2021	2/4	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261246	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Pyrexia/ fever (38,6 C)#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001 1226 12261249	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/3	2	Yes		NA/TC	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261250	GENRL	Injection site pain/ Pain at the injection site#	3	03FEB2021	2/2	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1226 12261251	GASTR	Nausea/ Nausea#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261254	GASTR	Diarrhoea/ diarrhea	2	09SEP2020	1/1	1	Yes		NA	R (09SEP2020)	N/N
	GASTR	Abdominal pain/ abdominal pain	2	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Abdominal pain/ abdominal colic	2	16OCT2020	38/14	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1226 12261259	GENRL	Fatigue/ Tiredness#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	03FEB2021	2/2	2	Yes		NA/TC	R (04FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261262 16-55/ C4591001 1226 12261263	GENRL  NERV	Fatigue/ fatigue#  Headache/ headache#	3	04FEB2021	2/2	1	Yes	NA	NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261264	GENRL  MUSC	Fatigue/ fatigue  Pyrexia/ FEVER (38,8 C) Myalgia/ muscle pain	2 2	10SEP2020 10SEP2020	2/2 2/2	2 2	Yes Yes	NA/TC NA/TC	NA/TC NA/TC	R (11SEP2020) R (11SEP2020)	N/N N/N
16-55/ C4591001 1226 12261266	GENRL	Injection site pain/ Pain at the injection site#	3	11FEB2021	1/3	1	Yes	NA	NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261269	MUSC  MUSC NERV	Myalgia/ Myalgia#  Myalgia/ muscle pain# Headache/ headache#	3 4 4	04FEB2021 23FEB2021 23FEB2021	2/2 2/1 2/1	2 2 2	Yes Yes Yes	NA/TC NA/TC NA/TC	NA/TC NA/TC NA/TC	R (05FEB2021) R (23FEB2021) R (23FEB2021)	N/N N/N N/N
16-55/ C4591001	GENRL	Injection site erythema/ Redness at the injection site#	3	04FEB2021	1/6	2	Yes	NA	NA	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261271		Injection site swelling/ Swelling at the injection site#	3	04FEB2021	1/6	2	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261273	GENRL	Pain/ body pain	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261274	GENRL	Injection site pain/ Pain on injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1226 12261275	GENRL	Injection site pain/ Pain at injection site	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261276	GENRL	Pyrexia/ Fever (38 C)	1	19AUG2020	1/1	1	Yes		NA/TC	R (19AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261277	NERV	Headache/ headache	1	20AUG2020	2/2	1	Yes		NA/TC	R (21AUG2020)	N/N
	SKIN	Pruritus/ Diffuse itching	2	13SEP2020	3/7	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	25JAN2021	3/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	NERV	Headache/ headache#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	26JAN2021	2/1	2	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/4	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261280	GENRL	Injection site pain/ pain at injection site	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	1	19AUG2020	1/2	1	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261282	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N
16-55/ C4591001 1226 12261285	INFEC	Sinusitis bacterial/ Bacterial sinusitis	2	20SEP2020	11/7	2	No	O	NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261287	GENRL	Fatigue/ Fatigue#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261291	GENRL	Chills/ Chills#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N
		Fatigue/ Fatigue#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N
		Pyrexia/ Fever 38 C#	4	28FEB2021	2/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1226 12261292	GENRL	Injection site pain/ pain at injection site	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261294	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/Y
16-55/ C4591001 1226 12261295	GENRL	Pain/ body pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261299	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ headache#	3	05FEB2021	2/1	2	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261300	INFEC	Conjunctivitis/ Conjunctivitis	1	01SEP2020	13/7	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1226 12261301	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
		Myalgia/ Muscle pain	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	3	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1226 12261302	GENRL	Chills/ Chills#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
		Pain/ Body ache#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261303	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	2/3	1	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1226 12261307	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	2/3	2	Yes		NA	R (23AUG2020)	N/N
		Pyrexia/ fever	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261308	MUSC	Myalgia/ myalgia	1	21AUG2020	2/1	2	Yes		NA/TC	R (21AUG2020)	N/N
	NERV	Headache/ headache	1	21AUG2020	2/2	2	Yes		NA/TC	R (22AUG2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	14/2	1	No	O	NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pyrexia/ Fever 38.3 C#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12261312	MUSC	Myalgia/ Muscle pain#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1226 12261313	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	06OCT2020	26/C		No	O	NA	N	N/N
16-55/ C4591001 1226 12261314	GENRL	Injection site pain/ Pain at injection site#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site	1	20AUG2020	1/3	1	Yes		NA	R (22AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261319	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Arthralgia/ arthralgia	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261323	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	2/2	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1226 12261324	NERV	Headache/ headache#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261327	GENRL	Injection site pain/ Pain at the injection site#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/Y
16-55/ C4591001 1226 12261328	MUSC	Arthralgia/ Joint pain	1	20AUG2020	1/9	3	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C4591001	NERV	Headache/ headache	2	12SEP2020	1/1	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261330 16-55/ C4591001	RESP	Oropharyngeal pain/ sore throat	2	12OCT2020	22/1	1	No	O	NA	R (12OCT2020)	N/N
1226 12261331 16-55/ C4591001	GENRL	Injection site oedema/ edema at injection site	2	21SEP2020	1/6	2	Yes		NA	R (26SEP2020)	N/N
1226 12261332	MUSC	Myalgia/ muscle pain	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
1226 12261336	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ muscle pain	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
1226 12261337	NERV	Headache/ headache	2	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injecton site	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
1226 12261338											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261341	GENRL	Pain/ Body pain	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
		Pyrexia/ Fever	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	09SEP2020	1/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Chills/ chills	2	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	INFEC	Gastroenteritis/ Gastroenterocolitis	2	20NOV2020	73/10	2	No	O	NA/TC	R (29NOV2020)	Y/N
	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	1	Yes		NA/TCN	R (21SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Back pain/ Left back pain	2	19SEP2020	10/C	1	No	O	NA/TC	RG	N/N
	16-55/ C4591001 1226 12261348	GENRL	Injection site pain/ pain at injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)
GENRL	Pyrexia/ Fever (38,8 C)	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N	
MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261349	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	1/3	2	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1226 12261351	GENRL	Injection site pain/ Pain at injection site	1	21AUG2020	1/3	2	Yes		NA/TC	R (23AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	10SEP2020	1/5	2	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1226 12261352	GENRL	Injection site pain/ Pain at injection site	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
	NERV	Headache/ Headache	1	22AUG2020	2/1	2	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261354	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261355	GENRL	Pyrexia/ Fever (38.7 C)	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle pain	2	12SEP2020	2/1	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261357	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
	NERV	Headache/ headache#	3	04FEB2021	1/2	2	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261358	GENRL	Injection site pain/ pain at injection site	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Pyrexia/ fever (37.9C)	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261359	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/4	2	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
		Pain/ Body ache#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261360	GENRL	Pain/ Body aches#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261361	GENRL	Application site reaction/ hyperemia at the application site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
		Injection site erythema/ Erythema at injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1226 12261362	GENRL	Pain/ Body pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261364	MUSC	Myalgia/ Muscle pain	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/2	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1226 12261365	GENRL	Injection site pain/ pain at the injection site	1	21AUG2020	1/3	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Pyrexia/ fever (38.3C)	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1226 12261369	GENRL	Injection site pain/ Pain at the injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261373	GENRL	Injection site pain/ Pain at the injection site#	3	04FEB2021	1/1	2	Yes		NA	R (04FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Somnolence/ Somnolence#	3	04FEB2021	1/1	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1226 12261375	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/1	2	Yes		NA	R (24AUG2020)	N/N
16-55/ C4591001 1226 12261376	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261377	SKIN	Pruritus/ itching (arms and left hand)	2	26NOV2020	74/42	1	No	O	NA	R (06JAN2021)	N/N
16-55/ C4591001 1226 12261379	GENRL	Chills/ chills	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
		Pyrexia/ Fever (38,7 C)	1	25AUG2020	2/2	2	Yes		NA/TC	R (26AUG2020)	N/N
	MUSC	Myalgia/ muscle pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1226 12261382	GENRL	Fatigue/ Tiredness	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N
		Pyrexia/ Fever	1	25AUG2020	2/3	2	Yes		NA/TC	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261383	GENRL	Malaise/ Malaise	1	15SEP2020	23/2	2	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pain/ Body pain	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261384		Malaise/ malaise#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	INV	Body temperature increased/ increased of body temperature#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Chills/ Chills#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
	INV	Body temperature increased/ Body increased temperature (37.8 C)#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N
MUSC	Myalgia/ Muscle pain#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N	
NERV	Headache/ Headache#	3	23FEB2021	2/3	2	Yes		NA/TC	R (25FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261387	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/2	1	Yes		NA	R (26AUG2020)	N/N
	GENRL	Chills/ chills	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261390	MUSC	Myalgia/ Muscle pain	2	14SEP2020	1/3	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Back pain/ Backache	1	30AUG2020	7/3	2	No	O	NA/TC	R (01SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	15SEP2020	1/19	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever (38 C)	2	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Malaise/ Malaise	2	16SEP2020	2/28	2	Yes		NA	R (13OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea intermittent	2	18SEP2020	4/49	1	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
	METAB	Decreased appetite/ Inapetence	2	18SEP2020	4/26	2	Yes		NA	R (13OCT2020)	N/N
GASTR	Irritable bowel syndrome/ Irritable bowel syndrome	2	05NOV2020	52/C	2	Yes		NA/TC	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261391	MUSC	Torticollis/ torticollis	1	13SEP2020	21/5	2	No	O	NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ Chills#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	1/2	2	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261392	GENRL	Injection site pain/ Pain at injection site	1	24AUG2020	1/3	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1226 12261395	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	2/4	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Pain in extremity/ Right arm pain	2	14OCT2020	31/1	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261396	GENRL	Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1226 12261397	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261399	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1226 12261400	NERV	Neuritis/ (right submammary) Intercostal neuritis	2	28DEC2020	105/19	2	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261404	GENRL	Chills/ chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1226 12261406	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	1/2	2	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261408	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/3	2	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1226 12261409	MUSC	Myalgia/ Myalgia	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N
	NERV	Headache/ Headache	1	31AUG2020	7/3	2	Yes		NA/TC	R (02SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261410	SKIN	Rash pruritic/ Pruritic Papular eruption	1	08SEP2020	15/20	1	No	O	NA/TC	R (27SEP2020)	N/N
	GENRL	Pyrexia/ Fever (38.1 C)#	3	30JAN2021	2/1	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1226 12261411	GASTR	Vomiting/ Vomit	2	15SEP2020	1/6	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261412	INFEC	Cystitis/ cystitis	2	20SEP2020	6/6	2	No	O	NA/TC	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection site#	3	23JAN2021	1/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	25AUG2020	1/2	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1226 12261413	GENRL	Pyrexia/ Fever (39 C)	2	15SEP2020	1/2	3	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261415	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site swelling/ Swelling at the injection site#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1226 12261416	MUSC	Back pain/ backache	2	27SEP2020	13/4	3	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261417	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	BLOOD	Lymphadenopathy/ left axillary lymphadenomegaly	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	16SEP2020	2/5	2	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	17SEP2020	3/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261421	GENRL	Pyrexia/ Fever (38,3 C)	1	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261423	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261425	GENRL	Chills/ Chills	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	3/7	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261426	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
16-55/ C4591001 1226 12261427	GENRL	Injection site pain/ pain at the injection site#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261428	METAB	Vitamin D deficiency/ Hypovitaminosis D	1	27AUG2020	2/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	1/1	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	24FEB2021	1/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	1/1	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12261429	NERV	Headache/ Headache	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261430	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	NERV	Headache/ Headache	1	26AUG2020	1/2	1	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the site of injection	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261432	GASTR	Diarrhoea/ Diarrhea	1	29AUG2020	4/1	1	Yes		NA	R (29AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	31AUG2020	6/1	1	Yes		NA	R (31AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/5	1	Yes		NA	R (29JAN2021)	N/N
	BLOOD	Lymphadenopathy/ axillary lymphadenopathy#	3	26JAN2021	2/7	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Pyrexia/ fever (38.2 C)#	3	26JAN2021	2/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ Fever 38.3 C#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261433	MUSC	Torticollis/ torticollis	2	02OCT2020	14/20	1	No	O	NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261434	GENRL	Injection site pain/ pain at the injection site#	2	08FEB2021	146/4	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261436	MUSC	Myalgia/ Myalgia	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261437	MUSC	Myalgia/ Muscle pain#	3	24JAN2021	2/1	1	Yes		NA/TC	R (24JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	PSYCH	Anxiety/ Anxiety#	3	01FEB2021	10/C	2	No	O	NA/TC	RG	N/N	
	GENRL	Fatigue/ fatigue#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
		Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N	
16-55/ C4591001 1226 12261439	GENRL	Injection site pain/ Pain at the injection site	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N	
		Pyrexia/ Fever (38 C)	1	27AUG2020	2/1	1	Yes		NA/TC	R (27AUG2020)	N/N	
16-55/ C4591001 1226 12261441	GENRL	Injection site pain/ Pain at the injection site#	2	05FEB2021	143/2	1	Yes		NA	R (06FEB2021)	N/N	
16-55/ C4591001 1226 12261442	MUSC	Myalgia/ muscle pain	1	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N	
	GENRL	Pain/ Body pain	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N	
		Pyrexia/ Fever 38.5 C	2	15SEP2020	2/4	1	Yes		NA	R (18SEP2020)	N/N	
16-55/ C4591001 1226 12261444	GENRL	Pyrexia/ Fever 38.5 C	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N	
16-55/ C4591001	INJ&P	Fibula fracture/ Fracture of the left fibula	2	01DEC2020	77/C	3	No	O	NA/TC/TCN	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261447 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
1226 12261448 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
1226 12261449	MUSC	Myalgia/ myalgia#	4	13FEB2021	2/1	2	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/1	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261451	GENRL	Chills/ Chills	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261452	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261454	GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Pilonidal cyst/ Pilonidal cyst	2	01OCT2020	13/16	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261456	MUSC	Myalgia/ Muscle pain	2	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261457	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1226 12261460	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261463	RESP	Oropharyngeal discomfort/ throat discomfort	2	22OCT2020	34/1	1	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261465	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
16-55/ C4591001 1226 12261466	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/18	2	Yes		NA	R (10OCT2020)	N/N
	NERV	Somnolence/ Somnolence	2	23SEP2020	3/18	2	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261470	GASTR	Nausea/ Nausea#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/7	2	Yes		NA/TC	R (03SEP2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	02SEP2020	7/2	3	Yes		NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1226 12261471	GENRL	Injection site pain/ Pain at injection site	1	28AUG2020	2/3	1	Yes		NA	R (30AUG2020)	N/N
		Pyrexia/ Fever	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ fever	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261472	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261475	GENRL	Fatigue/ fatigue	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ headache	2	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261480	GENRL	Pyrexia/ fever 37.9 C	2	19SEP2020	1/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261482	GENRL	Fatigue/ fatigue	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
	NERV	Headache/ headache	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261484 16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
1226 12261485 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N
1226 12261486	GENRL	Chills/ chills	2	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ pain at injection site	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	15SEP2020	1/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	15SEP2020	1/4	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
1226 12261488		Injection site pain/ Pain at injection site	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Vomiting/ Vomiting	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
		Fatigue/ Fatigue	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle pain	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261489	GENRL	Pyrexia/ Fever (38C)#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261490	GENRL	Chills/ Chills#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261491	GENRL	Chills/ Chills	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ Fever 38.5 C	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261492	PSYCH	Insomnia/ Insomnia	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	19SEP2020	1/2	2	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261493	MUSC	Myalgia/ muscle pain	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ headache	1	28AUG2020	1/2	1	Yes		NA/TC	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
	GENRL	Injection site pain/ injection site pain	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Pyrexia/ fever (38 C)	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	1/1	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261502	GENRL	Injection site pain/ Pain at the injection site	2	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	NERV	Headache/ Headache	1	28AUG2020	1/3	2	Yes		NA	R (30AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261503	NERV	Headache/ headache#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/1	2	Yes		NA	R (29AUG2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ Fatigue	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261504	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	INFEC	Herpes zoster/ Herpes zoster (chest)	2	29NOV2020	70/68	2	No	O	NA/TC	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261505	GENRL	Chills/ Chills	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1226 12261508	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261509	GENRL	Injection site pain/ Pain at injection site#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1226 12261511	MUSC	Myalgia/ Muscle pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38 C#	4	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Injection site lymphadenopathy/ supraclavicular adenomegaly at injection site#	4	13FEB2021	2/7	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261512	MUSC	Myalgia/ Muscle pain	1	02SEP2020	2/1	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1226 12261515	GENRL	Pain/ body pain#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261516	GENRL	Fatigue/ Fatigue	1	06SEP2020	2/1	2	Yes		NA/TCN	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261517	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/3	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/2	2	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ myalgia	2	24SEP2020	2/2	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261518	MUSC	Back pain/ Acute mechanical low back pain	2	14OCT2020	23/1	2	No	O	NA/TC	R (14OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261519	NERV	Headache/ Headache	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	REPRO	Testicular pain/ Testicles Pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site*		02SEP2020	-1/4	2	Yes		NA	R (05SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261520 16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site#	3	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
1226 12261521 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	03SEP2020	1/3	1	Yes		NA	R (05SEP2020)	N/N
1226 12261522 16-55/ C4591001	GENRL	Injection site pain/ Pain in the injection	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
1226 12261525	GENRL	Pain/ body pain	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261526	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/Y
16-55/ C4591001 1226 12261529	GENRL	Pyrexia/ Fever 38 C#	4	13FEB2021	2/1	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261530	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261531	NERV	Headache/ Headache	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261532	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/5	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261535	GENRL	Injection site oedema/ edema at injection site	1	06SEP2020	2/3	1	Yes		NA	R (08SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	06SEP2020	2/3	2	Yes		NA/TC	R (08SEP2020)	N/N
		Malaise/ Malaise	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	1	06SEP2020	2/6	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	08SEP2020	4/4	2	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pain/ body pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ fever (38.4C)	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
	VASC	Hypotension/ Hypotension (48x32mmHg)	2	05JAN2021	104/1	3	No	O	NA/TCN	R (05JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261538	PSYCH	Panic disorder/ Panic disorder	2	17OCT2020	20/2	2	No	O	NA/TC	R (18OCT2020)	N/N
	GENRL	Fatigue/ Tiredness#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Pain/ Body ache#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ headache#	4	25FEB2021	2/2	2	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1226 12261540	GENRL	Injection site pain/ Pain at injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1226 12261542	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	6/3	2	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site erythema/ erythema at the injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
		Injection site oedema/ edema at injection site	1	12SEP2020	8/4	1	Yes		NA/TC/TCN	R (15SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261544	MUSC	Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ Fever 38.5 C	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pain in extremity/ Pain in both legs	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	2	Yes		NA	R (07SEP2020)	N/N
	NERV	Headache/ headache	1	05SEP2020	1/3	2	Yes		NA/TC	R (07SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	1/1	1	Yes		NA	R (24SEP2020)	N/N
	BLOOD	Lymphadenopathy/ enlargement of left axillary lymph node	2	25SEP2020	2/34	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Pain/ Body pain	2	26SEP2020	3/1	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261546	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261548	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261549	GENRL	Pain/ Body ache#	3	06FEB2021	1/3	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261551	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1226 12261553	GENRL	Injection site pain/ pain at injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
		Injection site swelling/ swelling at the injection site	1	05SEP2020	1/4	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	1	Yes		NA/TC	R (07SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	25SEP2020	2/2	2	Yes		NA	R (26SEP2020)	N/N
	GENRL	Pyrexia/ fever (38.1 C)	2	26SEP2020	3/1	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261554 16-55/ C4591001 1226 12261555	GENRL	Injection site pruritus/ itching at the injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
	INJ&P	Contusion/ Knee contusion	2	26OCT2020	33/4	1	No	O	NA/TC	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	27FEB2021	2/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1226 12261557	GENRL	Injection site pain/ Pain at injection site	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1226 12261559	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever 38.5 C	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1226 12261560	GENRL	Fatigue/ fatigue	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ headache	2	25SEP2020	1/3	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261561	MUSC	Myalgia/ myalgia#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ headache#	3	20FEB2021	1/6	2	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12261562	NERV	Headache/ headache	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261564	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever (38.1C)	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Chills/ chills	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	METAB	Decreased appetite/ inapetence	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261566	GENRL	Chills/ chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261567	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/2	1	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1226 12261568	GENRL	Injection site swelling/ swelling at the injection site	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Neck pain/ neck pain	2	30SEP2020	6/2	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261569	NERV	Headache/ Headache	2	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ fever (38 C)#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ headache#	3	25FEB2021	1/2	2	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1226 12261570	GENRL	Injection site pain/ pain at the injection site#	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N
		Pyrexia/ fever (38 C)#	3	25FEB2021	1/4	1	Yes		NA/TC	R (28FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261571	INJ&P	Cervical vertebral fracture/ Fracture of the fourth cervical vertebra	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
		Contusion/ Bruises in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N	
		Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N	
		Skin abrasion/ Excoriations in various regions of the body	2	21OCT2020	27/10	2	No	O	NA/TC	R (30OCT2020)	N/N	
		Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N		
16-55/ C4591001 1226 12261572	GENRL	Chills/ chills	1	06SEP2020	2/2	2	Yes		NA/TC	R (07SEP2020)	N/N	
	GENRL	Injection site pain/ pain at injection site	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N	
		Pyrexia/ fever (38.2 C)	1	07SEP2020	3/1	2	Yes		NA/TC	R (07SEP2020)	N/N	
	MUSC	Myalgia/ myalgia	1	07SEP2020	3/2	1	Yes		NA	R (08SEP2020)	N/N	
	INFEC	Rhinitis/ Coryza	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ diarrhea	2	25SEP2020	2/1	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	25SEP2020	2/1	3	Yes		NA	R (25SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	2/1	2	Yes		NA	R (25SEP2020)	N/N
		Pyrexia/ fever (38.5 C)	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1226 12261574	GENRL	Injection site pain/ Pain at injection site	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1226 12261575	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
	NERV	Headache/ Worsening of Headache#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261577	GENRL	Chills/ chill	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	06SEP2020	2/1	1	Yes		NA	R (06SEP2020)	N/N
	GASTR	Nausea/ nausea	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261578	GENRL	Fatigue/ fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	4/1	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261579	GASTR	Nausea/ Nausea	1	14SEP2020	10/1	1	Yes		NA	R (14SEP2020)	N/N
	SKIN	Seborrhoeic dermatitis/ Seborrheic Dermatitis in the Scalp	2	06JAN2021	101/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12261581	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261582	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Chills/ Chills	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	28SEP2020	1/3	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261583	GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/2	2	Yes		NA	R (08SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261584	RENAL	Ureterolithiasis/ Left ureteral stone	2	13NOV2020	46/3	2	No	O	NA/TCN	R (15NOV2020)	Y/N
	GENRL	Fatigue/ discreet tiredness#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	INV	Body temperature increased/ temperature increase (37,5 C)#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261585	GASTR	Diarrhoea/ diarrhea	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261586	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	13SEP2020	7/1	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.2 C#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	09SEP2020	3/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261588	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1226 12261590	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	2	02OCT2020	1/2	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261591	GENRL	Injection site oedema/ Edema at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at site injection	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N
		Fatigue/ Fatigue	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261592	GENRL	Injection site pain/ Pain at injection site	2	29SEP2020	2/3	1	Yes		NA/TC	R (01OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	08SEP2020	2/2	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261593	NERV	Malaise/ Malaise	2	28SEP2020	1/2	1	Yes		NA/TC	R (29SEP2020)	N/N
		Headache/ headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	2	01OCT2020	4/4	2	No	O	NA/TC	R (04OCT2020)	N/N
	GENRL	Chills/ Chills	2	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261594	GENRL	Injection site pain/ Pain at the injection site#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261595	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261596		GENRL	Pyrexia/ Fever	1	08SEP2020	2/1	1	Yes		NA/TC	R (08SEP2020)
	GENRL	Pyrexia/ Fever 38 C	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001	NERV	Paraesthesia/ tingling in the left upper limb	2	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261597 16-55/ C4591001 1226 12261598	GENRL	Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
1226 12261598	GENRL	Injection site pain/ pain at the injection site#	4	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261599	GENRL	Fatigue/ fatigue	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	07SEP2020	1/4	1	Yes		NA/TC	R (10SEP2020)	N/N
	EYE	Ulcerative keratitis/ corneal ulcer right eye	1	20SEP2020	14/8	2	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1226 12261600	GENRL	Fatigue/ fatigue	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261601	MUSC	Myalgia/ Muscle pain	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	2/2	1	Yes		NA	R (09SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	28SEP2020	1/2	2	Yes		NA/TC	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261602	GENRL	Injection site pain/ Pain at the injection site	1	07SEP2020	1/3	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1226 12261603	NERV	Headache/ Headache	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/2	2	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Pain/ Body ache#	4	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261604	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N
		Pyrexia/ Fever (38 C)#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N
	NERV	Headache/ Headache#	4	13FEB2021	2/3	1	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001	GENRL	Asthenia/ Asthenia	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261606		Pyrexia/ Fever 38 C	2	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261607	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/2	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	29SEP2020	2/2	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261609	GENRL	Injection site pain/ Pain at injection site	1	08SEP2020	2/1	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1226 12261610	GENRL	Injection site pain/ Pain at Injection Site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Malaise/ indisposition#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ fever (38C)#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261612	MUSC	Myalgia/ muscle pain#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	15FEB2021	1/3	2	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	07SEP2020	1/4	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/4	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site erythema/ Erythema at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261614		Injection site swelling/ Swelling at the injection site	2	29SEP2020	2/3	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1226 12261616		Injection site pain/ Pain at the injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Pyrexia/ fever (38C)#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1226 12261618	NERV	Headache/ Headache	2	17OCT2020	17/5	2	No	O	NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261619	GENRL	Injection site pain/ Pain at the injection site	2	01OCT2020	2/3	2	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	3/2	2	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	3/2	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261621	GENRL	Chills/ chills	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
		Fatigue/ fatigue	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ pain at injection site	1	08SEP2020	2/3	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
		Nausea/ Nausea	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261623	GENRL	Fatigue/ fatigue	1	11SEP2020	4/2	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	11SEP2020	4/5	2	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	2/4	1	Yes		NA/TC	R (09FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261624	GENRL	Chills/ Chills#	3	08FEB2021	1/1	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261625	GENRL	Injection site pain/ pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261627	GENRL	Fatigue/ fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ pain at injection site	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ headache	1	08SEP2020	1/2	1	Yes		NA/TC	R (09SEP2020)	N/N
	GASTR	Nausea/ nausea	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
		Vomiting/ vomiting	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	29SEP2020	2/3	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	NERV	Headache/ headache	2	26OCT2020	29/2	2	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1226 12261628	MUSC	Myalgia/ Muscles pain	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261630	GENRL	Injection site oedema/ Edema at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	VASC	Hypertension/ Systemic arterial hypertension	1	14SEP2020	7/C	1	Yes		NA/TC	RG	N/N
16-55/ C4591001 1226 12261631	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Chills/ chills#	3	23JAN2021	1/2	2	Yes		NA/TC	R (24JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261632	NERV	Headache/ headache#	3	23JAN2021	1/2	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/1	2	Yes		NA/TC	R (30SEP2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261633	NERV	Headache/ Headache	2	29SEP2020	1/1	1	Yes		NA/TC	R (29SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/3	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261634	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261636	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/1	1	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1226 12261637	GENRL	Injection site pain/ pain at the injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261641	GENRL	Injection site pain/ pain at injection site	1	09SEP2020	1/3	2	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ diarrhea	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
		Nausea/ nausea	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
	MUSC	Arthralgia/ joint pain	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
		Myalgia/ muscle pain	1	10SEP2020	2/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	1	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Nausea/ Nauseas	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Myalgia/ Muscle pain	2	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261643	GENRL	Injection site pain/ Pain at injection site#	3	07FEB2021	2/4	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261644	GENRL	Injection site pain/ Pain at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261647	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever (39 C)	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261649	GASTR	Nausea/ nausea	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1226 12261650	GENRL	Fatigue/ fatigue	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
		Pyrexia/ fever	1	11SEP2020	2/1	2	Yes		NA/TC	R (11SEP2020)	N/N
	INFEC	Urinary tract infection/ urinary tract infection	2	11OCT2020	12/7	1	No	O	NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1226 12261650	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261651	GENRL	Fatigue/ Fatigue	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	01OCT2020	2/4	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1226 12261653	GENRL	Injection site pain/ Pain at the injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261654	GENRL	Pyrexia/ Fever (38.7 C)	2	29SEP2020	1/2	2	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261655	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261656	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
16-55/ C4591001 1226 12261657	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261659	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261660	GENRL	Fatigue/ fatigue#	3	09FEB2021	2/1	1	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Pain/ body pain#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261661		Pyrexia/ fever#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site erythema/ erythema at the injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N
		Injection site pain/ pain at injection site	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	14SEP2020	4/3	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Fatigue/ Tiredness	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Pain in extremity/ Right arm pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1226 12261664	GENRL	Injection site pain/ pain at the injection site#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261665	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/1	2	Yes		NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261666	GENRL	Injection site pain/ Pain at the injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
		Asthenia/ Asthenia	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	1/2	1	Yes		NA/TC	R (02OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature (37.8 C)	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261667	GENRL	Injection site pain/ Injection site pain	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ chills#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261668	GENRL	Malaise/ malaise#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ headache#	3	07FEB2021	2/2	2	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261669	NERV	Headache/ Headache#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261670	GENRL	Injection site pain/ Pain at the injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.9	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
		Headache/ headache	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	RESP	Sneezing/ Sneezing	2	02NOV2020	32/2	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1226 12261672	GENRL	Injection site pain/ Pain at injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261673	GENRL	Fatigue/ fatigue	1	12SEP2020	1/5	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ pain at injection site	1	12SEP2020	1/5	2	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261674	GENRL	Injection site pain/ Pain at injection site#	3	07FEB2021	2/2	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261675	VASC	Hypertension/ Systemic arterial hypertension	1	19SEP2020	8/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261676	GENRL	Injection site pain/ Pain at the injection site#	3	05FEB2021	1/6	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261677	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1226 12261679	GENRL	Fatigue/ Fatigue	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ Chills	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261680	NERV	Injection site pain/ Pain at injection site	2	03OCT2020	2/2	3	Yes		NA/TC	R (04OCT2020)	N/N
		Headache/ headache	1	13SEP2020	2/1	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
		Myalgia/ Myalgia	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
NERV	Headache/ Headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1226 12261681	GENRL	Injection site pain/ pain at injection site	1	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N
	SURG	Vasectomy/ Vasectomy	2	23OCT2020	22/1	1	No	O	NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ mild headache#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	16-55/ C4591001 1226 12261682	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)
INV		Body temperature increased/ increased body temperature (37,5 C)#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261683	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	12SEP2020	1/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261685	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	2/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12261686	MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261687	MUSC	Myalgia/ myalgia#	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261688	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261689	MUSC	Pain in extremity/ Left arm pain	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Pyrexia/ fever (38C)#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261690	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/3	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261691		Pyrexia/ fever (38 C)	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ headache	2	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/4	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261693		Pyrexia/ Fever 38.6 C#	3	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	08FEB2021	1/2	2	Yes		NA/TC	R (09FEB2021)	N/N
	NERV	Headache/ headache#	3	08FEB2021	1/C	3	Yes		NA/TC	RG	N/N
16-55/ C4591001 1226 12261694	GENRL	Chills/ Chills#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
		Fatigue/ Tiredness#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261695	INV	Body temperature increased/ Increased oral temperature 37,8 C	2	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	2	05OCT2020	4/7	1	No	O	NA/TC	R (11OCT2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	2	04JAN2021	95/6	1	No	O	NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1226 12261696	GENRL	Injection site pain/ pain at injection site	1	12SEP2020	1/2	2	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	12SEP2020	1/2	3	Yes		NA	R (13SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261697	NERV	Headache/ Headache	1	12SEP2020	1/2	3	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	13SEP2020	2/1	2	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261698	GENRL	Pain/ Body ache#	3	06FEB2021	1/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261699	GASTR	Diarrhoea/ Diarrhea	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12261703	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ Chills	2	06OCT2020	2/1	2	Yes		NA	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06OCT2020	2/1	2	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1226 12261704	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261705	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature (37.5C)#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	GASTR	Abdominal pain/ Colic abdominal pain	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)	N/N
			Diarrhoea/ Diarrhea	1	16SEP2020	3/2	1	Yes		NA/TC	R (17SEP2020)
16-55/ C4591001 1226 12261706	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.9 C#	4	14FEB2021	2/1	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001	RESP	Oropharyngeal pain/ Sore throat	2	06OCT2020	2/2	1	No	O	NA/TC	R (07OCT2020)	N/N
	GENRL	Pyrexia/ fever (37,8 C)	2	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261707	BLOOD	Lymphadenopathy/ axillary lymphadenopathy in the left arm	2	06OCT2020	2/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261710	INFEC	Cystitis/ cystitis	1	18SEP2020	5/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ headache#	3	09FEB2021	1/5	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261711	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	2/5	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261712	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1226 12261713	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	01FEB2021	120/C		No	O	NA	UNK	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Axillary adenomegaly	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261714	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	2/2	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261715	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	2	Yes		NA/TCN	R (16SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
		Pyrexia/ Fever (38.5 C)	2	05OCT2020	1/2	2	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12261716	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261717	GENRL	Injection site erythema/ Erythema at the injection site	2	07OCT2020	3/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261717	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/3	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261718	NERV	Headache/ Headache	1	23SEP2020	10/1	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1226 12261719	GENRL	Injection site pain/ Pain at injection site#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1226 12261720	INV	Body temperature increased/ Body temperature elevated 37.8 C	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1226 12261721	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/3	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261721	GENRL	Injection site erythema/ Hyperemia at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261724	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261725	GENRL	Chills/ Chills#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
1226 12261725	NERV	Paraesthesia/ Paresthesia in lower limbs#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261726	GENRL	Injection site erythema/ Erythema at injection site	1	15SEP2020	1/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261729	GENRL	Chills/ chills	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
1226 12261729	NERV	Headache/ headache	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261730	GENRL	Injection site pain/ Pain at the injection site	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
1226 12261730	MUSC	Myalgia/ Muscle pain	1	16SEP2020	2/2	2	Yes		NA/TC	R (17SEP2020)	N/N
	PSYCH	Insomnia/ Insomnia	1	16SEP2020	2/4	2	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Arthralgia/ Joint pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261731	GASTR	Myalgia/ Muscle pain	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
		Diarrhoea/ diarrhea	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	12FEB2021	1/4	1	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1226 12261733	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	3/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261737	GASTR	Dysphagia/ SWALLOWING DIFFICULT	2	23OCT2020	18/2	1	No	O	NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site*		15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ headache	1	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Pyrexia/ Fever 38 C#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	27FEB2021	4/2	1	Yes		NA	R (28FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261740	MUSC	Myalgia/ muscle pain#	3	27FEB2021	4/2	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1226 12261741	GENRL	Chills/ Chills	1	16SEP2020	1/1	2	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ Fever (38,5 C)	1	16SEP2020	1/1	2	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/3	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	2/1	2	Yes		NA	R (17SEP2020)	N/N
	SKIN	Urticaria/ Urticaria localised (neck and forearm plaques, 1 plaque in each of these locations)	1	19SEP2020	4/11	1	No	O	NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261742	GENRL	Pyrexia/ fever (39.5 C)	2	07OCT2020	2/1	3	Yes		NA/TC	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261743 16-55/ C4591001	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N
1226 12261745 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	2/2	1	Yes		NA/TC	R (18SEP2020)	N/N
1226 12261746	GENRL	Fatigue/ Fatigue	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
		Pyrexia/ Fever 38.5	2	07OCT2020	2/1	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261747	GENRL	Injection site erythema/ erythema at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ pain at injection site	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261748	GENRL	Chills/ Chills#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site erythema/ Erythema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261751		Injection site oedema/ edema at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	18SEP2020	3/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Arthralgia/ joint pain in hands	2	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Joint swelling/ joint swelling in hands	2	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261752	GENRL	Injection site swelling/ Swelling at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261753	NERV	Headache/ Headache	1	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261754	GENRL	Fatigue/ tiredness#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ fever (38.2C)#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261756	GENRL	Injection site pain/ Pain at the injection site#	3	07FEB2021	2/4	2	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261759	GASTR	Diarrhoea/ diarrhea	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ pain at injection site	1	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261760	GENRL	Injection site oedema/ edema at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261761	GENRL	Injection site pain/ pain at the injection site#	3	23JAN2021	1/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12261763	GENRL	Injection site pain/ Pain at the injection site	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261764	GENRL	Injection site pain/ Pain at the injection site	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261765	NERV	Headache/ Headache	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261766	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever 38.7 C	2	08OCT2020	2/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261767	GENRL	Fatigue/ Fatigue	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/3	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ tiredness#	4	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ pain at the injection site#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261768	GENRL	Chills/ Chills	1	17SEP2020	1/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261769	GENRL	Injection site pruritus/ Pruritus at the injection site	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N
	INFEC	Postoperative wound infection/ surgical site infection (Flank)	2	03NOV2020	28/39	3	No	O	NA/TC	R (11DEC2020)	Y/N
16-55/ C4591001 1226 12261770	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/4	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1226 12261771	GENRL	Fatigue/ Tiredness	1	17SEP2020	1/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1226 12261773	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	2	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261775	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	2	Yes		NA/TC	R (14FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Ipsilateral axillary lymph node enlargement#	3	15FEB2021	3/3	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261776	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261778	GENRL	Pyrexia/ Fever (38.5 C)	1	17SEP2020	1/1	2	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1226 12261779	NERV	Headache/ Headache	1	19SEP2020	3/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	17OCT2020	11/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1226 12261780	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261781	GENRL	Injection site pain/ pain at the injection site#	3	03MAR2021	1/5	1	Yes		NA	R (07MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261784	GENRL	Fatigue/ fatigue#	3	04MAR2021	2/4	1	Yes		NA	R (07MAR2021)	N/N
	METAB	Decreased appetite/ loss of appetite#	3	04MAR2021	2/4	1	Yes		NA	R (07MAR2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	2/8	2	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Pyrexia/ fever (38.4C)	2	08OCT2020	2/1	2	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261790	GENRL	Injection site erythema/ erythema at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	17SEP2020	1/12	2	Yes		NA	R (28SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	METAB	Decreased appetite/ inapetence	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261791	GENRL	Fatigue/ fatigue	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Pyrexia/ fever (38 C)	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261792	MUSC	Myalgia/ muscle pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	2/3	1	Yes		NA	R (28JAN2021)	N/N
	BLOOD	Lymphadenopathy/ (left) axillary lymph node enlargement#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261794	GENRL	Pain/ body pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Nausea/ nausea#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Fatigue/ tiredness#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
		Pain/ body pain#	4	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261795	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	1/5	2	Yes		NA	R (11OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38.1 C	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1226 12261796	GENRL	Injection site pain/ Pain at the injection site	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Asthenia/ Weakness	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INV	Body temperature increased/ Increased body temperature 37.5 C#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	INJ&P	Contusion/ BRUISING ON THE FOREHEAD#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N
		Facial bones fracture/ Nose fracture#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N
		Skin laceration/ Cut on the forehead#	3	14FEB2021	20/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261797 16-55/ C4591001 1226 12261800	GENRL	Chills/ chills	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Injection site erythema/ erythema at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ pain at injection site	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
		Pyrexia/ fever	1	17SEP2020	1/3	1	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	17SEP2020	1/6	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1226 12261801	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	1/4	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261802	GENRL	Fatigue/ Fatigue	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	5/1	2	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	2	Yes		NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261803	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ chills#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1226 12261806	GENRL	Chills/ Chills	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	METAB	Decreased appetite/ Inapetence	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	MUSC	Myalgia/ Muscular pain	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever 38.2 C	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261807	GENRL	Injection site pain/ Pain at injection site#	3	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N
	INFEC	Cystitis/ Cystitis#	3	09MAR2021	18/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever (38.1 C)	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261809	GENRL	Pyrexia/ Fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1226 12261810	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	3/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
		Pyrexia/ Fever 39 C#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pain#	4	19FEB2021	7/3	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12261812	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	2/3	2	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261813	GENRL	Fatigue/ Fatigue#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Pain at injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261815	GENRL	Injection site pain/ Pain at injection site	2	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261819 16-55/ C4591001 1226 12261820 16-55/ C4591001 1226 12261821 16-55/ C4591001 1226 12261823		Pyrexia/ Fever (38 C)	2	08OCT2020	1/3	1	Yes		NA/TC	R (10OCT2020)	N/N
	GASTR	Abdominal pain upper/ epigastric pain	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
		Diarrhoea/ diarrhea	2	09OCT2020	2/4	2	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ headache	2	09OCT2020	2/6	2	Yes		NA/TC	R (14OCT2020)	N/N
	SKIN	Skin lesion/ pruritic erimatosus lesions on the face	2	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N
	INV	Body temperature increased/ Body temperature increased 37.3 C	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/1	1	Yes		NA	R (24JAN2021)	N/N
	RESP	Rhinorrhoea/ runny nose	1	28SEP2020	11/1	1	No	O	NA	R (28SEP2020)	N/N
	GENRL	Pain/ body pain#	3	06FEB2021	1/4	2	Yes		NA/TC	R (09FEB2021)	N/N
GENRL	Fatigue/ fatigue#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261824	MUSC	Arthralgia/ joint pain#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N
		Myalgia/ muscle pain#	4	28FEB2021	2/3	1	Yes		NA/TC	R (02MAR2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ chills	2	08OCT2020	1/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261826	GENRL	Fatigue/ fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Pyrexia/ Fever 38 C	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261827	MUSC	Myalgia/ muscle pain	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	1	18SEP2020	1/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	09OCT2020	2/1	2	Yes		NA/TC	R (09OCT2020)	N/N
	SKIN	Pityriasis rosea/ Pityriasis rosea	2	20NOV2020	44/C	1	No	O	NA	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261828	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261830	GENRL	Injection site pain/ pain at the injection site#	3	07FEB2021	2/2	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261831	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	1/3	2	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1226 12261833	GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261835	MUSC	Arthralgia/ Joint pain	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
		Myalgia/ Myalgia	1	19SEP2020	2/4	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	2	NOV2020	24/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261836	PSYCH	Anxiety/ Anxiety	2	10NOV2020	33/C	2	No	O	NA/TC	RG	N/N
	GENRL	Fatigue/ Fatigue#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
	CARD	Supraventricular tachycardia/ Supraventricular tachycardia#	3	11FEB2021	20/1	2	No	O	NA/TC	R (11FEB2021)	N/N
	INJ&P	Road traffic accident/ automobile accident (driver)#	3	11FEB2021	20/1	2	No	O	NA	R (11FEB2021)	N/N
	NERV	Loss of consciousness/ Loss of consciousness#	3	11FEB2021	20/1	3	No	O	NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	21/2	3	No	O	NA/TC	R (13FEB2021)	Y/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ fever (37,8 C)#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261838	GENRL	Pyrexia/ Fever(39 C)	2	08OCT2020	1/3	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261839	GENRL	Fatigue/ fatigue	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
		Injection site erythema/ erythema at the injection site	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261840	MUSC	Myalgia/ Muscle pain	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
	MUSC	Myalgia/ myalgia	2	07OCT2020	1/3	2	Yes		NA/TC	R (09OCT2020)	N/Y
	GASTR	Abdominal pain/ Intermittent abdominal colic	2	24OCT2020	17/7	1	No	O	NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	2/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	10OCT2020	3/1	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	06FEB2021	1/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261846	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Asthenia/ asthenia	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	24SEP2020	7/1	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1226 12261847	GENRL	Injection site pain/ pain at injection site	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1226 12261848	GENRL	Chills/ Chills#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1226 12261850	GENRL	Pain/ Body ache#	4	17FEB2021	1/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261852	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261853	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Pain at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever 38 C	2	09OCT2020	1/3	2	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1226 12261854	GENRL	Injection site pain/ Pain at the injection site	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N
		Malaise/ Malaise	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/5	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261857	GENRL	Injection site pain/ Pain at the injection site#	3	06FEB2021	1/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261858		Injection site pain/ pain at injection site	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
	INV	Body temperature increased/ Increased body temperature (37.5)	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12261859	GENRL	Chills/ Chills#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261860	GENRL	Injection site erythema/ erythema at site injection	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ pain at injection site	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1226 12261863	GASTR	Abdominal pain upper/ Epigastric pain	1	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261864	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	10OCT2020	2/6	2	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/2	2	Yes		NA/TC	R (11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261865	NERV	Headache/ Headache	1	20SEP2020	2/4	2	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/5	2	Yes		NA	R (14OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
		Flatulence/ Flatulence	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
	MUSC	Arthralgia/ Generalized joint pain	2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N
Myalgia/ Muscle pain		2	12OCT2020	4/3	2	Yes		NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1226 12261866	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	09FEB2021	2/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1226 12261867	GENRL	Injection site pain/ Pain at injection site	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Fever (39 C)	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261868	GENRL	Injection site pain/ Pain at injection site	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1226 12261869	GENRL	Fatigue/ Fatigue	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	19SEP2020	1/1	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Neck pain/ Cervicalgia	1	08OCT2020	20/4	2	No	O	NA/TC	R (11OCT2020)	N/N
	GENRL	Pain/ Body ache	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/3	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261871	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	2	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	27JAN2021	2/1	2	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12261873	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261874	GENRL	Injection site pain/ Pain at injection site	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		Pyrexia/ Fever 38.1 C	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
		Injection site pain/ Pain at injection site#	3	23JAN2021	1/4	2	Yes		NA	R (26JAN2021)	N/N
		Fatigue/ Fatigue#	3	24JAN2021	2/2	1	Yes		NA	R (25JAN2021)	N/N
		Fatigue/ Tiredness#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261875	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Fatigue/ Fatigue	1	20SEP2020	2/2	1	Yes		NA	R (21SEP2020)	N/N
		Chills/ chills	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Fatigue/ fatigue	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1226 12261876	NERV	Injection site pain/ pain at injection site	2	09OCT2020	1/3	1	Yes		NA	R (11OCT2020)	N/N
		Headache/ Headache	1	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ pain at the injection site#	3	12FEB2021	1/3	2	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261877	NERV	Headache/ Headache	2	08NOV2020	31/1	1	No	O	NA/TC	R (08NOV2020)	N/N
	GASTR	Diarrhoea/ diarrhea#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261878	GENRL	Injection site pain/ pain at injection site	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever (38 C)	2	08OCT2020	1/2	2	Yes		NA/TC/TCN	R (09OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1226 12261880	GENRL	Pyrexia/ fever (38.4C)	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1226 12261881	GENRL	Injection site pain/ Pain at injection site	1	26SEP2020	2/1	2	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ diarrhea	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261882	GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1226 12261884	GASTR	Abdominal pain/ abdominal colic	1	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ Chills	1	25SEP2020	1/1	1	Yes		NA	R (25SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	1	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	19DEC2020	66/1	3	No	O	NA/TC	R (19DEC2020)	N/N
		Hemiparaesthesia/ Left hemiparesthesia	2	19DEC2020	66/1	3	No	O	NA/TC	R (19DEC2020)	N/N
16-55/ C4591001 1226 12261886	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261887	GENRL	Pyrexia/ Fever	1	25SEP2020	1/3	1	Yes		NA/TC	R (27SEP2020)	N/N
	INV	Body temperature increased/ Body temperature increased 37.5 C	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261888	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261889	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ chills#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ pain at injection site#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ fever (38 C)#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12261892	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261895	GENRL	Chills/ Chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1226 12261896	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	2/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261897	GENRL	Pyrexia/ Fever (39 C)#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1226 12261898	MUSC	Myalgia/ Muscle pain	2	16OCT2020	3/4	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001 1226 12261899	GENRL	Chills/ chills#	3	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
		Malaise/ Malaise#	3	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature#	3	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1226 12261900	GENRL	Injection site pain/ Pain at injection site	1	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Chills/ Chills	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Fatigue/ Fatigue	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1226 12261901	GENRL	Injection site pain/ Pain at injection site	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261902	GENRL	Injection site pain/ Pain at the injection site	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1226 12261904	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12261905	MUSC	Arthralgia/ Arthralgia in hands	2	15DEC2020	63/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1226 12261908	GENRL	Injection site pain/ Pain at the injection site	1	28SEP2020	1/2	2	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1226 12261912	GENRL	Injection site pain/ Pain at injection site	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	NERV	Headache/ Headache	1	28SEP2020	1/3	1	Yes		NA/TC	R (30SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	19OCT2020	22/4	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261914	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261917 16-55/ C4591001 1226 12261918	EYE	Keratitis/ Ocular keratitis	1	04OCT2020	7/8	1	No	O	NA/TC	R (11OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	24FEB2021	1/4	1	Yes		NA	R (27FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N
	METAB	Decreased appetite/ loss of appetite#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ headache#	3	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1226 12261919	GENRL	Injection site pain/ Pain at the injection site	2	19OCT2020	1/3	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Pain/ Body pain	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
		Pyrexia/ Fever	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	2/2	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261920	GASTR	Nausea/ Nausea	2	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	1	11OCT2020	14/2	1	No	O	NA	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261922	GENRL	Fatigue/ fatigue	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	NERV	Headache/ headache	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261923	GASTR	Diarrhoea/ Diarrhea	2	23OCT2020	3/3	2	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1226 12261925	MUSC	Myalgia/ Muscle pain#	3	14FEB2021	2/3	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261926	INFEC	Ear infection/ Left otitis#	4	09MAR2021	25/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12261928	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		Malaise/ Malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	2/3	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261929	NERV	Headache/ Headache	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261930	GENRL	Fatigue/ Fatigue	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Pain at the injection site	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1226 12261931	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261932	GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	1/2	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261933	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261934	GENRL	Injection site pain/ Pain at the injection site	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
			2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261935	NERV	Headache/ Headache	1	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Pain/ Body pain	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
		Pyrexia/ fever (38.2C)#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261936	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	21OCT2020	2/1	2	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261937	GENRL	Fatigue/ Fatigue	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261938	MUSC	Myalgia/ Muscle pain	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	NERV	Headache/ Headache	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site erythema/ redness at the injection site	2	05FEB2021	108/3	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1226 12261939		Injection site pain/ pain at the injection site	2	05FEB2021	108/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Chills/ chills	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ pain at injection site	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1226 12261940		Malaise/ malaise	1	29SEP2020	1/2	2	Yes		NA	R (30SEP2020)	N/N
	GENRL	Chills/ Chills	2	20OCT2020	1/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		Pyrexia/ Fever 39.5 C	2	20OCT2020	1/1	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1226 12261940	GENRL	Injection site pain/ Pain at injection site#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12261941	GENRL	Injection site pain/ pain at injection site	2	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261942	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	1	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	20OCT2020	1/5	2	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/5	2	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	2/2	2	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ myalgia	1	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	2/1	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1226 12261947	GENRL	Injection site pain/ Pain at injection site	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261950	GENRL	Malaise/ malaise	1	29SEP2020	1/2	1	Yes		NA/TC	R (30SEP2020)	N/N
		Fatigue/ fatigue	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature 37,8C	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/5	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Pyrexia/ Fever (38 C)	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
		Myalgia/ muscle pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ headache	1	01OCT2020	2/63	1	Yes		NA	R (02DEC2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
INV	Body temperature increased/ Increased body temperature (37.8 C)	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261953	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	2/1	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1226 12261954	GASTR	Diarrhoea/ Diarrhea	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Asthenia/ weakness	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ fatigue	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12261956	NERV	Headache/ Headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Chills/ chills	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261957	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261958	NERV	Headache/ Headache	2	21OCT2020	1/2	1	Yes	NA	R	(22OCT2020)	N/N
16-55/ C4591001 1226 12261959	GENRL	Injection site pain/ pain at the injection site#	3	10FEB2021	1/3	1	Yes	NA/TC	R	(12FEB2021)	N/N
16-55/ C4591001 1226 12261960	NERV	Headache/ Headache	1	03OCT2020	4/2	1	Yes	NA	R	(04OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	09FEB2021	1/2	1	Yes	NA	R	(10FEB2021)	N/N
	GENRL	Chills/ Chills#	4	12MAR2021	1/2	1	Yes	NA	R	(13MAR2021)	N/N
16-55/ C4591001 1226 12261961	GASTR	Nausea/ Nauseas	1	01OCT2020	2/2	1	Yes	NA	R	(02OCT2020)	N/N
	GENRL	Fatigue/ Tiredness	2	22OCT2020	2/1	1	Yes	NA	R	(22OCT2020)	N/N
16-55/ C4591001 1226 12261962	MUSC	Arthralgia/ joint pain	2	21OCT2020	1/2	2	Yes	NA/TC	R	(22OCT2020)	N/N
		Myalgia/ Myalgia	2	21OCT2020	1/2	2	Yes	NA/TC	R	(22OCT2020)	N/N
		Myalgia/ muscle pain	2	21OCT2020	1/2	2	Yes	NA/TC	R	(22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261963	NERV	Headache/ headache	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	SKIN	Linear erythematous lesions in the anterior thoracic region	2	22OCT2020	2/4	1	No	O	NA	R (25OCT2020)	N/N
	INFEC	Rhinitis/ Coryza	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C4591001 1226 12261964	RESP	Nasal congestion/ Nasal congestion	2	25OCT2020	5/1	1	No	O	NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261966	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	24OCT2020	2/2	1	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261967	GENRL	Injection site pain/ pain at injection site	1	30SEP2020	1/2	1	Yes		NA/TC	R (01OCT2020)	N/N
1226 12261968	NERV	Headache/ headache	1	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12261970	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12261971	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	NERV	Headache/ headache#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ headache#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Capsular contracture associated with breast implant/	1	08OCT2020	9/C	2	No	O	NA	RG	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1226 12261972		Capsular contracture in breast implants										
		Medical device site granuloma/ Granuloma in breast implants	1	08OCT2020	9/C	2	No	O	NA	RG	N/N	
16-55/ C4591001 1226 12261973	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
	MUSC	Myalgia/ myalgia#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261974	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N	
16-55/ C4591001 1226 12261975	GENRL	Pyrexia/ Fever 38.5 C	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1226 12261976	GENRL	Chills/ chills	2	22OCT2020	1/1	2	Yes		NA/TC	R (22OCT2020)	N/N	
		Injection site pain/ pain at injection site	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N	
16-55/ C4591001 1226 12261978	GENRL	Injection site pain/ Pain at injection site	1	01OCT2020	1/1	1	Yes		NA	R (01OCT2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261980	GENRL	Pyrexia/ Fever (38.5 C)	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ pain at the injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1226 12261981	GENRL	Fatigue/ Fatigue	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1226 12261983		Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	1/3	1	Yes		NA	R (25JAN2021)	N/N
GENRL	Injection site pain/ Pain at the injection site#	4	12FEB2021	1/7	1	Yes		NA/TC	R (18FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261987	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
		Injection site pain/ pain at the injection site#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12261988	GENRL	Injection site pain/ Pain at the injection site	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1226 12261989	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	2	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1226 12261992	GENRL	Injection site pain/ Pain at the injection site#	3	24JAN2021	2/2	1	Yes		NA/TC	R (25JAN2021)	N/N
	NERV	Headache/ Headache#	3	24JAN2021	2/2	1	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12261995	MUSC	Myalgia/ Muscle pain	1	02OCT2020	2/2	2	Yes		NA	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12261997	GENRL	Injection site pain/ Pain at the injection site#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12261998	GENRL	Injection site pain/ Pain at the injection site	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1226 12261999	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pyrexia/ Fever (38C)	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1226 12262000	CARD	Arrhythmia/ Arrhythmia	2	19NOV2020	29/3	1	No	O	NA	R (21NOV2020)	N/N
	GENRL	Chest pain/ Chest pain	2	19NOV2020	29/3	1	No	O	NA	R (21NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262001	INFEC	COVID-19/ COVID-19	2	20DEC2020	60/26	4	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N
	RENAL	Dysuria/ Dysuria	2	16FEB2021	118/C	1	No	O	NA/TC	RG	N/N
	GENRL	Malaise/ Malaise	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
		Pain/ Body pain	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ Fever 38.5 C	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1226 12262002	NERV	Headache/ Headache	2	23OCT2020	1/1	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
		Malaise/ malaise	1	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ headache	1	02OCT2020	2/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
NERV		Pain/ Body generalized pain	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N
		Headache/ Headache	2	23OCT2020	1/3	1	Yes		NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262003	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262007	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262008	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262010	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/1	2	Yes		NA/TC	R (25JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262011	GENRL	Asthenia/ Asthenia#	3	21FEB2021	2/4	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	3	21FEB2021	2/2	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12262012	GENRL	Injection site pain/ pain at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262013	GENRL	Fatigue/ fatigue	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12262014	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262015	GENRL	Fatigue/ fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ pain at injection site	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262015	GENRL	Injection site pain/ Paim at injection site	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001	GASTR	Toothache/ toothache	2	27OCT2020	7/7	2	No	O	NA/TC	R (02NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262016	NERV	Headache/ headache#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262017	GENRL	Injection site pain/ Pain at the injection site	2	21OCT2020	1/5	2	Yes		NA/TC	R (25OCT2020)	N/N
			2	21OCT2020	1/1	1	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site erythema/ Erythema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N
		Injection site oedema/ Edema at the injection site	2	22OCT2020	2/4	2	Yes		NA/TC	R (25OCT2020)	N/N
		Pyrexia/ Fever 38.7 C	2	22OCT2020	2/1	2	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262018	GENRL	Pyrexia/ fever (38 C)	2	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	2	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1226 12262019	MUSC	Arthralgia/ Joint pain in the right knee	1	04OCT2020	3/31	1	Yes		NA	R (03NOV2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills	1	02OCT2020	1/1	2	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262021	NERV	Headache/ headache	1	02OCT2020	1/3	2	Yes		NA	R (04OCT2020)	N/N
	MUSC	Arthralgia/ joint pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
	GASTR	Dyspepsia/ dyspepsia#	3	22FEB2021	10/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1226 12262023	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	02OCT2020	1/5	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	NERV	Headache/ headache#	3	01FEB2021	1/2	2	Yes		NA	R (02FEB2021)	N/N
	GENRL	Chills/ chills#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	02FEB2021	2/1	2	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ chills#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262024 16-55/ C4591001 1226 12262026	GENRL	Injection site pain/ Pain at the injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Chills/ Chills	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pyrexia/ Fever 39 C	2	23OCT2020	2/1	3	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/1	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/1	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1226 12262029	GASTR	Diarrhoea/ Diarrhea	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		Nausea/ Nausea	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1226 12262030	GASTR	Diarrhoea/ diarrhea#	3	16FEB2021	4/8	2	Yes		NA/TC	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262034	GENRL	Fatigue/ fatigue#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N
		Malaise/ unwell#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature (37,2 C)#	3	16FEB2021	4/5	2	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
		Malaise/ malaise	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
	NERV	Headache/ headache	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Pyrexia/ Fever 38.4 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1226 12262035	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA/TC	R (15FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262036	GENRL	Asthenia/ Asthenia	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
		Injection site pain/ Pain at injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Left axillary adenomegaly	2	29OCT2020	4/6	1	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1226 12262037	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	INV	Body temperature increased/ Body temperature increased 37.6 C	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1226 12262038	GENRL	Injection site pain/ pain at the injection site#	3	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	26JAN2021	2/1	2	Yes		NA	R (26JAN2021)	N/N
	GENRL	Chills/ chills#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ headache#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	04OCT2020	2/8	1	Yes		NA	R (11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262039	NERV	Headache/ Headache	1	04OCT2020	2/1	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	23OCT2020	2/8	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ headache	2	23OCT2020	2/8	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	12FEB2021	1/5	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262040	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/8	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	2	24OCT2020	2/7	2	Yes		NA/TC	R (30OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/7	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262041	MUSC	Myalgia/ Muscle pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262042	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/4	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/2	1	Yes		NA/TC	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262044	GENRL	Injection site pain/ Pain at injection site	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Tiredness	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
		Malaise/ Malaise	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/3	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Chills/ Chills	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	1	04OCT2020	2/4	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ pain at the injection site#	3	12FEB2021	1/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262046	GENRL	Pyrexia/ Fever (38,9 C)	2	26OCT2020	1/1	2	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1226 12262048	GASTR	Nausea/ nausea	1	04OCT2020	2/2	1	Yes		NA	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Neck pain/ Cervicalgia	2	26NOV2020	32/2	2	No	O	NA/TC	R (27NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	15FEB2021	1/2	2	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/1	2	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262049	GENRL	Pain/ Body ache	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	INV	Body temperature increased/ increased body temperature (37 C)	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1226 12262050	INV	Body temperature increased/ Increased body temperature (37.7 C)	2	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1226 12262051	GENRL	Injection site pain/ pain at injection site	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262052	VASC	Deep vein thrombosis/ Deep vein thrombosis in right lower limb	2	05JAN2021	72/9	2	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
	VASC	Venous thrombosis limb/ Vein thrombosis in right lower limb	2	14JAN2021	81/40	2	No	O	NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1226 12262056	GENRL	Fatigue/ Fatigue	2	27OCT2020	2/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1226 12262058	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/2	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	26OCT2020	1/3	1	Yes		NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262059	GASTR	Diarrhoea/ Diarrhea	1	03OCT2020	1/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
		Pyrexia/ fever (38 C)	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	MUSC	Pain in extremity/ arm pain	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ headache	2	26OCT2020	1/2	1	Yes		NA/TC	R (27OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262060	GENRL	Injection site pain/ Pain at the injection site	2	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262062	GASTR	Toothache/ Toothache	2	20NOV2020	26/7	2	No	O	NA/TC	R (26NOV2020)	N/N
	INJ&P	Tooth fracture/ Fracture of the lower right third molar	2	20NOV2020	26/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262063	GENRL	Injection site pain/ pain at the injection site#	3	08FEB2021	1/3	2	Yes		NA/TC	R (10FEB2021)	N/N
		Malaise/ malaise#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N
	INV	Body temperature increased/ increased body temperature#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N
	NERV	Somnolence/ somnia#	3	08FEB2021	1/3	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1226 12262064	GENRL	Injection site pain/ pain at injection site	1	03OCT2020	1/4	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	04OCT2020	2/2	2	Yes		NA	R (05OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262065	GENRL	Injection site pain/ Pain at injection site	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N
		Malaise/ Malaise	1	03OCT2020	1/2	2	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1226 12262067	MUSC	Pain in extremity/ Pain at right foot	1	10OCT2020	8/1	1	No	O	NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1226 12262068	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	10/2	2	No	O	NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	28OCT2020	1/1	2	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28OCT2020	1/1	2	Yes		NA/TC	R (28OCT2020)	N/N
		Injection site pain/ Pain at the injection site	2	28OCT2020	1/3	2	Yes		NA/TC	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/6	2	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 1226 12262071	NERV	Headache/ Headache	1	05OCT2020	1/1	1	Yes		NA/TC	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262072	GENRL	Pyrexia/ Fever 37.3 C	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	EYE	Eye pain/ retro eye pain	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12262075		Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ headache	1	05OCT2020	1/2	2	Yes		NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262076	MUSC	Myalgia/ muscle pain#	3	14FEB2021	2/2	2	Yes		NA	R (15FEB2021)	N/N
	GENRL	Injection site pain/ pain at injection site	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
	GASTR	Diarrhoea/ diarrhea	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N
		Pyrexia/ Fever 39.1 C	2	29OCT2020	2/2	2	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262078	GENRL	Injection site pain/ Pain at injection site#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262079	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
	GENRL	Chills/ Chills	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
		Pain/ Body ache	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262080	GENRL	Fatigue/ fatigue	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ headache	1	07OCT2020	3/3	2	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ fatigue#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
		Injection site pain/ Pain at the injection site#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/3	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the injection site	1	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262081	GENRL	Injection site pain/ Pain at injection site	2	27OCT2020	1/2	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1226 12262085	GENRL	Injection site pain/ injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1226 12262086	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1226 12262087	GENRL	Injection site pain/ Pain at injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262089	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N
	GASTR	Nausea/ Nausea	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N
		Malaise/ Malaise	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/1	1	Yes		NA/TC	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262090	GENRL	Chills/ Chills#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	MUSC	Arthralgia/ Arthralgia#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
	NERV	Headache/ Headache#	3	13FEB2021	1/4	2	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262092	GENRL	Chills/ chills#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	3	13FEB2021	1/2	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262095	GENRL	Injection site pain/ Pain at injection site	1	06OCT2020	1/3	2	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	07OCT2020	2/2	2	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	1	08OCT2020	3/26	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C4591001 1226 12262096	GENRL	Fatigue/ Fatigue#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ Increased body temperature 37.5 C#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Arthralgia/ Joint pain#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	3	14FEB2021	2/4	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1226 12262099	MUSC	Arthralgia/ Joint pain in elbows	1	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1226 12262103	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
	MUSC	Back pain/ Low back pain#	3	25FEB2021	13/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12262104	GENRL	Injection site pain/ pain at injection site	1	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ fever (38 C)	1	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	28OCT2020	1/1	1	Yes		NA/TC	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	29OCT2020	2/1	1	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
	GENRL	Chills/ Chills	2	30OCT2020	3/1	1	Yes		NA	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262105	MUSC	Costochondritis/ Costochondritis in the sternal region	2	30OCT2020	3/1	3	No	O	NA	R (30OCT2020)	N/N
	NERV	Headache/ Headache	1	15OCT2020	9/4	1	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1226 12262106	EAR	Ear pain/ (right) ear pain	2	15NOV2020	17/5	1	No	O	NA/TC	R (19NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262107	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux disease	1	16OCT2020	9/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1226 12262108	GENRL	Injection site pain/ Pain at the injection site#	3	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262110	MUSC	Myalgia/ muscle pain#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ headache#	3	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262110	GENRL	Injection site pain/ Pain at the injection site	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle pain	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	1	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	30OCT2020	2/1	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262111	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
	NERV	Somnolence/ somnolence#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262112	GENRL	Pyrexia/ fever	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	INJ&P	Wound/ piercing-sharp accident	1	17OCT2020	10/2	1	No	O	NA/TC	R (18OCT2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.6 C	2	29OCT2020	2/2	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 1226 12262113	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	INV	Body temperature increased/ Body temperature elevated 37.3 C	1	09OCT2020	2/2	2	Yes		NA	R (10OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262114	GENRL	Pyrexia/ Fever (39 C)	2	30OCT2020	1/2	2	Yes		NA/TC	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	14FEB2021	2/2	1	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262115		Pyrexia/ fever (38.5C)#	4	14FEB2021	2/1	2	Yes		NA/TC	R (14FEB2021)	N/N
	MUSC	Myalgia/ myalgia#	4	14FEB2021	2/2	2	Yes		NA/TC	R (15FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1226 12262117	GENRL	Chills/ Chills	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
		Fatigue/ Fatigue	2	28OCT2020	2/1	1	Yes		NA/TC	R (28OCT2020)	N/N
		Pyrexia/ Fever (38 C)	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
	MUSC	Myalgia/ muscle pain	1	10OCT2020	2/5	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Pyrexia/ fever (38.3 C)	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262119	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ headache#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262120	GENRL	Chills/ chills	1	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	29OCT2020	2/1	1	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1226 12262121	INFEC	Cystitis/ cystitis	1	20OCT2020	12/13	2	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262125	GENRL	Injection site pain/ pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262126	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	1/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/5	2	Yes		NA/TC	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever 39.6 C	1	10OCT2020	2/1	3	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N
		Myalgia/ Muscle pain	1	10OCT2020	2/4	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	2/4	2	Yes		NA	R (02NOV2020)	N/N
		Pyrexia/ Fever 39.8 C	2	30OCT2020	2/2	2	Yes		NA	R (31OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	30OCT2020	2/2	2	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1226 12262127	NERV	Headache/ Headache	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1226 12262128	MUSC	Myalgia/ Muscle pain	1	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/4	2	Yes		NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1226 12262129	REPRO	Pelvic pain/ Pelvic pain	1	13OCT2020	5/3	2	No	O	NA/TC	R (15OCT2020)	N/N
	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	04DEC2020	36/5	4	No	O	NA/TC	R (08DEC2020)	Y/N
	GENRL	Injection site pain/ Pain at the injection site#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262130	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	31OCT2020	2/4	2	Yes		NA	R (03NOV2020)	N/N
16-55/ C4591001 1226 12262131	GENRL	Injection site pain/ Pain at the injection site#	3	14FEB2021	2/2	2	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262133	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	INV	Body temperature increased/ increased body temperature (37.5C)#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	MUSC	Arthralgia/ arthralgias#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
	NERV	Headache/ headache#	4	06MAR2021	2/2	1	Yes		NA	R (07MAR2021)	N/N
16-55/ C4591001 1226 12262135	GENRL	Fatigue/ Fatigue	1	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262137 16-55/ C4591001 1226 12262138 16-55/ C4591001 1226 12262141	GENRL	Injection site pain/ Pain at the injection site	2	30OCT2020	1/2	1	Yes		NA	R (31OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	11OCT2020	3/2	1	Yes		NA/TC	R (12OCT2020)	N/N
	GENRL	Injection site erythema/ Redness at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	13OCT2020	1/3	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Chills/ Chills	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature (37.7 C)	1	14OCT2020	2/2	2	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	2/1	1	Yes		NA	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	2/1	1	Yes		NA/TC	R (04NOV2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	2/2	2	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262144	NERV	Headache/ headache#	3	16FEB2021	2/2	2	Yes	NA	NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12262146	MUSC	Arthralgia/ joint pain	1	16OCT2020	4/7	1	Yes	NA	NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262149	GENRL	Injection site pain/ Pain at injection site	2	12NOV2020	1/2	1	Yes	NA	NA	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262149	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/2	2	Yes	NA	NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262151	GENRL	Injection site pain/ Pain at injection site#	3	13FEB2021	1/2	2	Yes	NA	NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262151	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/1	1	Yes	NA	NA	R (14OCT2020)	N/N
16-55/ C4591001 1226 12262151	GENRL	Chills/ Chills	2	03NOV2020	1/3	1	Yes	NA/TC	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262153	GENRL	Injection site pain/ Pain at the injection site	2	03NOV2020	1/3	1	Yes	NA/TC	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262153	NERV	Headache/ Headache	2	03NOV2020	1/3	1	Yes	NA/TC	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262153	MUSC	Myalgia/ Muscle pain	2	03NOV2020	1/3	1	Yes	NA/TC	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	03NOV2020	1/3	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262157	GENRL	Injection site pain/ pain at the injection site#	3	14FEB2021	2/3	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262159	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/3	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1226 12262162	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262163	GENRL	Injection site pain/ Pain at the injection site	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	1	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262164	MUSC	Myalgia/ Myalgia	2	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262165	GENRL	Injection site pain/ pain at the injection site#	3	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262169	GENRL	Malaise/ Malaise#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1226 12262170	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	2/2	2	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	GENRL	Chills/ Chills	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
		Fatigue/ Fatigue	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	04NOV2020	2/1	2	Yes		NA	R (04NOV2020)	N/N
	NERV	Headache/ Headache	2	04NOV2020	2/1	2	Yes		NA/TC	R (04NOV2020)	N/N
16-55/ C4591001 1226 12262182	EYE	Vitreous detachment/ Vitreous detachment	2	10JAN2021	68/16	2	No	O	NA/TC	R (25JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at the injection site#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262183 16-55/ C4591001 1226 12262184	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/4	2	Yes		NA/TC	R (17OCT2020)	N/N
1226 12262184 16-55/ C4591001 1226 12262185	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/1	1	Yes		NA	R (05NOV2020)	N/N
1226 12262185 16-55/ C4591001 1226 12262186	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/3	2	Yes		NA	R (16OCT2020)	N/N
1226 12262186 16-55/ C4591001 1226 12262187	GENRL	Injection site pain/ Pain at injection site	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
1226 12262187 16-55/ C4591001 1226 12262188	GENRL	Injection site pain/ Pain at injection site	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
1226 12262188 16-55/ C4591001 1226 12262189	GENRL	Injection site pain/ Pain at the injection site	2	04NOV2020	1/1	1	Yes		NA	R (04NOV2020)	N/N
1226 12262189 16-55/ C4591001 1226 12262190	NERV	Syncope/ Lipothymia(Syncope)	2	02DEC2020	29/1	1	No	O	NA	R (02DEC2020)	N/N
1226 12262190 16-55/ C4591001 1226 12262191	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
1226 12262191 16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	28JAN2021	1/2	2	Yes		NA/TC	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262193	GENRL	Fatigue/ fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ fever (38C)#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ muscle pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1226 12262195	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262196	GASTR	Toothache/ Toothache	2	18JAN2021	76/7	1	No	O	NA/TC	R (24JAN2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	22FEB2021	1/4	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262198	GENRL	Chills/ chills	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ pain at injection site	1	15OCT2020	1/5	1	Yes		NA	R (19OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Somnolence/ somnolence	1	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ chills	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
		Injection site pain/ pain at injection site	2	04NOV2020	1/4	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ fever (38 C)	2	04NOV2020	1/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Somnolence/ somnolence	2	04NOV2020	1/4	2	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262199	GENRL	Fatigue/ Fatigue#	3	13FEB2021	1/4	1	Yes		NA/TC	R (16FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	13FEB2021	1/4	1	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262201	GENRL	Chills/ chills	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
		Injection site pain/ pain at injection site	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ muscle pain	2	04NOV2020	1/2	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262205	GENRL	Injection site pain/ Pain at the injection site	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262206	GENRL	Asthenia/ Asthenia	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262208	NERV	Headache/ Headache	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	17FEB2021	2/3	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1226 12262209	GENRL	Pyrexia/ Fever 38.2 C	2	05NOV2020	2/1	1	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262211	GENRL	Injection site pain/ Pain at injection site	1	15OCT2020	1/1	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
		Pain/ Body pain#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever 38 C#	3	19FEB2021	1/3	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262212	MUSC	Myalgia/ muscle pain	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262216	GENRL	Injection site pain/ Pain at the injection site#	3	13FEB2021	1/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1226 12262218	GENRL	Injection site pain/ Pain at the injection site#	3	14FEB2021	2/2	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1226 12262219	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Asthenia/ weakness	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
	NERV	Headache/ headache	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262220	GENRL	Injection site pain/ Pain at the injection site	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
	NERV	Headache/ Headache	1	15OCT2020	1/5	2	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262221	MUSC	Myalgia/ Muscle pain (lower limbs)#	3	29JAN2021	3/6	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Chills/ chills#	4	16FEB2021	2/1	3	Yes		NA/TC	R (16FEB2021)	N/N
		Pyrexia/ fever (38.5C)#	4	16FEB2021	2/1	2	Yes		NA/TC	R (16FEB2021)	N/N
16-55/ C4591001 1226 12262223	NERV	Headache/ headache	1	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
		Fatigue/ Fatigue#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262225	GENRL	Injection site pain/ Pain at injection site	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Malaise/ Malaise	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262226	RESP	Oropharyngeal discomfort/ Throat discomfort	2	21DEC2020	45/1	1	No	O	NA	R (21DEC2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1226 12262227	GENRL	Injection site pain/ pain at the injection site#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1226 12262228	NERV	Headache/ Headache	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	1/1	2	Yes		NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1226 12262230	SKIN	Skin lesion/ Pruritic Cutaneous Lesion (in the central region of the right arm next to the elbow)	2	28NOV2020	25/25	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001 1226 12262231	GASTR	Nausea/ Nausea	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/1	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Injection site pain/ Pain at injection site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262232	GENRL	Pain/ Body pain	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/3	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262233	GENRL	Injection site pain/ pain at the injection site#	3	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12262234	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	3/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262236	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262237	GENRL	Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262239	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	2	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
		Injection site pain/ Pain at the injection site	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 1226 12262241	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ pain at the injection site#	3	18FEB2021	1/4	1	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262242	GENRL	Injection site pain/ Pain at the injection site#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1226 12262243	GENRL	Injection site pain/ pain at injection site	1	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 1226 12262245	MUSC	Pain in extremity/ Pain in the arm	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262247	GENRL	Pyrexia/ fever (39 C)#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1226 12262249	GENRL	Malaise/ Malaise#	3	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262251	GENRL	Chills/ Chills	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/2	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262252	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262255†	MUSC	Myalgia/ muscle pain	1	19OCT2020	4/4	2	Yes		NA/TC	R (22OCT2020)	N/N
	GASTR	Nausea/ Nauseas	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Vomiting/ Vomiting	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
	GENRL	Chills/ Chills	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	06NOV2020	1/3	3	Yes		NA	R (08NOV2020)	N/N
		Pyrexia/ Fever 39 C	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	06NOV2020	1/3	3	Yes		NA/TC	R (08NOV2020)	N/N
16-55/ C4591001 1226 12262256	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1226 12262258	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262259	MUSC	Myalgia/ diffuse myalgia#	3	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1226 12262263	GENRL	Chills/ Chills	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262267	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
		Chills/ Chills	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	2/3	1	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ headache#	3	22FEB2021	3/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
		Pyrexia/ Fever 39 C	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
	BLOOD	Lymphadenopathy/ left axillary lymph node enlargement#	3	24JAN2021	2/4	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	3	24JAN2021	2/4	1	Yes		NA/TC	R (27JAN2021)	N/N
GENRL	Fatigue/ fatigue#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262273	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	17OCT2020	1/3	2	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262274	INFEC	Upper respiratory tract infection/ Upper airway infection	2	20DEC2020	45/53	1	No	O	NA/TC	R (10FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	19FEB2021	1/3	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262276	GENRL	Injection site pain/ Pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	07NOV2020	2/1	1	Yes		NA/TC	R (07NOV2020)	N/N
	INV	Body temperature increased/ Body Increased Temperature (37 C)	2	04FEB2021	91/1	1	No	O	NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	25JAN2021	1/4	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1226 12262278	MUSC	Myalgia/ muscle pain#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262279	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262283	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Pain at the injection site#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Pain at injection site#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/1	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1226 12262284	GENRL	Asthenia/ Asthenia	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
		Chills/ Chills	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
		Pyrexia/ Fever (38 C)	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
	INV	Body temperature increased/ Increased body temperature 37.8 C	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1226 12262286	GASTR	Diarrhoea/ Diarrhea	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262287	GENRL	Fatigue/ Fatigue	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
		Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	05NOV2020	1/3	2	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	1/3	2	Yes		NA/TC	R (07NOV2020)	N/N
	GENRL	Chills/ chills#	3	20FEB2021	1/1	2	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ headache#	3	20FEB2021	1/3	2	Yes		NA/TC	R (22FEB2021)	N/N
	GASTR	Vomiting/ vomit#	3	22FEB2021	3/1	2	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	NERV	Headache/ headache#	3	20FEB2021	1/3	1	Yes		NA/TC	R (22FEB2021)	N/N
	16-55/ C4591001 1226 12262291	GENRL	Injection site oedema/ edema at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)
		Injection site pain/ pain at injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
NERV		Tension headache/ intermittent tension headache	1	05NOV2020	20/2	1	Yes		NA/TC	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262292	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ Headache	1	17OCT2020	1/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1226 12262293	GENRL	Fatigue/ Fatigue	1	19OCT2020	3/3	1	Yes		NA	R (21OCT2020)	N/N
	INV	Body temperature increased/ Increased body temperature (37.2 C)	2	23NOV2020	18/1	1	No	O	NA	R (23NOV2020)	N/N
	GASTR	Nausea/ Nausea	2	29NOV2020	24/1	1	No	O	NA/TC	R (29NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
		Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	3	21FEB2021	2/1	2	Yes		NA/TC	R (21FEB2021)	N/N
		Pyrexia/ Fever 39 C#	3	21FEB2021	2/1	3	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262295	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	2	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/1	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Fever 38.3 C	2	06NOV2020	2/1	1	Yes		NA/TC	R (06NOV2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262297	GENRL	Fatigue/ Fatigue	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262298	GENRL	Injection site pain/ pain at the injection site#	3	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1226 12262299	GASTR	Nausea/ Nauseas	1	18OCT2020	2/3	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	18OCT2020	2/3	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever 38 C	2	11NOV2020	1/5	2	Yes		NA/TC	R (15NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/5	2	Yes		NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1226 12262301	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/4	2	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262303	MUSC	Myalgia/ myalgia#	3	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262304	GENRL	Injection site pain/ Pain at the injection site	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	1/3	1	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Pain at the injection site	2	05NOV2020	1/3	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1226 12262307	GENRL	Injection site pain/ Pain at the injection site	1	17OCT2020	1/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1226 12262309	GENRL	Injection site pain/ pain at the injection site#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262311	GENRL	Injection site pain/ Pain at the injection site#	3	23FEB2021	1/4	2	Yes		NA	R (26FEB2021)	N/N
	GENRL	Chills/ Chills#	3	26FEB2021	4/1	1	Yes		NA	R (26FEB2021)	N/N
		Pain/ Body pain#	3	26FEB2021	4/1	1	Yes		NA	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262314	GENRL	Injection site pain/ pain at the injection site#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12262315	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1226 12262316	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1226 12262317	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262318	GENRL	Fatigue/ Fatigue#	3	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Pyrexia/ Fever 38.7 C#	3	23FEB2021	2/2	2	Yes		NA/TC	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262319	GENRL	Chills/ Chills	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1226 12262320	GENRL	Injection site pain/ Pain at injection site#	3	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1226 12262321	GENRL	Chills/ Chills	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever (38.6C)	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262327	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
		Malaise/ Unspecified malaise	1	19OCT2020	1/3	2	Yes		NA	R (21OCT2020)	N/N
		Pyrexia/ Fever 38 C	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Muscle pain	1	19OCT2020	1/3	2	Yes		NA/TC	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	07NOV2020	1/4	2	Yes		NA/TC	R (10NOV2020)	N/N
		Pain/ Body pain	2	07NOV2020	1/4	2	Yes		NA/TC	R (10NOV2020)	N/N
	NERV	Headache/ Headache	2	07NOV2020	1/7	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262329	MUSC	Arthralgia/ Arthralgia (knees and ankles)	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1226 12262330	NERV	Somnolence/ Somnolence	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1226 12262331	GENRL	Chills/ Chills	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
		Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	08NOV2020	2/1	2	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12262334	NERV	Headache/ Headache	1	20OCT2020	2/1	1	Yes	NA	R (20OCT2020)	N/N	
	GENRL	Pain/ Body pain	2	12NOV2020	2/2	1	Yes	NA/TC	R (13NOV2020)	N/N	
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes	NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001	GENRL	Pain/ body aches	1	20OCT2020	2/4	1	Yes	NA/TC	R (23OCT2020)	N/N	
1226 12262335	GENRL	Injection site pain/ Pain at the injection site#	3	28JAN2021	1/2	1	Yes	NA	R (29JAN2021)	N/N	
1226 12262337	GENRL	Asthenia/ Asthenia#	4	19FEB2021	2/2	1	Yes	NA/TC	R (20FEB2021)	N/N	
		Injection site pain/ Pain at injection site#	4	19FEB2021	2/3	1	Yes	NA/TC	R (21FEB2021)	N/N	
		Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes	NA/TC	R (20FEB2021)	N/N	
16-55/ C4591001	GENRL	Pain/ body aches	1	21OCT2020	3/1	1	Yes	NA/TC	R (21OCT2020)	N/N	
1226 12262338	GENRL	Fatigue/ Fatigue	2	07NOV2020	1/2	1	Yes	NA	R (08NOV2020)	N/N	
	MUSC	Myalgia/ Muscle pain	2	07NOV2020	1/2	1	Yes	NA	R (08NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262340	GASTR	Diarrhoea/ Diarrhea	1	19OCT2020	1/1	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	08NOV2020	2/2	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C4591001 1226 12262341	GENRL	Fatigue/ Fatigue#	3	19FEB2021	1/6	1	Yes		NA/TC	R (24FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	19FEB2021	1/6	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever (38.5 C)#	3	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262346	GENRL	Injection site pain/ pain at the injection site#	3	22FEB2021	1/4	1	Yes		NA	R (25FEB2021)	N/Y
16-55/ C4591001 1226 12262347	GENRL	Fatigue/ Fatigue	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
		Injection site pain/ Pain at injection site	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1226 12262348	GENRL	Pyrexia/ Fever 38.3 C	1	23OCT2020	5/3	1	Yes		NA	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	3	29JAN2021	5/3	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1226 12262350	GENRL	Injection site pain/ Pain at the injection site	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	11NOV2020	1/3	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1226 12262351	GENRL	Injection site pain/ Pain at the injection site	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Asthenia/ Asthenia	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1226 12262353	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/2	2	Yes		NA	R (21FEB2021)	N/N
	NERV	Dizziness/ dizziness#	3	20FEB2021	1/1	2	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1226 12262354	GENRL	Injection site pain/ pain at the injection site#	3	20FEB2021	1/3	2	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1226 12262356	GENRL	Injection site pain/ Pain at injection site	2	19NOV2020	1/2	1	Yes		NA	R (20NOV2020)	N/N
	NERV	Syncope/ Vasovagal syncope	2	01DEC2020	13/1	2	No	O	NA/TCN	R (01DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262357	GENRL	Injection site pain/ Pain at the injection site	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	1/4	2	Yes		NA/TC	R (14NOV2020)	N/N
		Pyrexia/ Fever 39 C	2	11NOV2020	1/4	2	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1229 12291012	MUSC	Myalgia/ localised non specific myalgia	2	19OCT2020	5/9	1	No	CND	NA	R (27OCT2020)	N/N
16-55/ C4591001 1229 12291016	NERV	Hemiplegia/ Left Sided Hemiplegia#	4	10MAR2021	10/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1229 12291031	NERV	Headache/ Headache	1	28SEP2020	1/1	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1229 12291033	NERV	Headache/ Headache	2	03NOV2020	15/17	1	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1229 12291037	MUSC	Pain in extremity/ Mechanical Pain on left arm	2	25NOV2020	37/12	1	No	O	NA/TC	R (06DEC2020)	N/N
16-55/ C4591001	INFEC	Gingivitis/ Gingivitis	2	25OCT2020	5/5	1	No	O	NA/TC	R (29OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1229 12291059	GENRL	Injection site injury/ Soft tissue injury on left shoulder(injection site)	2	21OCT2020	1/8	1	Yes		NA/TC	R (28OCT2020)	N/N
1229 12291061	INFEC	Urinary tract infection/ Urinary tract infection	2	22OCT2020	2/4	1	No	O	NA/TC	R (25OCT2020)	N/N
1229 12291062	MUSC	Back pain/ Lower back pain	2	19NOV2020	30/8	1	No	O	NA/TC	R (26NOV2020)	N/N
1229 12291063†	VASC	Hypertension/ hypertension	1	09OCT2020	10/C	1	No	O	NA/TC	N	N/N
1229 12291064	NERV	Burning sensation/ Sensation of burning feet	1	11OCT2020	12/20	1	No	O	NA	R (30OCT2020)	N/N
1229 12291066	MUSC	Back pain/ Lower backache	2	01NOV2020	12/22	1	No	O	NA/TC	R (22NOV2020)	N/N
1229 12291083†	METAB	Diabetes mellitus/ Diabetes Mellitus	2	28DEC2020	68/C	4	No	O	NA	N	Y/N
	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1229 12291096†	GASTR	Gastrooesophageal reflux disease/ Reflux Oesophagitis	2	29OCT2020	7/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1229 12291104	GENRL	Peripheral swelling/ Painful Swelling Feet	1	12OCT2020	8/30	1	No	O	NA	R (10NOV2020)	N/N
16-55/ C4591001 1229 12291119	SKIN	Dermatitis allergic/ allergic dermatitis on left hand	2	06NOV2020	11/C	1	No	CND	NA/TC/TCN	N	N/N
16-55/ C4591001 1229 12291130†	PSYCH	Insomnia/ Insomnia	1	14OCT2020	8/19	1	No	O	NA	R (01NOV2020)	N/N
	INFEC	Folliculitis/ Folliculitis on head.	2	23NOV2020	27/17	1	No	O	NA/TC	R (09DEC2020)	N/N
16-55/ C4591001 1229 12291135†	SKIN	Urticaria/ Urticaria	2	20NOV2020	24/13	1	No	O	NA/TC	R (02DEC2020)	N/N
16-55/ C4591001 1229 12291141	NERV	Headache/ HEADACHE	2	17NOV2020	21/3	2	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1229 12291181†	NERV	Dizziness/ Dizziness	1	27OCT2020	16/3	1	No	O	NA	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1229 12291188	SKIN	Eczema/ Eczema-Neck	2	18NOV2020	17/25	1	No	O	NA/TC	R (12DEC2020)	N/N
16-55/ C4591001 1229 12291190	GENRL	Injection site reaction/ Left arm stiffness on injection side.	1	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1229 12291209	NERV	Migraine/ Worsening Migraine	1	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/Y
16-55/ C4591001 1229 12291215†	GASTR	Dyspepsia/ Heartburn	1	02NOV2020	20/7	1	No	O	NA/TC	R (08NOV2020)	N/N
16-55/ C4591001 1229 12291216	GASTR	Gastritis/ Gastritis	2	15NOV2020	12/41	1	No	O	NA/TC	R (25DEC2020)	N/N
16-55/ C4591001 1230 12301001	SKIN	Erythema/ Erythema medial aspect on Humerus Left upper extremity (not by injection site)	1	23SEP2020	1/7	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1230 12301011	INJ&P	Ankle fracture/ Broken Ankle	1	12OCT2020	20/22	1	No	O	NA/TC/TCN	R (02NOV2020)	N/N
16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1230 12301045†	MUSC	Myalgia/ New onset of muscle pain.#	3	08FEB2021	1/3	2	Yes		NA	R (10FEB2021)	N/Y
1230 12301047	MUSC	Myalgia/ New onset of muscle pain.#	3	29JAN2021	2/4	3	Yes		NA/TC	R (01FEB2021)	N/N
1230 12301057	GENRL	Injection site pain/ Pain at injection site.#	3	07FEB2021	11/14	2	Yes		NA	R (20FEB2021)	N/N
	GENRL	Peripheral swelling/ Swelling left upper arm.#	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ New onset of muscle pain.#	4	17FEB2021	2/4	2	Yes		NA	R (20FEB2021)	N/N
	MUSC	Arthralgia/ New onset of joint pain left upper wrist#	4	19FEB2021	4/15	3	Yes		NA/TC	R (05MAR2021)	N/N
16-55/ C4591001 1230 12301060	NERV	Headache/ Headache#	3	11FEB2021	1/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1230 12301077	MUSC	Myalgia/ Muscle pain in left arm.#	3	17FEB2021	1/2	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1230 12301114	MUSC	Myalgia/ Muscle pain in upper arms and legs.#	3	18FEB2021	2/1	2	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1230 12301129	GENRL	Fatigue/ Moderate Fatigue	1	08OCT2020	4/2	2	Yes		NA/TC	R (09OCT2020)	N/N
1230 12301129	NERV	Headache/ Severe Headache	1	08OCT2020	4/2	3	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1230 12301134	INJ&P	Thermal burn/ Burn Wound on Left forearm	1	23OCT2020	19/C	2	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1230 12301147	METAB	Hyperlipidaemia/ Hyper Lipidemia	2	22DEC2020	57/C	1	No	CND	NA/TC	N	N/N
16-55/ C4591001 1230 12301181	MUSC	Myalgia/ Muscle pain in left upper arm#	3	16FEB2021	1/2	2	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1230 12301211	RESP	Bronchospasm/ BRONCHOSPASM	2	13JAN2021	76/2	1	No	O	NA/TC	R (14JAN2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Generalized Muscle Pain	2	31OCT2020	2/3	3	Yes		NA/TC	R (02NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1230 12301214 16-55/ C4591001 1231 12311001	SKIN	Rash/ abdomen skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
		Rash/ back skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
		Rash/ both arms skin rash	2	17SEP2020	22/4	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1231 12311003	MUSC	Back pain/ mild low back pain	2	18SEP2020	23/14	1	No	O	NA/TC	R (01OCT2020)	N/N
	INFEC	Tooth infection/ Odontogenic infection#	3	25FEB2021	6/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1231 12311008	NERV	Headache/ Headache	2	19SEP2020	24/1	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C4591001 1231 12311027	NERV	Sciatica/ chronic lumbociatalgia exacerbated	1	25AUG2020	16/12	2	No	O	NA/TC	R (05SEP2020)	N/N
	INFEC	Soft tissue infection/ Right elbow soft tissue infection	1	03SEP2020	25/12	1	No	O	NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ MUSCLE PAIN IN BOTH UPPER LIMBS	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311036	INFEC	Tooth infection/ Upper molar infection	2	09SEP2020	8/8	1	No	O	NA/TC	R (16SEP2020)	N/N	
16-55/ C4591001 1231 12311043	PSYCH	Anxiety disorder/ Anxiety Disorder	2	26SEP2020	26/1	2	No	O	NA	R (26SEP2020)	N/N	
	INJ&P	Heat stroke/ insolation	2	01NOV2020	62/2	1	No	O	NA/TC	R (02NOV2020)	N/N	
16-55/ C4591001 1231 12311051	VASC	Hypertension/ high blood pressure	2	24SEP2020	24/1	1	No	O	NA/TC	R (24SEP2020)	N/N	
16-55/ C4591001 1231 12311052	INFEC	Tooth infection/ odontogenic infection	2	03SEP2020	3/29	2	No	O	NA/TCN	R (01OCT2020)	N/N	
	MUSC	Back pain/ low back pain	2	24OCT2020	54/7	1	No	O	NA	R (30OCT2020)	N/N	
16-55/ C4591001 1231 12311058	EAR	Deafness unilateral/ hearing loss in the left ear	2	27SEP2020	27/12	1	No	O	NA	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12311065	MUSC	Myalgia/ Myalgia	2	20OCT2020	50/2	1	No	O	NA/TC	R (21OCT2020)	N/N	
16-55/ C4591001	MUSC	Back pain/ Low back pain#	3	26JAN2021	2/1	1	No	O	NA	R (26JAN2021)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311072	REPRO	Metrorrhagia/ metrorrhagia#	3	30JAN2021	6/3	1	No	O	NA	R (01FEB2021)	N/N
16-55/ C4591001 1231 12311074	EAR	Tinnitus/ exacerbation of bilateral tinnitus.	1	30AUG2020	19/31	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1231 12311077	INJ&P	Tooth fracture/ BROKEN SECOND MOLAR	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1231 12311081	SURG	Dental care/ DENTAL TREATMENT	2	28SEP2020	28/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
16-55/ C4591001 1231 12311085	INFEC	Arthritis bacterial/ septic arthritis of the right knee.	2	13DEC2020	104/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311095	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	1	17AUG2020	6/64	2	No	O	NA/TC/TCN	R (19OCT2020)	N/N
16-55/ C4591001 1231 12311097	EYE	Chalazion/ Chalazion	2	03OCT2020	33/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311097	GASTR	Diarrhoea/ Diarrhea	1	23AUG2020	12/3	1	No	O	NA	R (25AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Diarrhoea/ Diarrhea	2	09SEP2020	8/1	1	No	O	NA/TCN	R (09SEP2020)	N/N
16-55/ C4591001 1231 12311105	GASTR	Dyspepsia/ dyspepsia	2	20SEP2020	19/9	1	No	O	NA	R (28SEP2020)	N/N
16-55/ C4591001 1231 12311109	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1231 12311112	VASC	Phlebitis superficial/ Superficial phlebitis of the left arm	2	11OCT2020	38/19	2	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1231 12311118	RENAL	Nephrolithiasis/ worsening of renal lithiasis	2	21NOV2020	79/7	3	No	O	NA/TC	R (27NOV2020)	Y/N
16-55/ C4591001 1231 12311121	MUSC	Myalgia/ Myalgia	1	19AUG2020	7/11	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C4591001 1231 12311126	INJ&P	Joint dislocation/ right shoulder dislocation	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N
		Road traffic accident/ MOTOR VEHICLE ACCIDENT	2	22SEP2020	22/1	3	No	O	NA/TC/TCN	RS (22SEP2020)	N/N
16-55/ C4591001	NERV	Peripheral nerve lesion/ Right index finger collateral nerve lesion	2	08OCT2020	37/63	3	No	O	NA/TC/TCN	R (09DEC2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311128 16-55/ C4591001	NERV	Headache/ headache	2	13SEP2020	11/3	1	No	O	NA/TC	R (15SEP2020)	N/N
1231 12311130 16-55/ C4591001	NERV	Dizziness/ Dizziness#	3	12MAR2021	4/2	1	No	O	NA	R (13MAR2021)	N/N
1231 12311135 16-55/ C4591001	INFEC	Genital herpes/ exacerbated genital herpes	2	27SEP2020	26/9	1	No	O	NA/TC/TCN	R (05OCT2020)	N/N
1231 12311141 16-55/ C4591001	INJ&P	Exposure during pregnancy/ Exposure during pregnancy (female partner)	1	07NOV2020	87/C		No	O	NA	UNK	N/N
1231 12311147 16-55/ C4591001	MUSC	Arthralgia/ Joint pain	2	10SEP2020	7/36	2	No	O	NA/TC	R (15OCT2020)	N/N
1231 12311152 16-55/ C4591001	MUSC	Arthralgia/ pain in right knee	2	07OCT2020	34/C	1	No	O	NA/TC	N	N/N
1231 12311164 16-55/ C4591001	GASTR	Abdominal pain/ Abdominal pain	2	02SEP2020	1/2	3	No	O	NA/TC/TCN	R (03SEP2020)	N/N
16-55/ C4591001	SKIN	Dermatitis bullous/ bullous lesion on right hand	2	30SEP2020	28/31	1	No	O	NA/TC	R (30OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311166	MUSC	Arthralgia/ Left shoulder arthralgia	2	20OCT2020	48/8	1	No	O	NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1231 12311176	INFEC	Tooth infection/ Dental infection	2	08SEP2020	5/7	1	No	O	NA/TC	R (14SEP2020)	N/N
	INJ&P	Tooth fracture/ Tooth fracture	2	08SEP2020	5/C	1	No	O	NA/TC	RG	N/N
	INFEC	Oral herpes/ Cold sores	2	31OCT2020	58/3	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C4591001 1231 12311183	GASTR	Toothache/ Toothache	2	27SEP2020	26/4	2	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12311191	INFEC	Cystitis/ Cystitis	1	09OCT2020	57/3	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1231 12311195	INFEC	Conjunctivitis/ Conjunctivitis	1	20AUG2020	7/2	1	No	O	NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1231 12311199	INFEC	Genital herpes simplex/ Genital herpes simplex type 2	2	16SEP2020	14/13	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001	INFEC	Tooth infection/ Odontogenic infection	2	26FEB2021	177/2	2	No	O	NA/TC/TCN	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311202	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/149	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N
1231 12311205	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	01JAN2021	120/38	1	No	O	NA/TC/TCN	RS (07FEB2021)	N/N
1231 12311207	SURG	Tooth extraction/ Lower right canine extraction	1	03SEP2020	21/3	1	No	O	NA/TC	R (05SEP2020)	N/N
1231 12311208	INJ&P	Fall/ Fall from his own height	1	19SEP2020	37/1	2	No	O	NA	R (19SEP2020)	N/N
1231 12311211	MUSC	Coccydynia/ Coccigodinia	1	19SEP2020	37/22	2	No	O	NA/TC/TCN	R (10OCT2020)	N/N
1231 12311229	CARD	Tachycardia/ tachycardia	2	06OCT2020	33/39	2	No	O	NA	R (13NOV2020)	N/N
1231 12311231	INFEC	Tooth infection/ dental infection	1	24AUG2020	11/7	2	No	O	NA/TC	R (30AUG2020)	N/N
1231 12311231	GENRL	Injection site pain/ injection site pain#	3	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311232	INFEC	Hordeolum/ stye in left eye#	3	21JAN2021	2/5	1	No	O	NA/TC	R (25JAN2021)	N/N
	GENRL	Asthenia/ asthenia#	3	22JAN2021	3/2	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ mild headache#	3	22JAN2021	3/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Asthenia/ asthenia#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N
		Chills/ chills#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N
	INV	Body temperature increased/ Increased body temperature#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgias#	4	11FEB2021	3/2	1	Yes		NA	R (12FEB2021)	N/N
		Myalgia/ myalgia#	4	11FEB2021	3/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1231 12311233	VASC	Hypertension/ exacerbation of arterial hypertension	2	15SEP2020	14/3	1	No	O	NA/TC/TCN	R (17SEP2020)	N/N
16-55/ C4591001 1231 12311238	GASTR	Odynophagia/ Odynophagia	2	16SEP2020	15/4	1	No	O	NA	R (19SEP2020)	N/N
	GENRL	Asthenia/ asthenia	2	16SEP2020	15/2	1	No	O	NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311243	SKIN	Rash pruritic/ pruritic rash	1	18AUG2020	5/4	2	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1231 12311246	MUSC	Back pain/ low back pain	2	31JAN2021	152/28	2	No	O	NA/TC	R (27FEB2021)	N/N
16-55/ C4591001 1231 12311248	EYE	Blepharitis/ Left blepharitis	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N
		Eyelid pain/ PAIN OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N
		Eyelids pruritus/ ITCHING OF THE UPPER LEFT EYELID	2	30SEP2020	27/10	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1231 12311251	MUSC	Intervertebral disc protrusion/ disc herniation L4-L5#	2	25JAN2021	144/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311281	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
	INV	Electrocardiogram QT prolonged/ QT interval prolongation	2	18SEP2020	15/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C4591001	INFEC	Pyelonephritis/ pyelonephritis	2	12SEP2020	6/9	3	No	O	NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311294	INJ&P	Bone fissure/ Fissure of left elbow bone	2	23OCT2020	47/37	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N
		Joint dislocation/ Dislocation of the left elbow	2	23OCT2020	47/37	1	No	O	NA/TC/TCN	R (28NOV2020)	N/N
	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	12DEC2020	97/33	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
16-55/ C4591001 1231 12311295	BLOOD	Lymphadenopathy/ Left axillary adenopathy	2	05SEP2020	3/16	1	Yes		NA/TC/TCN	R (20SEP2020)	N/N
	NERV	Tension headache/ Tension headache	2	05OCT2020	33/11	2	No	O	NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1231 12311301	RESP	Asthma/ Moderate asthma attack	1	26AUG2020	12/5	2	No	O	NA/TC	R (30AUG2020)	N/N
	GENRL	Asthenia/ Asthenia#	3	28JAN2021	1/7	2	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/4	3	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	28JAN2021	1/2	2	Yes		NA	R (29JAN2021)	N/N
	INFEC	Urinary tract infection/ urinary infection#	3	09FEB2021	13/9	1	No	O	NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1231 12311306	GENRL	Chest pain/ Self-limited oppressive chest pain	1	02SEP2020	19/1	1	No	O	NA	R (02SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311315	BLOOD	Anaemia/ anemia	2	25SEP2020	23/12	2	No	O	NA/TC	R (06OCT2020)	N/N
	NEOPL	Malignant melanoma/ Pigmented epithelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311334	INFEC	Genitourinary chlamydia infection/ Genital Chlamydia trachomatis infection	2	15FEB2021	162/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311336	INJ&P	Procedural dizziness/ Post blood extraction dizziness	2	07OCT2020	35/1	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12311338	GASTR	Gastrointestinal disorder/ Gastrointestinal syndrome	2	09SEP2020	3/2	2	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12311348	GENRL	Injection site pain/ Injection site pain*		15AUG2020	1/4	1	Yes		NA/TC	R (18AUG2020)	N/N
16-55/ C4591001 1231 12311352	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/9	3	No	O	NA	R (28AUG2020)	Y/N
	INFEC	Urinary tract infection/ high urinary infection	1	20AUG2020	6/71	2	No	O	NA/TC	R (29OCT2020)	N/N
	GASTR	Vomiting/ Vomiting	1	29AUG2020	15/4	1	No	O	NA	R (01SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311361	NERV	Paraesthesia/ Both upper limbs paresthesia	2	04SEP2020	1/1	1	No	O	NA	R (04SEP2020)	N/N
	PSYCH	Generalised anxiety disorder/ generalized anxiety	2	07OCT2020	34/48	1	No	O	NA/TC/TCN	R (23NOV2020)	N/N
	MUSC	Arthralgia/ Polyarthralgias	2	12OCT2020	39/43	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001 1231 12311375	MUSC	Myalgia/ Myalgia in the region of the shoulder and left shoulder blade	2	06SEP2020	4/1	2	Yes		NA/TC	R (06SEP2020)	N/N
	MUSC	Myalgia/ Myalgia of moderate intensity below the left shoulder blade	2	26SEP2020	24/1	2	No	O	NA/TC	R (26SEP2020)	N/N
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	01OCT2020	29/143	1	No	O	NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1231 12311387	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	2	07NOV2020	65/C		No	O	NA	UNK	N/N
	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
16-55/ C4591001 1231 12311388	NERV	Headache/ headache	1	16AUG2020	2/8	1	No	O	NA	R (23AUG2020)	N/N
	MUSC	Myalgia/ GENERALIZED MYALGIA	1	18AUG2020	4/7	1	Yes		NA	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ ARTHRALGIA	1	21AUG2020	7/4	1	No	O	NA	R (24AUG2020)	N/N
	SURG	Tooth extraction/ Programmed extraction of the right third molar	2	26SEP2020	24/1	1	No	CND	NA/TC/TCN	R (26SEP2020)	N/N
16-55/ C4591001 1231 12311402	NERV	Headache/ worsening headache	1	08OCT2020	55/2	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12311403	MUSC	Synovial cyst/ Right wrist ganglion	2	04NOV2020	60/42	1	No	O	NA/TC	R (15DEC2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	15JAN2021	1/3	2	Yes		NA/TC	R (17JAN2021)	N/N
16-55/ C4591001 1231 12311409	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N
	NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N
16-55/ C4591001 1231 12311410	REPRO	Amenorrhoea/ Amenorrhea	2	16SEP2020	11/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1231 12311412	MUSC	Musculoskeletal chest pain/ Torax pain. refered muscular. type opressive.	2	15SEP2020	1/52	2	No	O	NA	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311414	INFEC	Urinary tract infection/ urinary infection	1	30AUG2020	16/8	1	No	O	NA/TC	R (06SEP2020)	N/N
	SKIN	Rash/ Skin rash on the back (dorsal and lumbar area)	2	29OCT2020	56/1	1	No	O	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1231 12311418	GASTR	Inguinal hernia/ bilateral inguinal hernia	1	27AUG2020	13/2	2	No	O	NA	R (28AUG2020)	N/N
		Irritable bowel syndrome/ irritable bowel syndrome	1	27AUG2020	13/C	2	No	O	NA/TC/TCN	RG	N/N
	EYE	Eye pruritus/ Eye itching#	2	03FEB2021	153/7	1	No	O	NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1231 12311427	RESP	Bronchospasm/ Bronchospasm	2	08SEP2020	6/39	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12311428	GENRL	Pyrexia/ fever	2	18SEP2020	12/1	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C4591001 1231 12311436	GASTR	Diarrhoea/ diarrhea	2	30SEP2020	28/2	1	No	O	NA/TCN	R (01OCT2020)	N/N
16-55/ C4591001 1231 12311444	SKIN	Dermatitis contact/ contact dermatitis	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
		Rash maculo-papular/ non pruritic maculopapular cervical rash	1	19AUG2020	5/53	1	No	O	NA	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12311448	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	2	09NOV2020	64/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1231 12311465	RESP	Bronchospasm/ MILD BRONCHOSPASM	2	30SEP2020	28/2	1	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12311473	MUSC	Back pain/ low back pain	1	20AUG2020	6/2	1	No	O	NA/TC	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12311475	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	8/2	1	No	O	NA	R (23AUG2020)	N/N	
16-55/ C4591001 1231 12311479	METAB	Dyslipidaemia/ worsening of dyslipidemia	2	02JAN2021	121/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12311480	SKIN	Rash/ skin rash, left laterocervical region	2	27SEP2020	25/14	1	No	O	NA/TC	R (10OCT2020)	N/N	
16-55/ C4591001 1231 12311481	RESP	Rhinitis allergic/ Allergic rhinitis worsening#	3	30JAN2021	10/26	1	No	O	NA/TC	R (24FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311483 16-55/ C4591001 1231 12311492 16-55/ C4591001 1231 12311499 16-55/ C4591001 1231 12311507 16-55/ C4591001 1231 12311513	MUSC	Myalgia/ Generalized muscle pain#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	RESP	Rhinitis allergic/ allergic rhinitis	2	30SEP2020	28/1	1	No	O	NA/TC	R (30SEP2020)	N/N
	REPRO	Penile vein thrombosis/ Thrombosis of superficial vein of penis	2	14SEP2020	8/27	1	No	O	NA/TC	R (10OCT2020)	N/N
	INJ&P	Post procedural haemorrhage/ Bleeding after sampling	2	07OCT2020	31/1	1	No	O	NA/TCN	R (07OCT2020)	N/N
	MUSC	Plantar fasciitis/ PLANTAR FASCITIS	1	10SEP2020	26/120	1	No	O	NA/TC	R (07JAN2021)	N/N
	GENRL	Chills/ Chills	2	20OCT2020	30/54	2	No	O	NA/TC	R (12DEC2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	30/45	2	No	O	NA/TC	R (03DEC2020)	N/N
	INFEC	Vulvovaginal mycotic infection/ Vaginal mycosis	2	17SEP2020	11/3	1	No	O	NA/TC	R (19SEP2020)	N/N
	SURG	Tooth extraction/ Elective extraction of three third molars	2	03OCT2020	26/1	1	No	O	NA/TC	R (03OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311520	INFEC	Folliculitis/ Folliculitis in upper dorsal area and nape.	2	07NOV2020	62/12	1	No	O	NA/TC	R (18NOV2020)	N/N	
16-55/ C4591001 1231 12311530	PSYCH	Anxiety disorder/ Anxiety disorder	2	26OCT2020	49/3	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1231 12311532	VASC	Hypertension/ arterial hypertension	1	27AUG2020	12/4	1	No	O	NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12311538	INFEC	Gangrene/ Rightfoot transmetatarsal limited gangrene	2	03DEC2020	88/77	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N	
16-55/ C4591001 1231 12311544	GENRL	Chills/ chills	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site erythema/ Erythema at the injection site	2	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	04SEP2020	1/2	1	Yes		NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1231 12311548	EYE	Eyelid oedema/ unilateral bipalpebral edema	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N	
	SKIN	Pruritus/ Pruritus of the face and neck	2	09SEP2020	2/34	1	No	O	NA	R (12OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311550	BLOOD	Anaemia/ Anemia	2	17FEB2021	164/9	1	No	O	NA/TC	RS (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1231 12311556	GENRL	Asthenia/ Asthenia	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N
	INJ&P	Ligament rupture/ Rupture of the anterior cruciate ligament of the left knee	2	21NOV2020	76/75	2	No	O	NA/TCN	R (03FEB2021)	Y/N
		Meniscus injury/ Rupture of the external meniscus of the left knee	2	21NOV2020	76/75	2	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
16-55/ C4591001 1231 12311580	RESP	Rhinitis allergic/ Allergic rhinitis#	3	05MAR2021	14/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311584	INFEC	Conjunctivitis/ Conjunctivitis	2	16SEP2020	9/8	1	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1231 12311607	MUSC	Muscle contracture/ Left deltoid muscle contracture	2	01OCT2020	24/2	1	No	O	NA/TC	R (02OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311635	INJ&P	Exposure during pregnancy/ Drug exposed pregnancy ( female partner )	2	20NOV2020	78/		No	O	NA	R	N/N
	NEOPL	Benign hydatidiform mole/ Molar pregnancy in partner	2	JAN2021	120/	3	No	O	NA	R	Y/N
16-55/ C4591001 1231 12311638	MUSC	Neck pain/ cervical pain	2	04OCT2020	27/54	1	No	O	NA/TC	R (26NOV2020)	N/N
	PSYCH	Anxiety disorder/ Anxiety disorder	2	12OCT2020	35/29	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
		Depression/ Depression	2	12OCT2020	35/29	2	No	O	NA/TC/TCN	RS (09NOV2020)	N/N
16-55/ C4591001 1231 12311643	GASTR	Gastrooesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	10/6	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12311651	NERV	Dizziness/ Lipothymia Dizziness	1	17AUG2020	2/3	1	No	O	NA/TC/TCN	R (19AUG2020)	N/N
	INFEC	Urinary tract infection/ urinary infection#	3	09FEB2021	13/8	1	No	O	NA/TC	R (16FEB2021)	N/N
	PSYCH	Anxiety/ Anxiety#	3	15FEB2021	19/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311653	CARD	Palpitations/ worsening heart palpitations	2	SEP2020	1/	1	No	O	NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ Fever	2	08SEP2020	2/1	3	Yes		NA/TC	R (08SEP2020)	N/N
	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N
		Hypocalcaemia/ Hypocalcemia	2	28SEP2020	22/19	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12311660	RESP	Dyspnoea/ Dyspnea	1	22AUG2020	7/2	1	No	O	NA	R (23AUG2020)	N/N
16-55/ C4591001 1231 12311661	GENRL	Injection site pain/ pain at the injection site	2	27SEP2020	21/10	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Peripheral swelling/ swelling in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N
	INJ&P	Contusion/ bruise in the left arm	2	29SEP2020	23/8	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1231 12311683	GENRL	Pyrexia/ fever	2	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1231 12311686	GASTR	Haemorrhoids/ hemorrhoids	2	21SEP2020	14/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311689	GENRL	Oedema peripheral/ Left ankle Edema	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ pain in the left ankle	1	01SEP2020	16/63	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C4591001 1231 12311691	NERV	Headache/ Headache#	3	05FEB2021	12/1	2	No	O	NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1231 12311701	GASTR	Dyspepsia/ Dyspepsia	1	17AUG2020	1/8	3	Yes		NA/TC/TCN	R (24AUG2020)	N/N
16-55/ C4591001 1231 12311711	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N
16-55/ C4591001 1231 12311712	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	16/1	1	No	O	NA/TCN	R (23SEP2020)	N/N
16-55/ C4591001 1231 12311714	REPRO	Genital erythema/ Nonspecific glans erythema	2	24SEP2020	18/2	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1231 12311719	NERV	Headache/ headache	2	07SEP2020	1/3	2	Yes		NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1231 12311724	INFEC	Rhinitis/ rhinitis	1	19AUG2020	3/8	1	No	O	NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Rhinitis allergic/ allergic rhinitis	2	02OCT2020	26/2	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C4591001 1231 12311730	NEOPL	Invasive ductal breast carcinoma/ Right breast invasive ductal carcinoma	2	15NOV2020	70/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1231 12311731	NERV	Headache/ HEADACHE	1	05SEP2020	20/2	2	No	O	NA/TC/TCN	R (06SEP2020)	N/N
	NERV	Headache/ headache	2	03OCT2020	26/1	2	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1231 12311734	GASTR	Dyspepsia/ Dyspepsia	2	22OCT2020	46/3	1	No	O	NA	R (24OCT2020)	N/N
16-55/ C4591001 1231 12311735	INJ&P	Fall/ Bicycle fall	2	04FEB2021	151/1	1	No	O	NA	R (04FEB2021)	N/N
		Limb injury/ Right hand scaphoid trauma	2	04FEB2021	151/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12311740	EAR	Tinnitus/ ringing in both ears	2	08SEP2020	2/C	3	No	O	NA	N	N/N
16-55/ C4591001 1231 12311746	EAR	Vertigo/ Vertigo	2	01OCT2020	25/8	2	No	O	NA	R (08OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311755	SKIN	Pruritus allergic/ allergic reaction producing pruritus at the chin	1	22AUG2020	6/2	1	Yes		NA	R (23AUG2020)	N/N
	SKIN	Rash pruritic/ pruritic rash on arm, armpit and part of the left chest.	2	13SEP2020	7/4	1	No	O	NA/TC	R (16SEP2020)	N/N
	INJ&P	Limb injury/ Stabbing trauma on right thumb	2	08OCT2020	32/1	1	No	O	NA/TC	R (08OCT2020)	N/N
	INFEC	Cellulitis/ cellulitis of the righth thumb	2	10OCT2020	34/15	1	No	O	NA/TC/TCN	R (24OCT2020)	N/N
	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis#	3	09MAR2021	2/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311760	SKIN	Pruritus/ pruritus upper region of both feet and palmar aspect of both wrists	1	24AUG2020	8/2	1	No	O	NA	R (25AUG2020)	N/N
16-55/ C4591001 1231 12311761	SKIN	Alopecia/ alopecia	2	05FEB2021	151/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311763	GENRL	Injection site pain/ injection site pain	2	08SEP2020	2/14	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1231 12311766	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311769	NERV	Dizziness/ dizziness	1	18AUG2020	2/11	1	No	O	NA	R (28AUG2020)	N/N
16-55/ C4591001 1231 12311770	GASTR	Diarrhoea/ diarrhea	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N
	NERV	Headache/ headache	2	14SEP2020	8/3	1	No	O	NA	R (16SEP2020)	N/N
	GASTR	Odynophagia/ odynophagia	2	17SEP2020	11/4	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1231 12311780	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	28AUG2020	12/91	1	No	O	NA/TC	R (26NOV2020)	N/N
16-55/ C4591001 1231 12311786	INJ&P	Fall/ Subject fell down on the street	2	23SEP2020	17/1	1	No	O	NA	R (23SEP2020)	N/N
	NEOPL	Chondroma/ Right knee chondroma	2	29SEP2020	23/C	1	No	O	NA	N	N/N
	RESP	Asthmatic crisis/ Asthmatic crisis	2	04OCT2020	28/4	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1231 12311788	PSYCH	Depression/ depression.	1	20AUG2020	4/36	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C4591001	MUSC	Back pain/ Low back pain	1	05SEP2020	20/2	1	No	O	NA/TC	R (06SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311793 16-55/ C4591001	METAB	Insulin resistance/ Worsening of the insuline resistance.	2	20SEP2020	14/19	2	No	O	NA/TC	R (08OCT2020)	N/N
1231 12311794 16-55/ C4591001	VASC	Hypertension/ arterial hypertension	2	25SEP2020	19/8	1	No	O	NA/TC	R (02OCT2020)	N/N
1231 12311797 16-55/ C4591001	MUSC	Back pain/ Left low back pain	2	23SEP2020	16/C	1	No	O	NA	N	N/N
1231 12311799	RESP	Dysphonia/ Intermittent Dysphonia	2	23SEP2020	16/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1231 12311801	MUSC	Muscle contracture/ Left back, muscle contracture	1	29AUG2020	13/4	2	No	O	NA/TC/TCN	R (01SEP2020)	N/N
16-55/ C4591001 1231 12311811	SKIN	Pityriasis/ Pityriasis	1	25AUG2020	9/51	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1231 12311812	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	05JAN2021	121/60		No	O	NA	R (05MAR2021)	N/N
	PREG	Abortion spontaneous/ Complete miscarriage	2	27FEB2021	174/12	3	No	O	NA/TC	R (10MAR2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311816	GASTR	Gastrooesophageal reflux disease/ Gastroesophageal reflux disease	1	15DEC2020	121/79	1	No	O	NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1231 12311819	VASC	Hypertension/ Exacerbation of arterial hypertension.#	2	09MAR2021	183/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12311825	NERV	Migraine/ Migraine crisis	1	05SEP2020	20/1	2	No	O	NA	R (05SEP2020)	N/N
	NERV	Migraine/ Migraine crisis	2	08NOV2020	35/2	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1231 12311827	MUSC	Osteoarthritis/ Right acromioclavicular osteoarthritis	2	17SEP2020	10/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001 1231 12311834	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N
16-55/ C4591001 1231 12311836	INFEC	Herpes simplex/ herpes simplex type 1 in the right nasal wing	1	19AUG2020	3/4	1	No	O	NA/TC	R (22AUG2020)	N/N
	INFEC	Herpes simplex/ herpes simplex type 1 on the left wing of the nose	2	10SEP2020	3/3	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001	PSYCH	Anxiety/ anxiety crisis	2	03OCT2020	27/2	2	No	O	NA/TC/TCN	R (04OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311837	INFEC	Oral herpes/ Herpes labialis, single lesion	2	20OCT2020	44/8	1	No	O	NA	R (27OCT2020)	N/N
	IMMUN	Jarisch-Herxheimer reaction/ Jarisch-herxheimer	2	13NOV2020	68/2	2	No	O	NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1231 12311844	METAB	Hypoglycaemia/ severe hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N
	NERV	Seizure/ seizure	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 1231 12311850	SKIN	Rash/ Skin Rash on legs, arms and back	1	25AUG2020	9/2	1	No	O	NA/TC	R (26AUG2020)	N/N
	GASTR	Abdominal pain upper/ Abdominal pain in the right upper quadrant#	3	22JAN2021	3/2	1	No	O	NA	R (23JAN2021)	N/N
		Diarrhoea/ diarrhea#	3	22JAN2021	3/2	1	Yes		NA	R (23JAN2021)	N/N
	INFEC	Subcutaneous abscess/ Right armpit abscess#	4	02MAR2021	22/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12311854	GASTR	Gastrooesophageal reflux disease/ gastroesophageal reflux	2	21OCT2020	45/85	2	No	O	NA/TC	R (13JAN2021)	N/N
	INFEC	Helicobacter infection/ Helicobacter Pylori infection	2	21OCT2020	45/104	2	No	O	NA/TC	R (01FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	BLOOD	Lymphadenopathy mediastinal/ mediastinal lymphadenopathy	2	23DEC2020	108/63	2	No	O	NA	RS (23FEB2021)	N/N	
		Lymphadenopathy/ Cervical lymphadenopathy	2	23DEC2020	108/63	2	No	O	NA	RS (23FEB2021)	N/N	
16-55/ C4591001 1231 12311862	VASC	Aortic stenosis/ Severe aortic stenosis	2	13OCT2020	35/C	3	No	O	NA/TC	RG	Y/N	
	RESP	Pulmonary mass/ pulmonary nodules	2	04JAN2021	118/51	1	No	O	NA	RS (23FEB2021)	N/N	
16-55/ C4591001 1231 12311863	EYE	Episcleritis/ bilateral episcleritis	1	04SEP2020	19/19	1	No	O	NA/TC	R (22SEP2020)	N/N	
16-55/ C4591001 1231 12311865	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	10SEP2020	3/3	1	Yes		NA	R (12SEP2020)	N/N	
16-55/ C4591001 1231 12311885	INFEC	Urinary tract infection/ urinary infection	2	29SEP2020	22/5	1	No	O	NA/TC	R (03OCT2020)	N/N	
16-55/ C4591001 1231 12311888	NERV	Migraine/ Worsening migraine	1	25AUG2020	8/14	1	No	O	NA/TC	R (07SEP2020)	N/N	
16-55/ C4591001 1231 12311889	SKIN	Rash pruritic/ Pruritic rash in abdomen.	2	10SEP2020	3/3	1	No	O	NA/TCN	R (12SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311901	NERV	Headache/ headache	2	04OCT2020	27/2	2	No	O	NA/TC	R (05OCT2020)	N/N	
	HEPAT	Cholecystitis chronic/ chronic lithiasic cholecystitis	2	27OCT2020	50/134	2	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
16-55/ C4591001 1231 12311908	GASTR	Odynophagia/ odynophagia	2	09SEP2020	2/2	2	No	O	NA	R (10SEP2020)	N/N	
	NERV	Headache/ headache	2	09SEP2020	2/2	2	No	O	NA/TC	R (10SEP2020)	N/N	
16-55/ C4591001 1231 12311926	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N	
16-55/ C4591001 1231 12311941	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	07JAN2021	121/C	1	No	O	NA/TC	RG	N/N	
	INFEC	Infected dermal cyst/ Sebaceous cyst infection in thoracic region	2	01FEB2021	146/12	1	No	O	NA/TC	R (12FEB2021)	N/N	
16-55/ C4591001 1231 12311951	INFEC	Tooth infection/ Odontogenic infection	2	23SEP2020	15/23	1	No	O	NA/TC	R (15OCT2020)	N/N	
16-55/ C4591001 1231 12311964	INFEC	Tooth abscess/ Periodontogenic abscess	2	15SEP2020	9/8	1	No	O	NA/TC	R (22SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311969	REPRO	Erectile dysfunction/ Erectile dysfunction*		18AUG2020	1/81	1	No	O	NA	R (06NOV2020)	N/N
	CARD	Tricuspid valve incompetence/ mild tricuspid regurgitation	2	03OCT2020	27/24	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001 1231 12312002	NERV	Headache/ headache	1	01SEP2020	15/1	3	No	O	NA	R (01SEP2020)	N/N
16-55/ C4591001 1231 12312004	PSYCH	Generalised anxiety disorder/ generalized anxiety disorder	2	15SEP2020	6/1	2	No	O	NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1231 12312010	INFEC	Gastroenteritis/ gastroenteritis	2	17SEP2020	10/7	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N
16-55/ C4591001 1231 12312019	INJ&P	Contusion/ bruising on both upper limbs	2	30SEP2020	22/14	1	No	O	NA	R (13OCT2020)	N/N
16-55/ C4591001 1231 12312024	GASTR	Dyspepsia/ Pyrosis	2	27SEP2020	20/30	1	No	O	NA	R (26OCT2020)	N/N
		Salivary gland mucocoele/ Lower lip mucocele	2	27SEP2020	20/110	1	No	O	NA	R (14JAN2021)	N/N
		Stomatitis/ mouth sores	2	27SEP2020	20/110	1	No	O	NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312029	MUSC	Pain in extremity/ Lower limbs pain	2	07OCT2020	30/2	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1231 12312029	GASTR	Toothache/ odontogenic pain	1	27AUG2020	10/44	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312036	GASTR	Abdominal pain/ abdominal pain	2	25SEP2020	17/7	1	No	O	NA/TC/TCN	R (01OCT2020)	N/N
16-55/ C4591001 1231 12312037	SKIN	Hand dermatitis/ dermatitis on both hands	2	08OCT2020	30/14	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C4591001 1231 12312037	GASTR	Vomiting/ Threw up	2	09OCT2020	31/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312042	NERV	Headache/ headache	2	18OCT2020	41/3	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12312046	INJ&P	Skin laceration/ Cutting wound on left hand	2	04OCT2020	28/6	1	No	O	NA/TC/TCN	R (09OCT2020)	N/N
16-55/ C4591001 1231 12312048	GASTR	Toothache/ Worsening of odontogenic pain	2	13OCT2020	37/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Abdominal pain/ Abdominal pain	2	16OCT2020	33/4	2	No	O	NA	R (19OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312056 16-55/ C4591001	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	2	Yes		NA/TC	R (09SEP2020)	N/N
1231 12312063 16-55/ C4591001	SKIN	Rash maculo-papular/ generalized maculopapular rash	2	21NOV2020	73/4	1	No	O	NA/TC	R (24NOV2020)	N/N
1231 12312067 16-55/ C4591001	INFEC	Herpes zoster/ Herpes zoster in left dorsal region	2	08NOV2020	63/12	1	No	O	NA/TC	R (19NOV2020)	N/N
1231 12312068 16-55/ C4591001	RESP	Rhinitis allergic/ worsening of allergic rhinitis	2	01FEB2021	145/8	1	No	O	NA/TC	R (08FEB2021)	N/N
1231 12312069 16-55/ C4591001	PSYCH	Depression/ depression	2	15FEB2021	161/C	1	No	O	NA/TC	RG	N/N
1231 12312074 16-55/ C4591001	INFEC	Tooth infection/ Dental infection	2	02OCT2020	26/43	1	No	O	NA/TC	R (13NOV2020)	N/N
1231 12312075 16-55/ C4591001	IMMUN	Seasonal allergy/ seasonal rhinitis	2	08OCT2020	3/4	1	No	O	NA	R (11OCT2020)	N/N
1231 12312077											

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	INFEC	Gingivitis/ gingivitis	2	16OCT2020	11/5	1	No	O	NA/TC	R (20OCT2020)	N/N	
16-55/ C4591001 1231 12312078	NERV	Migraine/ Worsening of Migraine	1	25AUG2020	8/36	2	No	O	NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12312080	BLOOD	Lymphadenopathy/ left inguinal adenopathy	2	20OCT2020	43/15	1	No	O	NA	R (03NOV2020)	N/N	
16-55/ C4591001 1231 12312087	GENRL	Injection site pain/ Pain at the injection site	1	19AUG2020	2/3	1	Yes		NA	R (21AUG2020)	N/N	
16-55/ C4591001 1231 12312118	NEOPL	Uterine leiomyoma/ uterine myoma	2	16OCT2020	39/76	1	No	O	NA	R (30DEC2020)	N/N	
16-55/ C4591001 1231 12312119	GASTR	Toothache/ Left upper 2nd molar pain	2	16SEP2020	10/15	1	No	O	NA/TC/TCN	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312125	INFEC	Appendicitis/ Acute appendicitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Peritonitis/ Peritonitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
	CARD	Atrial fibrillation/ Acute Paroxysmal Atrial Fibrillation with High Ventricular Response.	2	11JAN2021	127/5	1	No	O	NA/TC	RS (15JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312128	INJ&P	Joint injury/ right knee trauma	2	20SEP2020	13/11	2	No	O	NA/TC	R (30SEP2020)	N/N
		Road traffic accident/ Vehicular accident	2	20SEP2020	13/1	2	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1231 12312137	GENRL	Pyrexia/ Febrile syndrome	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312152	INFEC	Urinary tract infection/ URINARY INFECTION	1	04SEP2020	18/11	1	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1231 12312160	GASTR	Odynophagia/ Odynophagia	2	08SEP2020	2/2	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1231 12312168	GENRL	Pyrexia/ Fever	2	09SEP2020	1/2	1	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	2/2	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1231 12312174	GASTR	Dental caries/ dental caries	2	08NOV2020	61/2	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001	RESP	Rhinitis allergic/ Allergic rhinitis.	2	01OCT2020	22/2	1	No	O	NA/TC	R (02OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12312191 16-55/ C4591001 1231 12312204	EYE	Chalazion/ chalazion	2	11OCT2020	31/4	2	No	O	NA	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12312205	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29SEP2020	23/62		No	O	NA	R (29NOV2020)	N/N	
16-55/ C4591001 1231 12312211	PREG	Abortion spontaneous/ Spontaneous abortion	2	26NOV2020	81/4	2	No	O	NA/TC/TCN	R (29NOV2020)	Y/N	
16-55/ C4591001 1231 12312211	GENRL	Injection site pain/ Injection site pain in right deltoid	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1231 12312212	MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1231 12312216	SURG	Drug titration/ dose search to achieve euthyroidism	2	08OCT2020	29/1	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12312216	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	10FEB2021	155/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12312219	NERV	Headache/ Headache	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312227	GENRL	Injection site pain/ Injection site pain#	2	21JAN2021	136/2	1	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Asthenia/ asthenia#	3	22JAN2021	2/1	1	Yes		NA/TC	R (22JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	2/3	1	Yes		NA/TC	R (24JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	4/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Back pain/ Dorsalgia	2	30SEP2020	22/3	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1231 12312236		Neck pain/ Cervicalgia	2	30SEP2020	22/3	1	No	O	NA/TCN	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/2	3	No	O	NA	R (20AUG2020)	N/N
	PSYCH	Anxiety/ anxiety crisis	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1231 12312242		Depression/ Depression	2	14SEP2020	4/27	2	No	O	NA/TC	R (10OCT2020)	N/N
	IMMUN	Seasonal allergy/ Exacerbation of usual seasonal allergic rhinitis	2	27SEP2020	19/2	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1231 12312244	NERV	Headache/ Headache	1	25AUG2020	7/52	1	No	O	NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312245	GENRL	Injection site pain/ Pain at injection site#	3	08MAR2021	3/3	1	Yes		NA/TC	R (10MAR2021)	N/N
	MUSC	Neck pain/ Cervicalgia#	3	08MAR2021	3/3	1	Yes		NA/TC/TCN	R (10MAR2021)	N/N
	NERV	Headache/ headache#	3	08MAR2021	3/1	1	Yes		NA/TC	R (08MAR2021)	N/N
16-55/ C4591001 1231 12312266	GENRL	Pyrexia/ fever#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ headache#	3	23FEB2021	1/6	1	Yes		NA/TC	R (28FEB2021)	N/N
	GASTR	Vomiting/ vomiting#	3	25FEB2021	3/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1231 12312268	MUSC	Tendonitis/ Bilateral hand tendinitis	2	27SEP2020	17/73	1	No	O	NA/TC	R (08DEC2020)	N/N
		Tendonitis/ Right shoulder tendinitis	2	27SEP2020	17/73	1	No	O	NA/TC	R (08DEC2020)	N/N
16-55/ C4591001 1231 12312270	INJ&P	Limb injury/ Wound on the right leg	2	18OCT2020	38/9	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1231 12312276	GENRL	Injection site pain/ Pain at Injection site#	3	27JAN2021	2/4	2	Yes		NA/TC	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312282	MUSC	Muscle contracture/ muscle contracture in left quadriceps	2	29SEP2020	22/1	3	No	O	NA	R (29SEP2020)	N/N
16-55/ C4591001 1231 12312284	GASTR	Dental caries/ dental cavities	1	20AUG2020	2/84	1	No	O	NA/TC/TCN	R (11NOV2020)	N/N
16-55/ C4591001 1231 12312286	GASTR	Odynophagia/ Odynophagia	1	29AUG2020	11/2	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12312287	GASTR	Abdominal pain upper/ Mild and intermittent epigastric abdominal pain.	2	10SEP2020	2/28	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12312296	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
16-55/ C4591001 1231 12312300	RESP	Sleep apnoea syndrome/ sleep apnea	2	26SEP2020	17/153	2	No	O	NA/TCN	RS (25FEB2021)	N/N
	MUSC	Back pain/ Back pain	2	05OCT2020	26/2	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1231 12312303	MUSC	Arthralgia/ Left omalgia	1	19AUG2020	1/116	2	No	O	NA	R (12DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312317	NERV	Headache/ Headache	2	09SEP2020	3/9	1	Yes		NA/TC/TCN	R (17SEP2020)	N/N
16-55/ C4591001 1231 12312320	EAR	Vertigo/ vertiginous syndrome	1	08SEP2020	21/14	2	No	O	NA/TC	R (21SEP2020)	N/N
	EAR	Vertigo/ vertiginous syndrome	1	20SEP2020	33/27	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12312330	NERV	Dizziness/ Dizziness	1	20AUG2020	2/16	2	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1231 12312333	MUSC	Tenosynovitis stenosaurs/ exacerbation of Right hand pain secondary to previous Quervain's tenosynovitis	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N
	SURG	Medical device implantation/ Radiocarpal clamping	2	28SEP2020	22/2	2	No	O	NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1231 12312335	METAB	Hypoglycaemia/ Severe hypoglycemia	2	16DEC2020	100/8	3	No	O	NA/TC	R (23DEC2020)	Y/N
16-55/ C4591001 1231 12312346	RESP	Rhinitis allergic/ Exacerbation of allergic rhinitis	2	15SEP2020	9/4	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	NERV	Paraesthesia/ left upper limb paresthesia	2	15SEP2020	5/22	1	No	O	NA	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312351 16-55/ C4591001	GASTR	Acute abdomen/ Acute medical abdomen	2	22SEP2020	14/4	2	No	O	NA	R (25SEP2020)	N/N
1231 12312360 16-55/ C4591001	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	1	05OCT2020	48/C	1	No	O	NA/TC	RG	N/N
1231 12312365 16-55/ C4591001	REPRO	Testicular torsion/ Testicular torsion	2	28OCT2020	50/2	2	No	O	NA/TCN	R (29OCT2020)	N/N
1231 12312366 16-55/ C4591001	INFEC	Tooth infection/ odontogenic infection#	3	13MAR2021	19/C	1	No	O	NA	N	N/N
1231 12312369 16-55/ C4591001	NERV	Headache/ Intermittent Headache	1	21AUG2020	3/94	2	No	O	NA/TC	R (22NOV2020)	N/N
1231 12312372	EAR	Meniere's disease/ Worsening of Meniere's Syndrome	1	24SEP2020	37/15	2	No	O	NA/TC/TCN	R (08OCT2020)	N/N
	PSYCH	Mental disorder/ Worsening of psychiatric disorder	2	15OCT2020	7/20	1	No	O	NA/TC/TCN	R (03NOV2020)	N/N
16-55/ C4591001 1231 12312373	INFEC	Skin infection/ scar infection	2	14OCT2020	30/9	1	No	O	NA/TC	R (22OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312378	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	24DEC2020	108/C		No	O	NA	UNK	N/N
16-55/ C4591001 1231 12312382	GENRL	Pyrexia/ fever (39 C)	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	2/5	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1231 12312384	METAB	Dyslipidaemia/ worsening dyslipidemia	2	20SEP2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12312385	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312390	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N
16-55/ C4591001 1231 12312391	GENRL	Pyrexia/ FEVER	2	11SEP2020	3/1	2	Yes		NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312405	SURG	Dental implantation/ Dental implant	2	19SEP2020	13/1	1	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1231 12312411	MUSC	Neck pain/ Neck pain#	3	11FEB2021	15/12	1	No	O	NA/TC/TCN	R (22FEB2021)	N/N
16-55/ C4591001 1231 12312414	GASTR	Gastroesophageal reflux disease/ gastroesophageal reflux	1	25AUG2020	7/15	2	No	O	NA/TC/TCN	R (08SEP2020)	N/N
	GASTR	Abdominal pain upper/ Epigastralgia#	3	08FEB2021	19/5	1	No	O	NA	R (12FEB2021)	N/N
	MUSC	Back pain/ Chronic low back pain exacerbation#	3	08FEB2021	19/4	2	No	O	NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1231 12312419	GENRL	Chills/ Chills	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	2/1	3	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312420	INFEC	Appendicitis/ Acute Appendicitis	2	28DEC2020	110/16	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N
16-55/ C4591001 1231 12312424	GENRL	Illness/ Sickness	2	11NOV2020	65/3	1	No	O	NA	R (13NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312426	MUSC	Back pain/ Low back pain	1	31AUG2020	13/4	2	No	O	NA/TC/TCN	R (03SEP2020)	N/N
16-55/ C4591001 1231 12312434	NERV	Dizziness/ dizziness	2	10SEP2020	2/16	1	No	O	NA/TCN	R (25SEP2020)	N/N
	INV	Blood cholesterol increased/ increased total cholesterol	2	15DEC2020	98/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1231 12312435	MUSC	Back pain/ Acute low back pain	1	08SEP2020	21/3	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312439	MUSC	Back pain/ acute low back pain	1	31AUG2020	13/11	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312444	MUSC	Myalgia/ muscle pain in left arm	1	21AUG2020	2/2	3	Yes		NA/TCN	R (22AUG2020)	N/N
16-55/ C4591001 1231 12312464	NERV	Headache/ Intermittent headache	2	17SEP2020	8/80	1	No	O	NA/TC	R (05DEC2020)	N/N
		Paraesthesia/ Upper limb paresthesias	2	17SEP2020	8/135	1	No	O	NA/TC/TCN	R (29JAN2021)	N/N
	CONG	Arnold-Chiari malformation/ Chiari Syndrome Type I	2	03DEC2020	85/C	1	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312472	INFEC	Urinary tract infection/ urinary infection	2	21FEB2021	166/6	1	No	O	NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1231 12312476	HEPAT	Bile duct stone/ Choledochal lithiasis	2	23JAN2021	136/C	3	No	O	NA	N	Y/N
	HEPAT	Biliary colic/ Biliary colic	2	25FEB2021	169/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1231 12312477	RESP	Rhinitis allergic/ worsening of allergic rhinitis	1	26AUG2020	7/1	1	No	O	NA	R (26AUG2020)	N/N
	ENDO	Hypothyroidism/ WORSE OF HYPOTHYROIDISM	2	04FEB2021	147/36	1	No	O	NA/TC	R (11MAR2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08MAR2021	1/2	1	Yes		NA/TC	R (09MAR2021)	N/N
	NERV	Headache/ HEADACHE#	3	09MAR2021	2/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1231 12312488	INFEC	Vulvovaginal mycotic infection/ vaginal yeast infection	2	03OCT2020	23/4	2	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1231 12312491	CARD	Tachycardia/ tachycardia#	3	20FEB2021	1/1	1	No	O	NA	R (20FEB2021)	N/N
	ENDO	Thyroid disorder/ Thyroid dysfunction#	3	20FEB2021	1/C	1	No	O	NA	N	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312503	VASC	Hypertension/ arterial hypertension#	3	20FEB2021	1/1	1	No	O	NA	R (20FEB2021)	N/Y	
16-55/ C4591001 1231 12312503	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	28SEP2020	19/62	1	No	O	NA/TC	R (28NOV2020)	N/N	
16-55/ C4591001 1231 12312529	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	30NOV2020	81/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1231 12312531	INFEC	Tooth infection/ dental infection	2	16SEP2020	4/10	1	No	O	NA/TC/TCN	R (25SEP2020)	N/N	
16-55/ C4591001 1231 12312532	INFEC	Gingivitis/ gingivitis	2	29SEP2020	19/8	1	No	O	NA	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12312533	MUSC	Tendonitis/ exacerbation of tendonitis in the left wrist	2	30SEP2020	21/14	2	No	O	NA	R (13OCT2020)	N/N	
16-55/ C4591001 1231 12312538	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	16SEP2020	7/34	1	No	O	NA/TC	R (19OCT2020)	N/N	
16-55/ C4591001 1231 12312546	NERV	Presyncope/ lipothymia (presyncope)	2	09OCT2020	29/1	2	No	O	NA	R (09OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312559	NERV	Dizziness/ dizziness	1	23AUG2020	4/2	1	No	O	NA	R (24AUG2020)	N/N
16-55/ C4591001 1231 12312572	INFEC	Abscess limb/ Right gluteal abscess	2	04FEB2021	150/C	1	No	O	NA/TC/TCN	RG	N/N
	SKIN	Peau d'orange/ right buttock cellulite.	2	04FEB2021	150/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12312573	NERV	Headache/ Intermittent Headache#	4	11MAR2021	22/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1231 12312576	RENAL	Renal colic/ Renal colic	2	20OCT2020	42/1	2	No	O	NA/TC	R (20OCT2020)	N/N
	RENAL	Hydronephrosis/ Right hydronephrosis	2	05NOV2020	58/C	2	No	O	NA/TC	N	N/N
		Nephrolithiasis/ nephrolithiasis	2	05NOV2020	58/47	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N
	HEPAT	Cholelithiasis/ Gallstones	2	06NOV2020	59/3	1	No	O	NA	R (08NOV2020)	N/N
	GENRL	Injection site erythema/ erythema at the injection site#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/Y
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312593	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N
		Bundle branch block right/ right bundle branch block	2	16SEP2020	6/4	1	No	O	NA	R (19SEP2020)	N/N
16-55/ C4591001 1231 12312611	SKIN	Eczema/ Acute eczema in the cervical region and on the wrists	2	11SEP2020	3/20	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12312617	RESP	Snoring/ primary snoring	2	11SEP2020	2/46	2	No	O	NA/TC/TCN	R (26OCT2020)	N/N
	MUSC	Back pain/ Back pain	2	01OCT2020	22/3	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1231 12312639	GENRL	Axillary pain/ right armpit pain	2	29SEP2020	21/2	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12312645	RENAL	Renal colic/ mild renal colic	1	04SEP2020	16/2	1	No	O	NA/TC	R (05SEP2020)	N/N
16-55/ C4591001 1231 12312647	MUSC	Myalgia/ myalgia in left hemibody predominantly left arm and cervical region	2	10SEP2020	1/23	1	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001	METAB	Type 2 diabetes mellitus/ Diabetes mellitus type 2	2	20DEC2020	104/57	2	No	O	NA/TC	RS (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312648 16-55/ C4591001	REPRO	Menstruation delayed/ menstrual delay	2	18SEP2020	8/18	1	No	O	NA	R (05OCT2020)	N/N
1231 12312649 16-55/ C4591001	INFEC	Otitis externa/ External otitis#	3	08MAR2021	17/C	1	No	O	NA/TC	N	N/N
1231 12312660 16-55/ C4591001	INJ&P	Procedural dizziness/ post-blood extraction lipothymia (dizziness)	2	07OCT2020	29/1	2	No	O	NA	R (07OCT2020)	N/N
1231 12312666 16-55/ C4591001	CARD	Sinus tachycardia/ Sinus tachycardia	2	27SEP2020	19/3	2	No	O	NA	R (29SEP2020)	N/N
1231 12312674 16-55/ C4591001	INJ&P	Hand fracture/ left hand, ring finger, first phalange fracture.#	2	11MAR2021	185/C	1	No	O	NA/TCN	N	N/N
1231 12312681 16-55/ C4591001	INFEC	Rhinitis/ RHINITIS	2	13SEP2020	5/8	1	No	O	NA	R (20SEP2020)	N/N
1231 12312683 16-55/ C4591001	MUSC	Myalgia/ Myalgia on internal area of left arm#	3	26FEB2021	2/11	2	Yes		NA/TC	R (08MAR2021)	N/N
1231 12312687											

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	BLOOD	Lymphadenopathy/ Adenopathy in the left supraclavicular area#	3	27FEB2021	3/9	2	Yes		NA/TC	R (07MAR2021)	N/N
16-55/ C4591001 1231 12312688	MUSC	Pain in extremity/ Lower limb pain	2	09SEP2020	1/2	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C4591001 1231 12312696	CARD	Acute coronary syndrome/ acute coronary syndrome	2	22NOV2020	74/48	3	No	O	NA/TC/TCN	R (08JAN2021)	Y/N
16-55/ C4591001 1231 12312712	GASTR	Toothache/ First lower left molar pain	2	20SEP2020	13/6	1	No	O	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1231 12312714	MUSC	Myalgia/ Muscle Pain in left arm	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	1/6	2	Yes		NA/TC	R (25AUG2020)	N/N
	MUSC	Back pain/ LOW BACK PAIN	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	06SEP2020	18/7	2	No	O	NA/TC	R (12SEP2020)	N/N
	SKIN	Rash erythematous/ Pruritic erythematous rash of the legs, face, and trunk	2	10SEP2020	2/3	2	Yes		NA	R (12SEP2020)	N/N
	MUSC	Back pain/ Back pain	2	29SEP2020	21/98	1	No	O	NA/TC	R (04JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Generalised anxiety disorder/ Generalized anxiety disorder	2	10DEC2020	93/23	2	No	O	NA/TC	RS (01JAN2021)	N/N
	PSYCH	Generalised anxiety disorder/ worsening of generalized anxiety disorder#	3	04MAR2021	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12312725	SKIN	Dermatitis allergic/ Skin allergy due to mites	2	14NOV2020	68/19	1	No	O	NA/TC	R (02DEC2020)	N/N
16-55/ C4591001 1231 12312743	GENRL	Chest pain/ precordial pain	2	26SEP2020	18/5	2	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12312747	NERV	Sciatica/ lumbociatalgia	2	12SEP2020	2/2	2	No	O	NA	R (13SEP2020)	N/N
16-55/ C4591001 1231 12312753	GENRL	Injection site pain/ Injection site pain.	2	16OCT2020	36/85	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1231 12312759	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	2/2	1	Yes		NA	R (23AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Arthralgia/ arthralgia	2	12SEP2020	2/C	1	Yes		NA/TC	N	N/N
	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1231 12312761	NERV	Paraesthesia/ left foot paresthesia	2	31OCT2020	51/2	1	No	O	NA	R (01NOV2020)	N/N
		Paraesthesia/ right upper limb paresthesia	2	31OCT2020	51/3	1	No	O	NA	R (02NOV2020)	N/N
16-55/ C4591001 1231 12312770	MUSC	Arthralgia/ Left knee pain	2	14SEP2020	4/24	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12312787	GENRL	Pyrexia/ fever	2	12SEP2020	2/1	3	Yes		NA/TC	R (12SEP2020)	N/N
	EAR	Sudden hearing loss/ sudden hearing loss in the right ear	2	02OCT2020	22/15	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12312790	NERV	Headache/ headache	1	29AUG2020	9/1	1	No	O	NA	R (29AUG2020)	N/N
16-55/ C4591001 1231 12312796	RESP	Dysphonia/ Worsening of dysphonia	2	28SEP2020	20/72	1	No	O	NA	R (08DEC2020)	N/N
16-55/ C4591001	EYE	Keratitis/ corneal keratitis	2	23NOV2020	75/6	2	No	O	NA/TC	R (28NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12312807 16-55/ C4591001	PSYCH	Anxiety/ exacerbation of anxiety disorder	1	04SEP2020	15/11	1	No	CD	NA/TC/TCN	R (14SEP2020)	N/N
1231 12312826 16-55/ C4591001	MUSC	Arthralgia/ Bilateral hip arthralgia	2	11SEP2020	1/72	1	Yes		NA	R (21NOV2020)	N/N
1231 12312836 16-55/ C4591001	NERV	Sciatica/ Lumbociatalgia	2	21SEP2020	11/122	3	No	O	NA/TC/TCN	R (20JAN2021)	N/N
1231 12312840 16-55/ C4591001	MUSC	Myalgia/ Generalized muscle pain#	4	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
1231 12312842 16-55/ C4591001	MUSC	Back pain/ Low back pain	2	07DEC2020	86/51	1	No	O	NA/TC	R (26JAN2021)	N/N
1231 12312847 16-55/ C4591001	INJ&P	Animal bite/ Cat bite	2	28SEP2020	18/1	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
1231 12312850 16-55/ C4591001	NERV	Headache/ headache	2	16SEP2020	6/38	1	Yes		NA/TC	R (23OCT2020)	N/N
1231 12312853											

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312854	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N	
16-55/ C4591001 1231 12312868	INJ&P	Craniocerebral injury/ minor cranioencephalic trauma	2	08OCT2020	1/1	1	No	O	NA	R (08OCT2020)	N/N	
	NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N	
16-55/ C4591001 1231 12312871	INFEC	Skin infection/ Dermal infection	1	27AUG2020	7/9	1	No	O	NA/TC	R (04SEP2020)	N/N	
16-55/ C4591001 1231 12312874	NERV	Paraesthesia/ Paresthesias on the right side of the face#	4	28FEB2021	5/1	1	No	O	NA	R (28FEB2021)	N/N	
16-55/ C4591001 1231 12312883	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	27AUG2020	7/35	1	No	O	NA	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12312892	GENRL	Pyrexia/ Febrile syndrome	2	11SEP2020	2/3	2	Yes		NA/TC	R (13SEP2020)	N/N	
16-55/ C4591001 1231 12312895	PSYCH	Anxiety/ Anxiety crisis	2	29SEP2020	19/1	2	No	O	NA	R (29SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312911	INFEC	Pharyngitis/ Pharyngitis	2	01OCT2020	23/11	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1231 12312923	NERV	Headache/ Frontal headache with retroorbital pain	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	1	28AUG2020	8/4	1	No	O	NA	R (31AUG2020)	N/N
16-55/ C4591001 1231 12312927	INFEC	Tooth infection/ Tooth infection	2	04OCT2020	24/5	1	No	O	NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1231 12312928	GASTR	Oral mucosa haematoma/ left cheek internal mucosa hematoma	2	14SEP2020	4/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1231 12312930	SKIN	Pruritus/ pruritus in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA	R (07OCT2020)	N/N
		Rash/ skin rash in hemiright face, neck, torso, upper back, upper abdomen both arms from shoulder to hand	2	04OCT2020	25/4	1	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1231 12312933	INFEC	Urinary tract infection/ urinary infection	2	25SEP2020	15/6	1	No	O	NA	R (30SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12312941	MUSC	Myalgia/ Generalized Myalgia	1	31AUG2020	11/5	1	No	O	NA	R (04SEP2020)	N/N	
	SKIN	Urticaria/ intermittent urticaria on lower limbs	2	07DEC2020	88/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1231 12312947	METAB	Type 2 diabetes mellitus/ Type 2 diabetes	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N	
	VASC	Hypertension/ Hypertension	2	23SEP2020	13/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12312955	RESP	Cough/ cough	2	30SEP2020	22/7	1	No	O	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1231 12312982	GENRL	Injection site pain/ mild pain at the injection site	1	23AUG2020	3/3	1	Yes		NA	R (25AUG2020)	N/N	
	INFEC	Suspected COVID-19/ Suspected COVID-19 illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N	
	PSYCH	Anxiety/ severe anxiety	2	23SEP2020	15/22	3	No	O	NA	R (14OCT2020)	N/N	
16-55/ C4591001 1231 12312984	GENRL	Injection site pain/ Shooting pain at injection site	2	11SEP2020	2/40	1	Yes		NA	R (20OCT2020)	N/N	
	GENRL	Injection site pruritus/ itching at the injection site	2	15OCT2020	36/1	1	Yes		NA	R (15OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312985	MUSC	Back pain/ Low back pain	1	08SEP2020	19/1	3	No	O	NA/TC/TCN	R (08SEP2020)	N/N
16-55/ C4591001 1231 12312990	GENRL	Pyrexia/ febrile syndrome	1	22AUG2020	2/2	1	Yes		NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1231 12312991	MUSC	Muscle contracture/ interscapular muscle contracture in right dorsal region	2	12SEP2020	2/10	2	No	O	NA/TC/TCN	R (21SEP2020)	N/N
	INFEC	Cellulitis/ Cellulitis (left maxillary region)	2	02OCT2020	22/19	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1231 12312994	INJ&P	Bone fissure/ LEFT ELBOW BONE FISSURE	2	03FEB2021	126/C	2	No	O	NA/TC	RG	N/N
		Fall/ fall from own height	2	03FEB2021	126/1	2	No	O	NA/TC	R (03FEB2021)	N/N
16-55/ C4591001 1231 12312996	RESP	Asthmatic crisis/ SEVERE ASTHMATIC CRYISIS	2	21OCT2020	42/9	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1231 12313002	RESP	Asthmatic crisis/ asthmatic crisis	2	15SEP2020	7/23	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001	NERV	Paraesthesia/ paresthesias in right upper limb	2	27SEP2020	17/1	1	Yes		NA	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313014 16-55/ C4591001	EAR	Tinnitus/ Bilateral tinnitus	1	24AUG2020	4/5	1	No	O	NA	R (28AUG2020)	N/N
1231 12313026 16-55/ C4591001	NERV	Migraine/ Migraine	1	22AUG2020	2/1	2	No	O	NA/TC	R (22AUG2020)	N/N
1231 12313028	GENRL	Injection site erythema/ Erythema at the injection site	2	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
		Injection site lymphadenopathy/ Axillary and cervical lymphadenopathy ipsilateral to the injection site	2	12SEP2020	2/6	1	Yes		NA	R (17SEP2020)	N/N
		Injection site warmth/ slight increase in temperature at injection site	2	12SEP2020	2/4	1	Yes		NA/TC	R (15SEP2020)	N/N
	REPRO	Metrorrhagia/ Metrorrhagia	2	13SEP2020	3/7	1	No	O	NA	R (19SEP2020)	N/N
	NERV	Optic neuritis/ Optic Neuritis	2	01DEC2020	82/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1231 12313034	GENRL	Injection site pain/ Pain at the injection site	1	22AUG2020	1/3	2	Yes		NA/TC	R (24AUG2020)	N/N
	NERV	Paraesthesia/ paresthesia in left arm	1	22AUG2020	1/3	2	No	O	NA/TC	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313045	INFEC	Cystitis/ Cystitis	2	20SEP2020	8/5	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1231 12313061	GENRL	Pyrexia/ fever	2	11SEP2020	2/2	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1231 12313070	PSYCH	Bruxism/ migraine associated with bruxism	1	22AUG2020	1/32	2	No	O	NA/TC	R (22SEP2020)	N/N
	PSYCH	Bruxism/ migraine associated with bruxism	1	06SEP2020	16/1	2	No	O	NA/TC	R (06SEP2020)	N/N
	GASTR	Haemorrhoids/ Worsening of external hemorrhoids#	3	13MAR2021	9/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1231 12313075	GENRL	Asthenia/ Asthenia#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	MUSC	Arthralgia/ generalized arthralgias#	4	12FEB2021	1/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1231 12313087	VASC	Hypotension/ Symptomatic hypotension	1	09SEP2020	19/1	1	No	O	NA	R (09SEP2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	3	Yes		NA/TC	R (15SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313088 16-55/ C4591001	SKIN	Rash/ Skin rash on face#	3	19FEB2021	29/7	1	No	O	NA/TC	R (25FEB2021)	N/N
1231 12313098 16-55/ C4591001	INFEC	Rhinitis/ Rhinitis	2	05OCT2020	23/6	1	No	O	NA/TC	R (10OCT2020)	N/N
1231 12313107 16-55/ C4591001	METAB	Vitamin D deficiency/ Vitamin D deficiency	2	06JAN2021	118/C	1	No	O	NA/TC	RG	N/N
1231 12313113 16-55/ C4591001	NERV	Headache/ headache	1	06SEP2020	16/11	1	No	O	NA	R (16SEP2020)	N/N
1231 12313115 16-55/ C4591001	RESP	Rhinitis allergic/ Worsening of Allergic rhinitis	2	01OCT2020	21/2	1	No	O	NA	R (02OCT2020)	N/N
1231 12313117 16-55/ C4591001	NERV	Headache/ right hemicrania headache	1	30AUG2020	9/2	2	No	O	NA/TC	R (31AUG2020)	N/N
1231 12313129	NERV	Headache/ right hemicrania headache	1	09SEP2020	19/2	2	No	O	NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Right hemicrania headache	2	20SEP2020	10/1	1	No	O	NA/TC	R (20SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313130	MUSC	Bone swelling/ Pain and swelling in the left cheekbone	1	07SEP2020	17/2	1	No	O	NA	R (08SEP2020)	N/N	
16-55/ C4591001 1231 12313140	ENDO	Thyroid mass/ Thyroid nodules	2	30OCT2020	47/C	1	No	O	NA	N	N/N	
	NEOPL	Papillary thyroid cancer/ Suspected papillary thyroid carcinoma	2	28JAN2021	137/C	3	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1231 12313160	MUSC	Arthralgia/ Joint pain	1	24AUG2020	3/3	3	No	O	NA/TC	R (26AUG2020)	N/N	
16-55/ C4591001 1231 12313161	REPRO	Menorrhagia/ Hypermenorrhea	2	07OCT2020	28/C	1	No	O	NA	RG	N/N	
16-55/ C4591001 1231 12313163	NERV	Syncope/ Vasovagal syncope	2	09OCT2020	29/1	1	No	O	NA	R (09OCT2020)	N/N	
16-55/ C4591001 1231 12313164	GASTR	Odynophagia/ Transient discomfort when swallowing	1	02SEP2020	12/1	1	No	O	NA	R (02SEP2020)	N/N	
16-55/ C4591001 1231 12313167	MUSC	Pain in extremity/ Lower right limb pain	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313174	SKIN	Erythema nodosum/ erythema nodosum	2	22OCT2020	40/35	1	No	O	NA	R (25NOV2020)	N/N	
16-55/ C4591001 1231 12313175	GENRL	Chest pain/ nonspecific chest pain	1	29AUG2020	8/3	1	No	O	NA	R (31AUG2020)	N/N	
	MUSC	Neck pain/ Neck pain	1	18SEP2020	28/44	2	No	O	NA/TC	R (31OCT2020)	N/N	
16-55/ C4591001 1231 12313179	REPRO	Breast pain/ increased pain in the left breast	1	03SEP2020	13/49	1	No	O	NA	R (21OCT2020)	N/N	
	BLOOD	Anaemia/ exacerbation of anemia	2	01OCT2020	22/21	1	No	O	NA	R (21OCT2020)	N/N	
16-55/ C4591001 1231 12313180	NERV	Headache/ Headache	2	13NOV2020	64/1	1	No	O	NA	R (13NOV2020)	N/N	
	INJ&P	Road traffic accident/ Bike accident	2	24NOV2020	75/1	1	No	O	NA	R (24NOV2020)	N/N	
		Tooth fracture/ Rupture of 2 teeth (upper right incisor and upper right canine)	2	24NOV2020	75/C	1	No	O	NA/TC/TCN	RG	N/N	
16-55/ C4591001 1231 12313182	CARD	Palpitations/ palpitations	2	24SEP2020	14/89	1	No	O	NA	R (21DEC2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313184	NERV	Carpal tunnel syndrome/ right carpal tunnel syndrome	2	15OCT2020	36/128	2	No	O	NA/TCN	R (19FEB2021)	Y/N	
16-55/ C4591001 1231 12313191	NERV	Headache/ Headhache	2	14SEP2020	1/13	1	Yes		NA	R (26SEP2020)	N/N	
	SKIN	Rash/ skin rash located on the face	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N	
16-55/ C4591001 1231 12313193	RENAL	Haematuria/ haematuria	1	25AUG2020	4/29	1	No	O	NA	R (22SEP2020)	N/N	
	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N	
16-55/ C4591001 1231 12313198	NERV	Migraine/ Exacerbation of migraine	2	20SEP2020	7/6	2	No	O	NA/TC	R (25SEP2020)	N/N	
16-55/ C4591001 1231 12313205	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/Y	
	NERV	Sciatica/ Worsening of lumbosciatalgia	2	22SEP2020	13/31	1	No	O	NA/TCN	R (22OCT2020)	N/N	
16-55/ C4591001 1231 12313211	GENRL	Fatigue/ fatigue	1	28AUG2020	7/1	1	Yes		NA	R (28AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313212	MUSC	Muscle contracture/ cervical contracture	1	11FEB2021	174/3	2	No	O	NA/TC	R (13FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	12SEP2020	3/1	1	Yes		NA	R (12SEP2020)	N/N
		Odynophagia/ Odynophagia	2	12SEP2020	3/3	1	No	O	NA	R (14SEP2020)	N/N
	MUSC	Neck pain/ CERVICAL PAIN	2	14NOV2020	66/13	1	No	O	NA	R (26NOV2020)	N/N
	NERV	Burning sensation/ Burning sensation in left elbow crease	2	18SEP2020	8/9	1	No	O	NA	R (26SEP2020)	N/N
	NERV	Headache/ headache	2	09OCT2020	27/2	2	No	O	NA/TC	R (10OCT2020)	N/N
	MUSC	Back pain/ low back pain	2	01JAN2021	110/52	1	No	O	NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ pain in the injection site	2	23SEP2020	11/3	1	Yes		NA	R (25SEP2020)	N/N
	VASC	Systolic hypertension/ Systolic Hypertension	2	18NOV2020	67/7	1	No	O	NA	R (24NOV2020)	N/N
16-55/ C4591001	INJ&P	Muscle strain/ righth calf muscle strain	2	07OCT2020	27/6	1	No	O	NA	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313238 16-55/ C4591001 1231 12313244	GENRL	Fatigue/ Fatigue#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
		Injection site pain/ Pain at injection site#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
		Pyrexia/ Fever#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
	NERV	Headache/ Headache#	3	27FEB2021	2/2	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1231 12313249	INFEC	Herpes zoster/ Herpes zoster	1	05SEP2020	15/6	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1231 12313255	ENDO	Hypothyroidism/ Exacerbation of hypothyroidism	2	16SEP2020	6/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313257	REPRO	Ovarian cyst/ ovarian cyst	2	05OCT2020	26/45	1	No	O	NA	R (18NOV2020)	N/N
16-55/ C4591001 1231 12313259	EYE	Ulcerative keratitis/ Corneal ulcer in left eye	2	31JAN2021	144/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GASTR	Odynophagia/ odynophagia	2	09OCT2020	29/8	1	No	O	NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313265 16-55/ C4591001 1231 12313283	GASTR	Colitis/ Sigmoiditis#	2	20JAN2021	132/11	2	No	O	NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	26JAN2021	1/2	2	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ fever of 38.9 C#	3	27JAN2021	2/2	3	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1231 12313284	INFEC	Papilloma viral infection/ human papillomavirus infection	1	12SEP2020	22/1	1	No	O	NA	R (12SEP2020)	N/N
16-55/ C4591001 1231 12313289	GENRL	Asthenia/ Asthenia	2	07OCT2020	2/3	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12313290	GASTR	Abdominal pain/ Nonspecific abdominal pain	2	09OCT2020	27/12	1	No	O	NA	R (20OCT2020)	N/N
	GENRL	Asthenia/ Asthenia#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Pain at the injection site#	3	29JAN2021	1/2	3	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1231 12313302	INFEC	Genital herpes/ Genital herpes#	3	30JAN2021	3/17	2	No	O	NA/TC	R (15FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313308	GENRL	Pyrexia/ FEVER (39 Degrees C)	2	11SEP2020	1/4	3	Yes		NA/TC	R (14SEP2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	15SEP2020	5/3	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1231 12313314	NERV	Presyncope/ Vasovagal episode	2	09OCT2020	30/1	2	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12313316	SURG	Cataract operation/ left eye cataract surgery	2	25SEP2020	15/1	2	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1231 12313326	PSYCH	Insomnia/ insomnia	2	29SEP2020	17/18	2	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12313327	GENRL	Injection site pruritus/ itching at the injection site	1	24AUG2020	2/15	1	Yes		NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1231 12313329	IMMUN	Seasonal allergy/ seasonal allergy	1	06SEP2020	15/48	1	No	O	NA/TC	R (23OCT2020)	N/N
	EAR	Allergic otitis media/ allergic otitis media	2	06OCT2020	24/33	1	No	O	NA	R (07NOV2020)	N/N
	GASTR	Nausea/ nausea	2	08OCT2020	26/2	1	No	CD	NA	R (09OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313335	NERV	Dizziness/ DIZZINESS	2	12OCT2020	30/1	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313340	GENRL	Injection site haematoma/ Injection site hematoma left deltoid	1	23AUG2020	1/8	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12313345	MUSC	Back pain/ low back pain	2	25SEP2020	15/8	1	No	O	NA	R (02OCT2020)	N/N
	MUSC	Neck pain/ cervicalgia	2	12OCT2020	32/31	2	No	O	NA/TC/TCN	R (11NOV2020)	N/N
	NEOPL	Clear cell renal cell carcinoma/ Clear cell renal cell carcinoma	2	12OCT2020	32/C	3	No	O	NA/TCN	N	Y/N
	EAR	Tinnitus/ bilateral tinnitus	2	13OCT2020	33/44	2	No	O	NA	R (25NOV2020)	N/N
16-55/ C4591001 1231 12313353	MUSC	Back pain/ Right back pain	1	27AUG2020	5/4	1	No	O	NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12313356	INFEC	Rhinitis/ Rhinitis	2	14SEP2020	2/34	1	No	O	NA	R (17OCT2020)	N/N
16-55/ C4591001 1231 12313357	GENRL	Pyrexia/ Febrile Syndrome	1	25AUG2020	3/1	3	Yes		NA/TC	R (25AUG2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313369	INJ&P	Eyelid injury/ Right upper eyelid injury.	2	01DEC2020	79/4	1	No	O	NA	R (04DEC2020)	N/N	
16-55/ C4591001 1231 12313370	NERV	Headache/ Headache	2	20SEP2020	8/2	2	No	O	NA/TC	R (21SEP2020)	N/N	
16-55/ C4591001 1231 12313378	INJ&P	Tooth fracture/ Rupture of the lower left second molar#	3	02FEB2021	9/1	1	No	O	NA/TC/TCN	R (02FEB2021)	N/N	
16-55/ C4591001 1231 12313386	MUSC	Muscle contracture/ Cervical contracture	2	02OCT2020	22/3	2	No	O	NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1231 12313395	RESP	Rhinitis allergic/ allergic rhinitis	1	04OCT2020	43/2	1	No	O	NA	R (05OCT2020)	N/N	
16-55/ C4591001 1231 12313400	CARD	Palpitations/ Palpitations	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N	
	VASC	Hypertension/ Hypertension	2	10OCT2020	28/1	1	No	O	NA	R (10OCT2020)	N/N	
	IMMUN	Seasonal allergy/ Worsening of seasonal allergic rhinitis	2	29OCT2020	47/4	1	No	O	NA/TC	R (01NOV2020)	N/N	
16-55/ C4591001	NERV	Headache/ Headache	2	13SEP2020	1/8	1	Yes		NA/TC	R (20SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313404 16-55/ C4591001	GENRL	Fatigue/ Fatigue	1	24AUG2020	2/2	1	Yes		NA	R (25AUG2020)	N/N
1231 12313406 16-55/ C4591001	SKIN	Acne/ Acne	1	05SEP2020	14/3	1	No	O	NA/TC	R (07SEP2020)	N/N
1231 12313419 16-55/ C4591001	GENRL	Injection site pain/ Injection Site Pain	1	23AUG2020	1/7	2	Yes		NA/TC	R (29AUG2020)	N/N
1231 12313429 16-55/ C4591001	INFEC	Vulvovaginal candidiasis/ vulvovaginal candidiasis	2	12OCT2020	29/4	1	No	O	NA/TC	R (15OCT2020)	N/N
1231 12313430 16-55/ C4591001	SKIN	Acne/ acne exacerbation	2	02NOV2020	53/19	1	No	O	NA/TC	R (20NOV2020)	N/N
1231 12313432 16-55/ C4591001	SKIN	Pityriasis rosea/ Pityriasis rosea	2	29SEP2020	17/30	2	No	O	NA/TC	R (28OCT2020)	N/N
1231 12313437	INFEC	Renal abscess/ Right kidney abscess	2	07DEC2020	86/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	1	23AUG2020	1/2	1	Yes		NA/TC	R (24AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313454	INJ&P	Ligament sprain/ right ankle sprain	1	12SEP2020	21/26	3	No	O	NA/TC	R (07OCT2020)	N/N
	INFEC	Furuncle/ boils in interglutal cleft and right inguinal region	1	02NOV2020	72/2	2	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1231 12313465	METAB	Hypercholesterolaemia/ Hypercholesterolemia	2	08OCT2020	25/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313467	SURG	Tooth extraction/ extraction of 2 teeth#	1	22SEP2020	31/1	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N
16-55/ C4591001 1231 12313470	MUSC	Plantar fasciitis/ left plantar fasciitis	1	21SEP2020	30/8	1	No	O	NA/TC/TCN	R (28SEP2020)	N/N
	NERV	Carpal tunnel syndrome/ Right hand carpal tunnel syndrome	2	25JAN2021	126/C	1	No	O	NA	N	N/N
16-55/ C4591001 1231 12313471	MUSC	Myalgia/ Deltoid pain	1	06SEP2020	15/1	1	No	O	NA/TCN	R (06SEP2020)	N/N
	VASC	Haematoma/ hematoma in left deltoid region	2	18SEP2020	6/3	1	No	O	NA	R (20SEP2020)	N/N
	MUSC	Muscle contracture/ cervical contracture	2	07NOV2020	56/7	2	No	O	NA/TC/TCN	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313489	SKIN	Rash/ GENERALIZED RASH	1	12SEP2020	21/7	1	No	O	NA	R (18SEP2020)	N/N
16-55/ C4591001 1231 12313492	SOCCI	Stress at work/ Work Stress#	1	05OCT2020	44/32	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1231 12313497	INFEC	Furuncle/ Furunculosis in axillary and left inginal region#	1	14OCT2020	53/11	1	No	O	NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1231 12313501	INFEC	Tooth infection/ upper left second molar infection#	2	01OCT2020	17/4	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 1231 12313504	HEPAT	Cholelithiasis/ cholelithiasis	2	24DEC2020	103/13	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
16-55/ C4591001 1231 12313507	NERV	Headache/ Headache	1	04SEP2020	13/2	2	No	O	NA/TC	R (05SEP2020)	N/N
	GENRL	Injection site pain/ injection site pain in left arm	2	13SEP2020	1/26	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1231 12313508	MUSC	Arthralgia/ arthralgias#	2	01OCT2020	15/37	1	No	O	NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313512	EAR	Vertigo/ Vertiginous syndrome#	1	05SEP2020	14/1	3	No	O	NA/TCN	R (05SEP2020)	N/N
16-55/ C4591001 1231 12313513	GENRL	Asthenia/ asthenia	2	22SEP2020	10/6	2	No	O	NA	R (27SEP2020)	N/N
		Pyrexia/ fever	2	22SEP2020	10/2	1	No	O	NA/TC/TCN	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	22SEP2020	10/3	1	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1231 12313516	INFEC	Cellulitis/ facial cellulitis	1	23AUG2020	1/6	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1231 12313525	MUSC	Intervertebral disc degeneration/ Multiple degenerative disc disease	2	22FEB2021	165/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12313542	METAB	Metabolic syndrome/ Metabolic syndrome#	2	15OCT2020	31/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313547	GASTR	Nausea/ nausea#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Pyrexia/ fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1231 12313551	MUSC	Muscle contracture/ Cervical contracture#	1	21OCT2020	60/1	2	No	O	NA	R (21OCT2020)	N/N
	NERV	Headache/ Headache#	1	21OCT2020	60/1	2	No	O	NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1231 12313575	MUSC	Tendonitis/ Right forearm Tendinitis	1	24AUG2020	2/108	1	No	O	NA	R (09DEC2020)	N/N
16-55/ C4591001 1231 12313576	NERV	Sciatica/ Lumbociatalgia	2	03OCT2020	23/1	2	No	O	NA	R (03OCT2020)	N/N
16-55/ C4591001 1231 12313580	GENRL	Injection site erythema/ Erythema at the injection site of the left upper limb#	3	08MAR2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1231 12313605	GENRL	Fatigue/ Fatigue	1	23AUG2020	1/3	1	Yes		NA	R (25AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	23AUG2020	1/3	2	Yes		NA	R (25AUG2020)	N/N
	INFEC	Conjunctivitis/ Conjunctivitis	2	21NOV2020	70/3	1	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001	SKIN	Rash/ upper limbs rash	2	13JAN2021	123/5	1	No	O	NA/TC/TCN	R (17JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12313613 16-55/ C4591001 1231 12313631	REPRO	Pruritus genital/ genital itching	2	15SEP2020	3/46	1	No	O	NA/TC	R (30OCT2020)	N/N	
1231 12313636 16-55/ C4591001 1231 12313637	INV	Body temperature increased/ Body temperature increased	2	01OCT2020	18/2	1	No	O	NA	R (02OCT2020)	N/N	
1231 12313637 16-55/ C4591001 1231 12313644	NERV	Paraesthesia/ Paresthesia in the scapular and lumbar region	2	13SEP2020	1/30	1	No	O	NA	R (12OCT2020)	N/N	
1231 12313644 16-55/ C4591001 1231 12313646	INFEC	Tinea versicolour/ Tinea Versicolor	2	06OCT2020	24/57	1	No	O	NA	R (01DEC2020)	N/N	
1231 12313646 16-55/ C4591001 1231 12313646	MUSC	Myalgia/ Muscle pain	2	17SEP2020	2/2	3	No	O	NA/TC	R (18SEP2020)	N/N	
	MUSC	Trigger finger/ TRigger Finger	2	24SEP2020	9/16	2	No	O	NA/TC	R (09OCT2020)	N/N	
	EYE	Conjunctival haemorrhage/ subconjunctival hemorrhage	2	02OCT2020	17/3	1	No	O	NA/TC	R (04OCT2020)	N/N	
	INJ&P	Skin laceration/ Cutting wound second phalanx of left hand	2	11OCT2020	26/4	2	No	O	NA/TC	R (14OCT2020)	N/N	



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313653	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/78	3	No	O	NA/TC	RS (22JAN2021)	Y/N	
16-55/ C4591001 1231 12313660	RENAL	Dysuria/ Dysuria#	3	05MAR2021	2/6	1	No	O	NA	R (10MAR2021)	N/N	
	INFEC	Urinary tract infection/ Urinary tract infection#	3	12MAR2021	9/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 1231 12313664	MUSC	Rheumatoid arthritis/ Rheumatoid arthritis	2	01NOV2020	50/C	1	No	O	NA	RG	N/N	
	METAB	Hyperuricaemia/ Hyperuricemia	2	14NOV2020	63/77	1	No	O	NA/TC	RS (29JAN2021)	N/N	
16-55/ C4591001 1231 12313682	MUSC	Arthralgia/ Arthralgia in the hands and feet	2	01JAN2021	109/C	1	No	O	NA	N	N/N	
16-55/ C4591001 1231 12313684	MUSC	Arthralgia/ left shoulder arthralgia	1	27AUG2020	4/8	1	No	O	NA	R (03SEP2020)	N/N	
16-55/ C4591001 1231 12313685	SKIN	Rash/ RASH ON LEFT ARM AND HEMITHORAX	2	18SEP2020	6/7	1	No	O	NA	R (24SEP2020)	N/N	
16-55/ C4591001	HEPAT	Cholecystitis/ Cholecystitis	2	25DEC2020	104/35	2	No	O	NA/TC/TCN	R (28JAN2021)	Y/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313689 16-55/ C4591001	GASTR	Toothache/ Left hemiarcaled upper premolar tooth pain	2	07OCT2020	25/15	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
1231 12313693 16-55/ C4591001	NERV	Dysgeusia/ Dysgeusia	2	19SEP2020	7/17	1	No	O	NA	R (05OCT2020)	N/N
1231 12313695 16-55/ C4591001	GENRL	Application site pain/ Application site pain#	3	25FEB2021	1/7	2	Yes		NA	R (03MAR2021)	N/N
1231 12313698 16-55/ C4591001	MUSC	Myalgia/ Muscle pain#	3	25FEB2021	1/3	1	Yes		NA/TC	R (27FEB2021)	N/N
1231 12313702 16-55/ C4591001	GASTR	Gastrooesophageal reflux disease/ Gastrooesophageal reflux	2	01OCT2020	17/91	1	No	O	NA/TC	R (30DEC2020)	N/N
1231 12313713 16-55/ C4591001	GASTR	Toothache/ Left lower third molar tooth pain	2	03OCT2020	19/2	1	No	O	NA	R (04OCT2020)	N/N
1231 12313715 16-55/ C4591001	GASTR	Nausea/ Nausea	2	13SEP2020	1/145	1	Yes		NA	R (04FEB2021)	N/N
1231 12313715 16-55/ C4591001	INJ&P	Ankle fracture/ Right Ankle Fracture	2	02JAN2021	112/59	3	No	O	NA/TC/TCN	RS (01MAR2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313718	NERV	Fall/ Fall from own height.	2	02JAN2021	112/1	3	No	O	NA	R (02JAN2021)	N/N
		Migraine/ Migraine exacerbation	2	03OCT2020	21/4	2	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1231 12313725	PSYCH	Anxiety disorder/ Anxiety disorder#	2	21FEB2021	162/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12313756	MUSC	Arthralgia/ Stabbing pain in scapular region bilateral intermittent	2	05OCT2020	23/15	2	No	O	NA/TC	R (19OCT2020)	N/N
	GENRL	Pain/ stabbing nonspecific trunk pain	2	10OCT2020	28/10	1	No	O	NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 1231 12313758	SKIN	Skin lesion/ Skin lesion in the left nasolabial fold	2	15DEC2020	94/C	2	No	O	NA	N	N/N
	MUSC	Back pain/ muscle pain in the back	1	22OCT2020	60/4	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1231 12313759	GASTR	Diarrhoea/ Diarrhea	2	16OCT2020	33/2	2	No	O	NA/TC/TCN	R (17OCT2020)	N/N
16-55/ C4591001 1231 12313773	GENRL	Asthenia/ Asthenia	1	24AUG2020	1/3	1	Yes		NA	R (26AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313777	BLOOD	Injection site pain/ Injection site pain	1	24AUG2020	1/63	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1231 12313777	BLOOD	Lymphadenopathy/ left supraclavicular and axillary adenomegaly	2	16SEP2020	2/8	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1231 12313778	RESP	Allergic sinusitis/ Seasonal sinusitis	2	22SEP2020	10/6	1	No	O	NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1231 12313780	GASTR	Aphthous ulcer/ oral aphthae	2	15SEP2020	3/8	2	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1231 12313785	INFEC	Appendicitis/ Acute appendicitis	2	22OCT2020	39/16	2	No	O	NA/TC/TCN	R (06NOV2020)	Y/N
16-55/ C4591001 1231 12313818	GASTR	Toothache/ Toothache	2	06OCT2020	24/11	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12313825	VASC	Intermittent claudication/ intermittent claudication	1	27AUG2020	3/21	2	No	O	NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1231 12313831	VASC	Varicose vein/ Worsening pain from varicose veins	2	07OCT2020	23/4	1	No	O	NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313832	GENRL	Asthenia/ asthenia	1	26AUG2020	2/2	1	No	O	NA	R (27AUG2020)	N/N
16-55/ C4591001 1231 12313836	MUSC	Back pain/ low back pain	2	07OCT2020	22/35	1	No	O	NA/TC/TCN	R (10NOV2020)	N/N
16-55/ C4591001 1231 12313837	PSYCH	Depression/ Depressive syndrome#	2	22FEB2021	160/C	1	No	CD	NA/TC	N	N/N
16-55/ C4591001 1231 12313854	GENRL	Injection site pain/ Pain at the injection site	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
16-55/ C4591001 1231 12313862	MUSC	Myalgia/ myalgia	2	20SEP2020	7/23	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313877	INFEC	Otitis media acute/ Left acute otitis media	2	09OCT2020	24/8	1	No	O	NA/TC	R (16OCT2020)	N/N
		Pharyngitis bacterial/ bacterial pharyngitis	2	09OCT2020	24/8	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12313879	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INJ&P	Exposure during pregnancy/ Exposure to Investigation product during pregnancy	1	12SEP2020	19/C		No	O	NA	UNK	N/N
	NERV	Headache/ headache	2	14SEP2020	2/9	3	No	O	NA/TC	R (22SEP2020)	N/N
	INFEC	Urinary tract infection/ Suspected Complicated Urinary Tract Infection	2	31JAN2021	141/18	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1231 12313884	BLOOD	Lymphadenopathy/ right axillary adenopathy	2	18SEP2020	3/5	1	No	O	NA	R (22SEP2020)	N/N
16-55/ C4591001 1231 12313893	GENRL	Vessel puncture site haematoma/ Blood draw site hematoma on left arm	2	14OCT2020	32/8	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C4591001 1231 12313896	GENRL	Injection site pain/ Injection Site Pain	1	25AUG2020	1/1	1	Yes		NA	R (25AUG2020)	N/Y
	GASTR	Dental caries/ Caries in premolar and molar	1	01SEP2020	8/53	2	No	O	NA/TC/TCN	R (23OCT2020)	N/N
16-55/ C4591001 1231 12313902	INJ&P	Contusion/ Traumatic contusion in the arms	1	04SEP2020	11/9	2	No	O	NA/TCN	R (12SEP2020)	N/N
		Contusion/ Traumatic contusion in the trunk	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N
		Contusion/ Traumatic contusion on the face	1	04SEP2020	11/9	2	No	O	NA/TC/TCN	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313904	PSYCH	Panic attack/ Panic attack	1	04SEP2020	11/42	2	No	O	NA/TC/TCN	R (15OCT2020)	N/N
	CARD	Palpitations/ Intermittent Palpitations.	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N
16-55/ C4591001 1231 12313915	INV	Body temperature increased/ Body temperature increased	2	15SEP2020	3/6	1	No	O	NA	R (20SEP2020)	N/N
	MUSC	Back pain/ low back pain#	3	27JAN2021	8/1	1	No	O	NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1231 12313916	MUSC	Back pain/ Low back pain	2	30SEP2020	18/26	1	No	O	NA/TC	R (25OCT2020)	N/N
16-55/ C4591001 1231 12313921	MUSC	Muscle contracture/ Cervical muscular contracture	1	07SEP2020	14/6	1	No	O	NA/TC/TCN	R (12SEP2020)	N/N
16-55/ C4591001 1231 12313925	RESP	Interstitial lung disease/ Right lung interstitial pneumonia	1	02SEP2020	9/8	2	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1231 12313927	MUSC	Arthralgia/ left shoulder pain	2	18SEP2020	6/C	2	No	O	NA/TC	N	N/N
		Rotator cuff syndrome/ left rotator cuff tendonitis	2	18SEP2020	6/120	2	No	O	NA/TC/TCN	R (15JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12313931	GASTR	Diarrhoea/ diarrhea	1	28AUG2020	4/3	1	No	O	NA	R (30AUG2020)	N/N	
	MUSC	Synovial cyst/ ganglion in right wrist joint	2	22SEP2020	10/C	1	No	O	NA	RG	N/N	
	MUSC	Back pain/ low back pain#	4	07MAR2021	23/C	2	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12313935	GENRL	Injection site pain/ mild pain at the injection site	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/N	
16-55/ C4591001 1231 12313939	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	23/2	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12313941	NERV	Headache/ Headache	1	30AUG2020	6/50	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001 1231 12313960	GENRL	Swelling face/ Swelling in cheeks	2	16OCT2020	32/1	1	No	O	NA/TC	R (16OCT2020)	N/N	
16-55/ C4591001 1231 12313964	GENRL	Application site erythema/ Erythema at the application site	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	
		Application site pain/ Pain at the application site	1	25AUG2020	1/4	1	Yes		NA	R (28AUG2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313967	MUSC	Tendon disorder/ righth shoulder tendinosis	1	07SEP2020	14/3	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1231 12313968	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	2/3	2	Yes		NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1231 12313971	INJ&P	Wound/ Superficial incised wound on the forehead	2	25JAN2021	132/1	2	No	O	NA/TCN	R (25JAN2021)	N/N
	IMMUN	Drug hypersensitivity/ Allergic reaction to naproxen	2	26JAN2021	133/1	2	No	O	NA/TC	R (26JAN2021)	N/N
16-55/ C4591001 1231 12313984	INJ&P	Ligament sprain/ right ankle sprain	2	30SEP2020	16/28	2	No	O	NA/TCN	R (27OCT2020)	N/N
16-55/ C4591001 1231 12313989	INFEC	Rhinitis/ rhinitis	2	24SEP2020	9/19	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1231 12313993	PSYCH	Depression/ Worsening Depression	2	14OCT2020	30/21	2	No	O	NA/TC/TCN	R (03NOV2020)	N/N
16-55/ C4591001 1231 12313996	MUSC	Back pain/ Low back pain	2	09FEB2021	149/29	1	No	O	NA/TC/TCN	R (09MAR2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313998	INJ&P	Exposure during pregnancy/ Drug exposed pregnancy	2	25DEC2020	102/35		No	O	NA	R (28JAN2021)	N/N
	PREG	Abortion spontaneous complete/ Complete spontaneous abortion#	2	24JAN2021	132/16	3	No	O	NA/TC	R (08FEB2021)	Y/N
16-55/ C4591001 1231 12314010	INJ&P	Skin injury/ ERYTHEMATOUS AND FLAKY SKIN INJURIES IN TRUNK AND THIGHS	2	02OCT2020	18/25	1	No	O	NA	R (26OCT2020)	N/N
16-55/ C4591001 1231 12314016	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia#	3	01FEB2021	4/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314022	GASTR	Dry mouth/ xerostomia	2	12OCT2020	28/42	1	No	O	NA/TCN	R (22NOV2020)	N/N
16-55/ C4591001 1231 12314032	MUSC	Musculoskeletal chest pain/ muscle-type chest pain	2	22SEP2020	9/3	1	No	O	NA	R (24SEP2020)	N/N
	GENRL	Chest pain/ Intermittent chest pain in the right pectoral	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N
	MUSC	Myalgia/ muscle pain in the upper inner third of the righth arm	2	06OCT2020	23/2	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary adenopathy	1	01SEP2020	8/17	2	No	O	NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314033 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	31AUG2020	7/71		No	O	NA	R (09NOV2020)	N/N
1231 12314059 16-55/ C4591001	SKIN	Rash papular/ Papular rash in deltoid region of the right arm.	2	17OCT2020	33/4	1	No	O	NA/TC/TCN	R (20OCT2020)	N/N
1231 12314073 16-55/ C4591001	RENAL	Pollakiuria/ NOCTURNE POLLAKIURIA	1	28AUG2020	3/62	2	No	O	NA	R (28OCT2020)	N/N
1231 12314075	MUSC	Back pain/ LOW BACK PAIN WORSENING	1	30AUG2020	5/24	2	No	O	NA/TC	R (22SEP2020)	N/N
	HEPAT	Cholelithiasis obstructive/ Cholestatic syndrome secondary to lithiasis#	2	05MAR2021	170/6	2	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001	INFEC	Tooth infection/ Left wisdom tooth infection	1	28AUG2020	3/27	2	No	O	NA/TC/TCN	R (23SEP2020)	N/N
1231 12314084 16-55/ C4591001	INJ&P	Chest injury/ Trauma to the posterior region of the right rib cage	2	05NOV2020	52/1	1	No	O	NA/TC	R (05NOV2020)	N/N
1231 12314104	MUSC	Musculoskeletal chest pain/ pain in right posterior rib	2	05NOV2020	52/14	2	No	O	NA/TC	R (18NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314111	NEOPL	Lipoma/ Lipoma in the right mid-axillary line	2	06NOV2020	53/1	1	No	O	NA	R (06NOV2020)	N/N
	EAR	Vertigo/ Vertigo	1	26AUG2020	1/13	1	No	O	NA/TC/TCN	R (07SEP2020)	N/N
16-55/ C4591001 1231 12314128	MUSC	Myalgia/ myalgia	1	26AUG2020	1/6	2	Yes		NA/TC/TCN	R (31AUG2020)	N/N
	BLOOD	Lymphadenopathy/ Left cervical adenopathy	1	27AUG2020	2/37	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1231 12314132	EAR	Ear pain/ left otalgia	1	27AUG2020	2/3	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ pain at the injection site.	1	11SEP2020	17/53	1	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 1231 12314134	NERV	Paraesthesia/ tingling in left arm	1	11SEP2020	17/C	1	Yes		NA/TC	N	N/N
	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	1	07DEC2020	104/69		No	O	NA	R (13FEB2021)	N/N
16-55/ C4591001 1231 12314135	PREG	Abortion incomplete/ incomplete abortion	1	11FEB2021	170/3	3	No	O	NA/TC/TCN	R (13FEB2021)	Y/N
	NERV	Headache/ Headache	2	12OCT2020	29/2	2	No	O	NA/TC	R (13OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314137	GENRL	Asthenia/ asthenia	2	19SEP2020	6/3	3	No	O	NA	R (21SEP2020)	N/N
	EYE	Blepharospasm/ blepharospasm	2	30SEP2020	17/3	1	No	O	NA	R (02OCT2020)	N/N
	ENDO	Hypothyroidism/ worsening of hypothyroidism	2	04MAR2021	172/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314143	SURG	Dental care/ dental treatment	2	13OCT2020	30/1	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1231 12314152	ENDO	Hypothyroidism/ Hypothyroidism	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1231 12314154	INFEC	Tooth infection/ Odontogenic infection#	4	13MAR2021	29/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314155	INJ&P	Ligament sprain/ Right ankle sprain	2	19SEP2020	6/6	2	No	O	NA/TC/TCN	R (24SEP2020)	N/N
16-55/ C4591001 1231 12314156	GENRL	Injection site pain/ Injection site pain#	3	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314188		Pyrexia/ Fever#	3	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain#	3	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	3	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	REPRO	Menstruation delayed/ Menstrual delay	2	15SEP2020	2/58	1	No	O	NA/TC	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Local pain at injection site	1	27AUG2020	2/2	2	Yes		NA/TC	R (28AUG2020)	N/N
	EYE	Conjunctival haemorrhage/ Subconjunctival hemorrhage left eye	2	12OCT2020	29/14	1	No	O	NA	R (25OCT2020)	N/N
	INFEC	Pustule/ Pustulosis in upper limbs and lumbar area.	2	17SEP2020	3/43	1	No	O	NA	R (29OCT2020)	N/N
	INJ&P	Joint injury/ Right knee trauma	2	29SEP2020	14/42	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1231 12314212	GASTR	Odynophagia/ odynophagia	2	29SEP2020	16/3	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1231 12314223											

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314224	REPRO	Metrorrhagia/ Metrorrhagia	2	01MAR2021	169/8	1	No	O	NA	R (08MAR2021)	N/N	
	NERV	Sciatica/ Flare-up of sciatica	2	19SEP2020	5/52	2	No	O	NA/TC/TCN	R (09NOV2020)	N/N	
	MUSC	Arthralgia/ Migratory arthralgias in upper limbs	2	10OCT2020	26/4	2	No	O	NA	R (13OCT2020)	N/N	
16-55/ C4591001 1231 12314229	GASTR	Irritable bowel syndrome/ irritable bowel	1	01SEP2020	7/45	1	No	O	NA/TC/TCN	R (15OCT2020)	N/N	
16-55/ C4591001 1231 12314230	SURG	Tooth extraction/ tooth extraction#	4	26FEB2021	9/1	1	No	O	NA/TC	R (26FEB2021)	N/N	
16-55/ C4591001 1231 12314251	NERV	Headache/ headache	2	23SEP2020	8/4	1	No	O	NA	R (26SEP2020)	N/N	
16-55/ C4591001 1231 12314256	INJ&P	Radius fracture/ Intra-articular Left Radius Fracture	2	09OCT2020	3/5	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N	
16-55/ C4591001 1231 12314263	SOCCI	High risk sexual behaviour/ Risky sexual behavior	2	24OCT2020	18/1	1	No	O	NA/TC	R (24OCT2020)	N/N	
	GENRL	Injection site papule/ multiple small itchy papule located on the left arm, extending from the injection site to the elbow	1	31AUG2020	6/3	1	Yes		NA	R (02SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site papule/ multiple small itchy papules located on the left arm, extending from the injection site to the elbow	2	18SEP2020	5/3	1	Yes		NA/TC	R (20SEP2020)	N/N
16-55/ C4591001 1231 12314265	MUSC	Synovitis/ Synovitis in both knees	1	31AUG2020	6/C	2	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12314267	INFEC	Tonsillitis/ tonsillitis	2	08OCT2020	25/6	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1231 12314269	GASTR	Stomatitis/ stomatitis	2	19SEP2020	2/19	2	No	O	NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1231 12314270	RENAL	Dysuria/ Dysuria	2	01OCT2020	18/39	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 1231 12314277	EAR	Tinnitus/ Left ear tinnitus	2	23SEP2020	8/77	2	No	O	NA/TC/TCN	R (08DEC2020)	N/N
	MUSC	Temporomandibular joint syndrome/ Temporomandibular joint dysfunction	2	23SEP2020	8/77	2	No	O	NA/TC/TCN	R (08DEC2020)	N/N
16-55/ C4591001 1231 12314278	GENRL	Pyrexia/ fever	2	15SEP2020	2/2	3	Yes		NA/TC	R (16SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314280	SKIN	Skin lesion/ Skin lesion on the thumb of the right hand#	4	28FEB2021	19/8	1	No	O	NA/TC/TCN	R (07MAR2021)	N/N
16-55/ C4591001 1231 12314290	GASTR	Abdominal pain upper/ Epigastralgia	1	28AUG2020	3/15	2	No	O	NA	R (11SEP2020)	N/N
16-55/ C4591001 1231 12314294	GENRL	Pyrexia/ Fever#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N
	MUSC	Arthralgia/ Generalized arthralgias#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N
		Myalgia/ generalized myalgias#	3	25FEB2021	1/3	2	Yes		NA	R (27FEB2021)	N/N
16-55/ C4591001 1231 12314297	METAB	Diabetes mellitus inadequate control/ Uncompensated diabetes	2	17SEP2020	4/14	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12314298	GASTR	Gastritis/ Worsening gastritis	1	27AUG2020	2/3	1	No	O	NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1231 12314308	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	10DEC2020	86/C		No	O	NA	UNK	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site#	4	13FEB2021	1/5	2	Yes		NA/TC	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314327 16-55/ C4591001	INFEC	Pharyngitis/ Pharyngitis	1	27AUG2020	2/5	2	No	O	NA/TC	R (31AUG2020)	N/N
1231 12314329 16-55/ C4591001	INFEC	Pharyngotonsillitis/ Putaceous pharyngotonsillitis	1	29AUG2020	4/4	2	No	O	NA/TC	R (01SEP2020)	N/N
1231 12314343 16-55/ C4591001	GENRL	Application site pain/ Pain at application site.#	4	12MAR2021	2/2	2	Yes		NA/TC	R (13MAR2021)	N/N
1231 12314351		Pyrexia/ Fever#	4	12MAR2021	2/1	3	Yes		NA/TC	R (12MAR2021)	N/N
16-55/ C4591001 1231 12314358	MUSC	Arthralgia/ Arthralgia in left elbow	2	24SEP2020	11/121	1	No	O	NA	R (22JAN2021)	N/N
		Musculoskeletal chest pain/ Intermittent chest muscle pain	2	24SEP2020	11/113	1	No	O	NA/TC	R (14JAN2021)	N/N
	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	27OCT2020	44/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314360	GENRL	Chills/ Chills	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	09OCT2020	24/1	1	No	O	NA	R (09OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314368	BLOOD	Lymphadenopathy/ Supraclavicular adenopathy (left)	1	29AUG2020	4/56	1	No	O	NA/TC	R (23OCT2020)	N/N	
	RESP	Tonsillar hypertrophy/ swollen tonsils	2	18SEP2020	3/21	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12314372	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	2	25OCT2020	39/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1231 12314395	REPRO	Haemospermia/ Hemospermia	2	26SEP2020	12/1	1	No	O	NA	R (26SEP2020)	N/N	
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy (female partner)	2	12NOV2020	59/C		No	O	NA	UNK	N/N	
16-55/ C4591001 1231 12314400	RESP	Asthma/ asthma exacerbation	2	26SEP2020	11/5	1	No	O	NA/TC	R (30SEP2020)	N/N	
16-55/ C4591001 1231 12314405	EAR	Vertigo/ two second-long episodes of vertigo	1	27AUG2020	1/1	1	No	O	NA	R (27AUG2020)	N/N	
	GENRL	Injection site pain/ local pain at the injection site	1	27AUG2020	1/3	1	Yes		NA	R (29AUG2020)	N/N	
16-55/ C4591001 1231 12314407	INJ&P	Multiple injuries/ Polytrauma	2	20SEP2020	5/93	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Epistaxis/ Epistaxis	2	20SEP2020	5/30	2	No	O	NA/TCN	R (19OCT2020)	N/N
	VASC	Subgaleal haematoma/ subgaleal hematoma	2	20SEP2020	5/51	2	No	O	NA/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1231 12314416	NERV	Sciatica/ lumbosciatica	1	11SEP2020	16/54	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1231 12314417	NERV	Syncope/ Vasovagal syncope	2	15DEC2020	91/1	2	No	O	NA/TCN	R (15DEC2020)	N/N
16-55/ C4591001 1231 12314421	INFEC	Urinary tract infection/ urinary infection	2	20OCT2020	36/6	1	No	O	NA	R (25OCT2020)	N/N
16-55/ C4591001 1231 12314429	INJ&P	Fall/ Fall from his own height#	4	03MAR2021	20/5	1	No	O	NA/TC	R (07MAR2021)	N/N
	INJ&P	Chest injury/ Right lower thoracic trauma#	4	07MAR2021	24/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12314434	VASC	Hypertension/ arterial hypertension	1	01SEP2020	6/85	2	No	O	NA/TC	R (24NOV2020)	N/N
16-55/ C4591001 1231 12314435	GENRL	Asthenia/ asthenia	1	27AUG2020	1/1	1	Yes		NA	R (27AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314436	GENRL	Pyrexia/ fever	2	15SEP2020	1/2	3	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1231 12314450	INFEC	Anal fistula infection/ anal fistula acute infection	1	15SEP2020	20/5	2	No	O	NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1231 12314464	EAR	Tinnitus/ tinnitus bilateral, intermittent	1	10SEP2020	15/38	1	No	O	NA	R (17OCT2020)	N/N
	CARD	Palpitations/ PALPITATIONS	2	16SEP2020	1/13	1	No	O	NA	R (28SEP2020)	N/N
	GASTR	Dental caries/ Dental Cavities	2	10OCT2020	25/8	1	No	O	NA/TC/TCN	R (17OCT2020)	N/N
16-55/ C4591001 1231 12314474	GENRL	Injection site pain/ Pain at the injection site.	1	27AUG2020	1/1	2	Yes		NA	R (27AUG2020)	N/N
	INFEC	Periodontitis/ Right lower molar periodontitis	1	28AUG2020	2/7	2	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1231 12314477	GENRL	Fatigue/ fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
		Injection site pain/ Injection site pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle pain	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314482	RESP	Rhinorrhoea/ rhinorrhea	2	23SEP2020	6/11	1	No	O	NA/TC	R (03OCT2020)	N/N
	INJ&P	Penis injury/ PENIS INJURY	2	15SEP2020	1/8	1	No	O	NA/TCN	R (22SEP2020)	N/N
16-55/ C4591001 1231 12314486	RESP	Rhinitis allergic/ Allergic rhinitis	2	07OCT2020	23/3	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 1231 12314494	GASTR	Food poisoning/ Food poisoning	2	03FEB2021	141/5	3	No	O	NA/TC	R (07FEB2021)	Y/N
16-55/ C4591001 1231 12314499	INFEC	Rhinitis/ Rhinitis	2	28SEP2020	13/3	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12314511	MUSC	Back pain/ low back pain	2	30SEP2020	15/6	1	No	O	NA	R (05OCT2020)	N/N
	MUSC	Pain in extremity/ Nonspecific upper limb pain.	2	18OCT2020	33/2	2	No	O	NA/TC	R (19OCT2020)	N/N
	REPRO	Metrorrhagia/ Metrorrhagia	2	11NOV2020	57/C	1	No	O	NA	N	N/N
	GENRL	Pyrexia/ Fever	1	28AUG2020	2/3	2	Yes		NA/TC	R (30AUG2020)	N/N
	GASTR	Stomatitis/ Stomatitis	1	07SEP2020	12/6	1	No	O	NA	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314513	NERV	Headache/ Headache	2	15SEP2020	1/15	1	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1231 12314515	GENRL	Axillary pain/ Regional pain (left axillary hollow)	2	29OCT2020	45/3	1	No	O	NA	R (31OCT2020)	N/N
16-55/ C4591001 1231 12314526	NERV	Dizziness/ Dizziness	2	06OCT2020	20/1	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1231 12314528	INFEC	Herpes zoster/ HERPES ZOSTER RIGHT THORACIC of one dermatome	2	01NOV2020	48/46	2	No	O	NA/TC	R (16DEC2020)	N/N
16-55/ C4591001 1231 12314529	MUSC	Myalgia/ Generalized muscle pain	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1231 12314531	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	30SEP2020	3/C		No	O	NA	UNK	N/N
	INFEC	Urinary tract infection/ Complicated urinary infection	2	08JAN2021	103/47	3	No	O	NA/TC	R (23FEB2021)	Y/N
16-55/ C4591001 1231 12314542	MUSC	Arthralgia/ Arthralgia	1	01SEP2020	6/50	1	No	O	NA/TC	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314547	METAB	Vitamin B12 deficiency/ vitamin B12 deficiency	2	01NOV2020	48/124	1	No	O	NA/TC	RS (04MAR2021)	N/N
16-55/ C4591001 1231 12314550	INJ&P	Epicondylitis/ Medial epicondylitis	2	16OCT2020	31/120	2	No	O	NA/TC/TCN	R (12FEB2021)	N/N
	NERV	Neuropathy peripheral/ Right upper limb neuropathy	2	16OCT2020	31/26	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1231 12314553	INFEC	Furuncle/ furunculosis	1	29AUG2020	3/16	2	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1231 12314554	MUSC	Neck pain/ right cervicalgia	1	07SEP2020	12/2	1	No	O	NA	R (08SEP2020)	N/N
16-55/ C4591001 1231 12314562	BLOOD	Lymphadenopathy/ left submandibular adenopathy.	2	03OCT2020	18/11	1	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 1231 12314573	VASC	Haematoma/ hematoma 8 cm in diameter, external face of right leg	2	17OCT2020	33/6	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1231 12314574	INJ&P	Limb injury/ Right leg, external side trauma.	1	11SEP2020	16/1	1	No	O	NA	R (11SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314575	NERV	Paraesthesia/ Paresthesia on the outer side of the right leg	1	11SEP2020	16/78	1	No	O	NA/TCN	R (27NOV2020)	N/N
	RESP	Asthma/ asthma attack	1	05SEP2020	10/2	2	No	O	NA/TC	R (06SEP2020)	N/N
	GENRL	Injection site pain/ Burning at injection site	1	08OCT2020	43/1	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Trigeminal neuralgia/ Trigeminal neuralgia	2	17OCT2020	31/10	2	No	O	NA/TC	R (26OCT2020)	N/N
	GASTR	Abdominal pain upper/ Epigastralgia	2	15OCT2020	31/5	1	No	O	NA	R (19OCT2020)	N/N
	GASTR	Pancreatitis acute/ acute pancreatitis	2	30NOV2020	77/15	2	No	O	NA/TC	R (14DEC2020)	Y/N
	INFEC	Tooth infection/ odontogenic infection	2	08FEB2021	147/30	1	No	O	NA/TC/TCN	R (09MAR2021)	N/N
	SKIN	Rash/ Rash in torso and arms.	1	01SEP2020	6/10	1	No	O	NA	R (10SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314633	INFEC	Orchitis/ Epididymitis orchitis	2	21OCT2020	37/40	2	No	O	NA/TC	R (29NOV2020)	N/N	
16-55/ C4591001 1231 12314639	GASTR	Abdominal pain upper/ Epigastralgia#	4	04MAR2021	15/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12314649	CARD	Tachycardia/ resting tachycardia	1	29AUG2020	3/1	1	No	O	NA	R (29AUG2020)	N/N	
16-55/ C4591001 1231 12314674	GENRL	Injection site pain/ Local pain at injection site	1	29AUG2020	2/2	1	Yes		NA/TC	R (30AUG2020)	N/N	
16-55/ C4591001 1231 12314678	MUSC	Back pain/ Low back pain	2	05OCT2020	20/4	1	No	O	NA/TC	R (08OCT2020)	N/N	
16-55/ C4591001 1231 12314679	CARD	Tachycardia/ tachycardia	1	29AUG2020	2/3	1	No	O	NA	R (31AUG2020)	N/N	
	MUSC	Neck pain/ Neck pain	1	01SEP2020	5/3	1	No	O	NA/TC/TCN	R (03SEP2020)	N/N	
	RENAL	Renal colic/ Renal colic	2	21NOV2020	18/4	3	No	O	NA/TC	R (24NOV2020)	N/N	
16-55/ C4591001	EAR	Vertigo/ Vertigo	2	25JAN2021	130/41	1	No	O	NA/TC/TCN	R (06MAR2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314693 16-55/ C4591001 1231 12314699	GENRL  NERV	Asthenia/ asthenia  Headache/ headache	1  2	05SEP2020  16SEP2020	9/3  1/24	2  1	No  Yes	O  O	NA/TC  NA/TC	R  R (07SEP2020)  (09OCT2020)	N/N  N/N
16-55/ C4591001 1231 12314712	GENRL	Pyrexia/ fever	2	17SEP2020	2/2	3	Yes	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1231 12314719	GASTR	Diarrhoea/ loose stools	2	30SEP2020	15/3	1	No	O	NA	R (02OCT2020)	N/N
16-55/ C4591001 1231 12314730	INFEC	Folliculitis/ Left Groin Folliculitis	2	04OCT2020	19/8	1	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1231 12314731	INJ&P	Meniscus injury/ Right knee meniscus tear	2	22SEP2020	7/46	2	No	O	NA/TC/TCN	R (06NOV2020)	N/N
16-55/ C4591001 1231 12314751	INFEC	Mastitis/ Left mastitis	2	05MAR2021	171/C	2	No	O	NA/TC/TCN	N	N/N
16-55/ C4591001	EAR	Ear pain/ Right otalgia	2	14OCT2020	29/14	1	No	O	NA/TC	R (27OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314756 16-55/ C4591001	NERV	Headache/ headache	2	15OCT2020	30/1	1	No	O	NA/TC	R (15OCT2020)	N/N
1231 12314764 16-55/ C4591001	GENRL	Pyrexia/ fever	2	18SEP2020	2/1	3	Yes		NA/TC/TCN	R (18SEP2020)	N/N
1231 12314768 16-55/ C4591001	GASTR	Gastritis/ Gastritis	2	08OCT2020	23/11	1	No	O	NA/TC	R (18OCT2020)	N/N
1231 12314771 16-55/ C4591001	EYE	Chalazion/ chalazion	2	24SEP2020	9/3	1	No	O	NA/TC	R (26SEP2020)	N/N
1231 12314774 16-55/ C4591001	GASTR	Nausea/ Nausea	2	30SEP2020	15/2	2	No	O	NA/TC	R (01OCT2020)	N/N
1231 12314790 16-55/ C4591001	INFEC	Gingivitis/ Gingivitis	1	03SEP2020	7/8	2	No	O	NA/TC	R (10SEP2020)	N/N
1231 12314804	VASC	Hypertension/ Arterial Hypertension	1	16SEP2020	20/1	2	No	O	NA/TC	R (16SEP2020)	N/N
	GASTR	Vomiting/ vomits	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314813	GENRL	Asthenia/ asthenia	2	03OCT2020	2/2	1	No	O	NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	MUSC	Back pain/ Low back pain	2	21SEP2020	5/22	2	No	O	NA/TC/TCN	R (12OCT2020)	N/N
		Intervertebral disc protrusion/ Worsening of herniated disc	2	21SEP2020	5/107	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
	INJ&P	Ligament injury/ grade 1 injury to the internal collateral ligament of the right knee	2	25SEP2020	10/C	2	No	O	NA/TC	RG	N/N
	INFEC	Tooth infection/ Dental infection	2	03OCT2020	18/44	1	No	O	NA	R (15NOV2020)	N/N
	INFEC	Appendicitis/ Acute Appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N
	INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/37	3	No	O	NA/TC/TCN	R (04DEC2020)	Y/N
	INFEC	Postoperative wound infection/ infection in surgical wound	2	30OCT2020	43/36	2	No	O	NA/TC/TCN	R (04DEC2020)	N/N
16-55/ C4591001 1231 12314836	NERV	Headache/ headache	2	20OCT2020	35/1	1	No	O	NA	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Tooth infection/ Odontogenic infection#	3	02MAR2021	12/4	1	No	O	NA/TC	R (05MAR2021)	N/N
16-55/ C4591001 1231 12314847	SKIN	Rash/ skin rash on chest and neck	2	08OCT2020	23/7	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1231 12314852	GENRL	Fatigue/ Fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ Pain at injection site	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12314857	MUSC	Neck pain/ Cervicalgia	1	16SEP2020	20/5	1	No	O	NA/TC	R (20SEP2020)	N/N
	METAB	Dyslipidaemia/ Dyslipidemia	2	20JAN2021	97/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12314870	GASTR	Toothache/ odontogenic pain	2	01OCT2020	16/1	1	No	O	NA/TCN	R (01OCT2020)	N/N
16-55/ C4591001 1231 12314873	GENRL	Injection site pain/ Injection site pain (left arm)	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
	EAR	Vertigo/ Vertigo	2	19SEP2020	2/25	2	No	O	NA/TCN	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Pain at the injection site	2	19SEP2020	2/62	1	Yes		NA	R (19NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12314877	INFEC	Oral herpes/ Worsening of herpes labialis	2	23OCT2020	36/10	1	No	O	NA/TC	R (01NOV2020)	N/N
16-55/ C4591001 1231 12314877	GASTR	Toothache/ exacerbation of dental pain	2	04OCT2020	19/6	2	No	O	NA/TC/TCN	R (09OCT2020)	N/N
16-55/ C4591001 1231 12314878	GENRL	Chills/ INTERMITENT CHILLS	1	05SEP2020	9/10	1	No	O	NA	R (14SEP2020)	N/N
16-55/ C4591001 1231 12314883	GASTR	Vomiting/ vomiting	1	30AUG2020	3/1	3	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1231 12314885	MUSC	Back pain/ low back pain	2	17OCT2020	32/50	2	No	O	NA/TC/TCN	R (05DEC2020)	N/N
16-55/ C4591001 1231 12314889	GENRL	Asthenia/ asthenia	1	05SEP2020	9/1	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1231 12314894	CARD	Myocarditis/ right retroatrial inflammation	2	21SEP2020	6/1	1	No	O	NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1231 12314919	IMMUN	Hypersensitivity/ Face allergic reaction	2	10OCT2020	24/1	1	No	O	NA/TC	R (10OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12314921	INJ&P	Burns second degree/ Second degree burn of the right arm and forearm.#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
		Burns third degree/ Third degree burn on the right hand#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1231 12314928	GENRL	Pyrexia/ Fever (38.8 degrees C)	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
	MUSC	Myalgia/ MYALGIA GENERALIZED	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
	NERV	Headache/ HEADACHE	2	17SEP2020	2/2	3	Yes		NA/TC	R (18SEP2020)	N/N	
16-55/ C4591001 1231 12314931	EYE	Eye allergy/ eye allergy	1	01SEP2020	5/11	1	No	O	NA	R (11SEP2020)	N/N	
16-55/ C4591001 1231 12314934	RESP	Rhinitis allergic/ Allergic rhinitis	2	15NOV2020	59/6	1	No	O	NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 1231 12314935	GENRL	Chest pain/ prechordalgia	1	31AUG2020	4/1	1	No	O	NA/TC	R (31AUG2020)	N/N	
16-55/ C4591001 1231 12314947	GENRL	Asthenia/ asthenia	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Somnolence/ DROWSINESS	1	04SEP2020	8/3	1	No	O	NA	R (06SEP2020)	N/N
16-55/ C4591001 1231 12314974	NERV	Headache/ Headache	2	01OCT2020	16/7	1	No	O	NA	R (07OCT2020)	N/N
16-55/ C4591001 1231 12314980	BLOOD	Leukopenia/ Leukopenia	2	21OCT2020	36/24	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C4591001 1231 12314987	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N
16-55/ C4591001 1231 12314998	INJ&P	Vulvovaginal injury/ Vulvar injury	2	20SEP2020	4/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1231 12315054	GENRL	Injection site pain/ Pain at the injection site#	3	20JAN2021	2/5	1	Yes		NA	R (24JAN2021)	N/N
	MUSC	Myalgia/ Generalized myalgia#	3	20JAN2021	2/5	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1231 12315073	INFEC	Bartholinitis/ inflammation of the bartolin glands	2	15OCT2020	29/4	2	No	O	NA/TC/TCN	R (18OCT2020)	N/N
16-55/ C4591001	GASTR	Toothache/ toothache	2	10OCT2020	23/1	1	No	O	NA/TC	R (10OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1231 12315087 16-55/ C4591001	MUSC	Back pain/ low back pain	1	29AUG2020	1/9	1	No	O	NA	R (06SEP2020)	N/N	
1231 12315089	MUSC	Back pain/ Low back pain	2	23SEP2020	7/7	2	No	O	NA/TC	R (29SEP2020)	N/N	
16-55/ C4591001 1231 12315093	BLOOD	Lymphadenopathy/ Adenopathy in low left cervical region.	2	19SEP2020	3/5	1	No	O	NA	R (23SEP2020)	N/N	
16-55/ C4591001 1231 12315094	MUSC	Neck pain/ Cervicalgia	2	23SEP2020	6/3	2	No	O	NA/TC	R (25SEP2020)	N/N	
	GENRL	Injection site pain/ Pain at injection site.#	3	20FEB2021	1/C	1	Yes		NA/TC	RG	N/N	
	GENRL	Asthenia/ Asthenia#	3	21FEB2021	2/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1231 12315095	NERV	Paraesthesia/ Paresthesias in both hands	2	29SEP2020	13/45	1	No	O	NA/TC/TCN	R (12NOV2020)	N/N	
16-55/ C4591001 1231 12315101	VASC	Hypertension/ Arterial hypertension	2	19SEP2020	3/1	1	No	O	NA/TC	R (19SEP2020)	N/N	
	SKIN	Rash maculo-papular/ Maculo psular rash on chest	2	23SEP2020	7/38	1	No	O	NA	R (30OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315167	MUSC	Intervertebral disc protrusion/ DISC PROTRUSION AT CERVICAL LEVEL	2	11OCT2020	25/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12315176	INFEC	Tooth infection/ dental infection	1	10SEP2020	13/4	2	No	O	NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1231 12315185	REPRO	Amenorrhoea/ functional amenorrhea	1	16SEP2020	19/61	1	No	O	NA/TC	R (15NOV2020)	N/N
16-55/ C4591001 1231 12315186	GASTR	Abdominal pain/ abdominal pain	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ abdominal myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N
	GASTR	Gastritis erosive/ worsening of antral erosive gastritis	2	24SEP2020	8/28	1	No	O	NA/TC/TCN	R (21OCT2020)	N/N
	METAB	Dyslipidaemia/ dyslipidemia	2	01DEC2020	76/C	1	No	O	NA	N	N/N
	NEOPL	Adenocarcinoma pancreas/ pancreatic ductal adenocarcinoma#	2	17FEB2021	154/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12315189	INFEC	Conjunctivitis/ Worsening of rhino conjunctivitis	1	01SEP2020	4/20	1	No	O	NA/TC	R (20SEP2020)	N/N
16-55/ C4591001	RESP	Asthma/ bronchial asthma	2	03NOV2020	48/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315190 16-55/ C4591001	INFEC	Tooth infection/ Odontogenic infection#	3	12MAR2021	15/C	2	No	O	NA/TC/TCN	N	N/N
1231 12315197 16-55/ C4591001	CARD	Palpitations/ PALPITATIONS	1	04SEP2020	7/6	1	No	O	NA/TCN	R (09SEP2020)	N/N
1231 12315201 16-55/ C4591001	GENRL	Asthenia/ asthenia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
1231 12315202	MUSC	Myalgia/ myalgia	1	30AUG2020	2/5	1	No	O	NA	R (03SEP2020)	N/N
	MUSC	Pain in extremity/ Severe pain in the left upper limb	1	30AUG2020	2/5	3	No	O	NA/TC	R (03SEP2020)	N/N
	MUSC	Arthralgia/ generalized arthralgias	1	17SEP2020	20/7	1	No	O	NA	R (23SEP2020)	N/N
	NERV	Headache/ headache	2	28SEP2020	1/4	2	No	O	NA	R (01OCT2020)	N/N
16-55/ C4591001 1231 12315204	MUSC	Neck pain/ cervicalgia	1	14SEP2020	17/1	2	No	O	NA/TC/TCN	R (14SEP2020)	N/N
16-55/ C4591001 1231 12315205	GASTR	Rectal haemorrhage/ Proctorrhagia	2	03OCT2020	17/2	1	No	O	NA	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315206	SURG	Endodontic procedure/ Endodontic treatment	2	22SEP2020	5/22	1	No	O	NA/TC/TCN	R (13OCT2020)	N/N
16-55/ C4591001 1231 12315208	PSYCH	Insomnia/ insomnia	2	22SEP2020	6/43	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1231 12315225	GASTR	Dyspepsia/ Dyspepsia	2	16NOV2020	61/7	1	No	O	NA/TC/TCN	R (22NOV2020)	N/N
16-55/ C4591001 1231 12315264	GENRL	Oedema peripheral/ Left upper limb edema#	4	05FEB2021	1/9	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1231 12315268	MUSC	Tendonitis/ Left elbow tendonitis#	3	09FEB2021	12/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12315271	GENRL	Asthenia/ asthenia	1	06SEP2020	9/2	1	No	O	NA	R (07SEP2020)	N/N
16-55/ C4591001 1231 12315276	GASTR	Lip oedema/ Lip Edema	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N
	SKIN	Pruritus/ perioral pruritus	1	03SEP2020	6/1	1	No	O	NA/TC	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Lip oedema/ Lip Edema	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
	SKIN	Pruritus/ perioral pruritus	2	29SEP2020	12/1	1	No	O	NA/TC	R (29SEP2020)	N/N
	MUSC	Muscle spasms/ muscle cramps	2	18OCT2020	31/1	1	No	O	NA/TC	R (18OCT2020)	N/N
	MUSC	Pain in extremity/ pain in left deltoid region	2	28OCT2020	41/C	2	No	O	NA	N	N/N
	INV	Blood immunoglobulin E increased/ Elevation IG E	2	30OCT2020	43/C	1	No	O	NA	N	N/N
16-55/ C4591001 1231 12315280	MUSC	Pain in extremity/ pain in soles and palms	2	25SEP2020	8/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12315286	GENRL	Oedema peripheral/ left foot edema	2	22SEP2020	4/1	1	No	O	NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1231 12315287	EYE	Keratitis/ Keratitis	2	29SEP2020	13/16	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1231 12315291	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/83	1	No	O	NA/TC	R (27NOV2020)	Y/N
16-55/ C4591001 1231 12315298	MUSC	Myalgia/ myalgia	2	18SEP2020	2/2	3	No	O	NA/TC	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315299	SKIN	Rash papular/ Erythematous papules in the right malar region	2	20SEP2020	4/52	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1231 12315311	GENRL	Asthenia/ Asthenia#	3	23FEB2021	1/C	1	Yes		NA	RG	N/N
16-55/ C4591001 1231 12315322	NERV	Injection site pain/ Injection site pain# Sciatica/ Worsening of Sciatica	3 1	23FEB2021 16SEP2020	1/12 19/1	1 2	Yes No	O	NA/TC NA/TC	R (06MAR2021) R (16SEP2020)	N/N N/N
16-55/ C4591001 1231 12315325	GENRL	Non-cardiac chest pain/ PRECORDIAL PAIN NON- CARDIAC	1	30SEP2020	33/1	2	No	O	NA	R (30SEP2020)	N/N
16-55/ C4591001 1231 12315325	VASC	Hot flush/ Hot flushes	2	03OCT2020	16/22	1	No	O	NA	R (24OCT2020)	N/N
16-55/ C4591001 1231 12315349	MUSC	Intervertebral disc protrusion/ Incipient disc herniation at L5	2	23SEP2020	7/11	2	No	O	NA/TCN	R (03OCT2020)	N/N
16-55/ C4591001 1231 12315351	BLOOD	Lymphadenopathy/ Left axillary adenopathy	2	19SEP2020	3/101	1	No	O	NA	R (28DEC2020)	N/N
	MUSC	Arthralgia/ Arthralgias	2	22SEP2020	6/98	2	No	O	NA	R (28DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315359	INJ&P	Facial bones fracture/ NASAL SEPTUM FRACTURE	1	01SEP2020	4/C	1	No	O	NA/TC	RG	N/N
		Fall/ Fell from own height	1	01SEP2020	4/1	2	No	O	NA/TC/TCN	RS (01SEP2020)	N/N
	REPRO	Amenorrhoea/ amenorrhea	1	16SEP2020	19/69	1	No	O	NA	R (23NOV2020)	N/N
16-55/ C4591001 1231 12315362	INFEC	Rash pustular/ pustular rash on the inner right thigh	2	28SEP2020	12/29	1	No	O	NA	R (26OCT2020)	N/N
	GASTR	Abdominal pain upper/ Epigastric pain	2	01OCT2020	15/87	1	No	O	NA	R (26DEC2020)	N/N
16-55/ C4591001 1231 12315370	PSYCH	Depression/ Depression	2	05OCT2020	19/36	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N
16-55/ C4591001 1231 12315373	GENRL	Chest pain/ Nonspecific chest pain	2	23OCT2020	36/25	1	No	O	NA	R (16NOV2020)	N/N
16-55/ C4591001 1231 12315400	EYE	Asthenopia/ Eye fatigue	1	03SEP2020	5/2	1	No	O	NA	R (04SEP2020)	N/N
16-55/ C4591001 1231 12315401	GENRL	Asthenia/ asthenia	1	03SEP2020	5/3	1	Yes		NA/TC	R (05SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	PSYCH	Depression/ depression	2	25SEP2020	7/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1231 12315412	INV	Alanine aminotransferase increased/ Increased alanine aminotransferase 164 U/l (normal range 15-45 U/l)	2	05NOV2020	48/17	1	No	O	NA	R (21NOV2020)	N/N
		Aspartate aminotransferase increased/ Increased aspartate aminotransferase 113 U/l (normal range 5-40 U/l) 05- nov-2020	2	05NOV2020	48/17	1	No	O	NA	R (21NOV2020)	N/N
16-55/ C4591001 1231 12315429	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y
16-55/ C4591001 1231 12315441	PSYCH	Depression/ Depressive syndrome	1	10SEP2020	12/137	3	No	O	P/TC	RS (24JAN2021)	N/N
16-55/ C4591001 1231 12315446	NERV	Tension headache/ TENSION HEADACHE	1	14SEP2020	16/2	1	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001 1231 12315450	INFEC	Tooth infection/ Left lower wisdom tooth infection	2	09OCT2020	18/8	1	No	O	NA/TCN	R (16OCT2020)	N/N
	SURG	Wisdom teeth removal/ Dental piece extraction (lower left wisdom tooth)	2	16OCT2020	25/1	1	No	O	NA/TCN	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315453	REPRO	Mammary duct ectasia/ Breast ductal ectasia	2	07OCT2020	19/33	1	No	O	NA	R (08NOV2020)	N/N	
16-55/ C4591001 1231 12315460	NERV	Tension headache/ worsening of tensional headache	2	21SEP2020	3/47	1	No	O	NA	R (06NOV2020)	N/N	
16-55/ C4591001 1231 12315464	GASTR	Odynophagia/ Odynophagia	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhea	1	13SEP2020	15/5	1	No	O	NA	R (17SEP2020)	N/N	
16-55/ C4591001 1231 12315467	RESP	Rhinitis allergic/ Allergic rhinitis	2	13OCT2020	25/18	1	No	O	NA/TCN	R (30OCT2020)	N/N	
16-55/ C4591001 1231 12315470	NERV	Headache/ HEADACHE	1	05SEP2020	7/1	1	No	O	NA/TC	R (05SEP2020)	N/N	
16-55/ C4591001 1231 12315473	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N	
16-55/ C4591001 1231 12315477	MUSC	Back pain/ LOW BACK PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315497	GASTR	Neck pain/ CERVICAL PAIN	1	17SEP2020	19/7	1	No	O	NA/TC	R (23SEP2020)	N/N
		Dyspepsia/ Pyrosis	2	20SEP2020	3/6	1	No	O	NA	R (25SEP2020)	N/N
	NERV	Headache/ headache	2	20SEP2020	3/4	2	No	O	NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1231 12315498	RENAL	Nephrolithiasis/ Nephrolithiasis	2	05DEC2020	78/48	3	No	O	NA/TC	R (21JAN2021)	Y/N
16-55/ C4591001 1231 12315499	GENRL	Injection site bruising/ bruise at injection site of left arm	1	30AUG2020	1/18	1	Yes		NA	R (16SEP2020)	N/Y
16-55/ C4591001 1231 12315504	GASTR	Oral lichenoid reaction/ LICHENOID REACTION, in both jaw mucosa	2	22SEP2020	5/103	1	No	O	NA/TCN	RS (02JAN2021)	N/N
16-55/ C4591001 1231 12315514	VASC	Hypertension/ Arterial hypertension	2	04JAN2021	109/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 1231 12315516	NERV	Headache/ headache	1	30AUG2020	1/20	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001	RESP	Rhinorrhoea/ rhinorrhea	1	17SEP2020	19/3	1	No	O	NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315518 16-55/ C4591001	METAB	Type 2 diabetes mellitus/ Worsening of your type 2 diabetes.	1	17SEP2020	19/2	2	No	O	NA/TC	R (18SEP2020)	N/N
1231 12315528 16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axillary adenomegaly	2	20SEP2020	2/6	2	No	O	NA/TC	R (25SEP2020)	N/N
1231 12315542 16-55/ C4591001	GENRL	Asthenia/ Asthenia.	2	16OCT2020	28/8	1	No	O	NA	R (23OCT2020)	N/N
1231 12315546 16-55/ C4591001	VASC	Hypertension/ Worsening of Hypertension	1	19SEP2020	20/1	1	No	O	NA	R (19SEP2020)	N/N
1231 12315547 16-55/ C4591001	ENDO	Hyperprolactinaemia/ Hyperprolactinemia	1	15SEP2020	16/149	1	No	CD	NA/TC	R (10FEB2021)	N/N
1231 12315550 16-55/ C4591001	GASTR	Flatulence/ meteorism (abdominal pain in the left iliac fossa)	2	04OCT2020	14/10	3	No	O	NA/TC	R (13OCT2020)	N/N
1231 12315559	GENRL	Fatigue/ Fatigue	2	19SEP2020	1/2	1	No	O	NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12315568	MUSC	Myalgia/ generalized myalgia	2	19SEP2020	1/2	1	Yes		NA/TC	R (20SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Left axillar adenomegaly	2	20SEP2020	2/7	2	Yes		NA/TC	R (26SEP2020)	N/N
	METAB	Dyslipidaemia/ dyslipidemia	1	17SEP2020	18/21	1	No	O	NA/TC/TCN	R (07OCT2020)	N/N
16-55/ C4591001 1231 12315600	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	1	05SEP2020	6/26	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1231 12315601	MUSC	Back pain/ LOW BACK PAIN	1	13SEP2020	14/1	2	No	O	NA/TC	R (13SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	25OCT2020	56/2	2	No	O	NA/TC	R (26OCT2020)	N/N
	INJ&P	Hand fracture/ Right fifth metacarpal fracture	2	18NOV2020	59/36	2	No	O	NA	R (23DEC2020)	N/N
16-55/ C4591001 1231 12315622		Road traffic accident/ Motorcyle accident	2	18NOV2020	59/1	2	No	O	NA	R (18NOV2020)	N/N
	INFEC	Gastroenteritis/ gastroenterocolitis	2	09JAN2021	113/3	2	No	O	NA/TC/TCN	R (11JAN2021)	Y/N
	GASTR	Vomiting/ Vomiting#	3	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Pain at injection site.#	3	21FEB2021	2/1	1	Yes		NA/TC	R (21FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12315626	NERV	Sciatica/ Lumbociatalgia	2	15OCT2020	27/12	1	No	O	NA/TC	R (26OCT2020)	N/N	
16-55/ C4591001 1231 12315627	MUSC	Arthralgia/ left omalgia	1	17SEP2020	18/15	1	No	O	NA/TC	R (01OCT2020)	N/N	
16-55/ C4591001 1231 12315636	GASTR	Gastritis/ Gastritis	2	23JAN2021	127/C	1	No	O	NA/TC	RG	N/N	
16-55/ C4591001 1231 12315645	MUSC	Myalgia/ Low Back Myalgia	1	01SEP2020	2/2	2	Yes		NA/TC	R (02SEP2020)	N/N	
	REPRO	Erectile dysfunction/ FUNCTIONAL IMPOTENCE	1	10SEP2020	11/2	2	No	O	NA/TC	R (11SEP2020)	N/N	
16-55/ C4591001 1231 12315677	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	2	12DEC2020	85/62		No	O	NA	R (11FEB2021)	N/N	
16-55/ C4591001 1231 12315681	SURG	Rhinoplasty/ COSMETIC RHINOPLASTY	1	07SEP2020	8/1	2	No	O	NA/TC	RS (07SEP2020)	N/N	
	SKIN	Urticaria contact/ generalized contact urticaria	1	03OCT2020	34/16	1	No	O	NA/TC	R (18OCT2020)	N/N	
16-55/ C4591001	GENRL	Pyrexia/ Fever	2	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1232 12321010	GENRL	Chills/ Chills	2	04SEP2020	3/2	2	Yes		NA	R (05SEP2020)	N/N
	INFEC	Sinusitis/ Sinusitis	2	09SEP2020	8/3	1	No	CND	NA	R (11SEP2020)	N/N
16-55/ C4591001 1232 12321053	NERV	Headache/ Headache	2	11SEP2020	2/4	1			NA	R (14SEP2020)	N/N
	GENRL	Axillary pain/ Under arm pain	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N
		Injection site pain/ Pain in arm at injection site	2	12SEP2020	3/2	1			NA	R (13SEP2020)	N/N
	EYE	Vision blurred/ Blurry vision	2	14SEP2020	5/9	1			NA	R (22SEP2020)	N/N
16-55/ C4591001 1232 12321086	NERV	Syncope/ Syncope*		25AUG2020	1/1	1	No	O	NA	R (25AUG2020)	N/N
16-55/ C4591001 1232 12321159	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	28DEC2020	97/C	1	No	O	NA	UNK	N/N
16-55/ C4591001 1232 12321173	BLOOD	Anaemia/ Worsening Anemia	2	16OCT2020	25/5	1	No	O	NA	R (20OCT2020)	N/N
	REPRO	Vaginal haemorrhage/ abnormal vaginal bleeding	2	19OCT2020	28/1	1	No	O	NA	R (19OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1232 12321175	VASC	Hypertension/ high blood pressure	1	25SEP2020	23/29	2	No	O	P	R (23OCT2020)	N/N	
16-55/ C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N	
16-55/ C4591001 1232 12321250	RESP	Cough/ cough	2	09OCT2020	12/3	1			NA	R (11OCT2020)	N/N	
		Respiratory tract congestion/ Chest congestion	2	09OCT2020	12/3	1			NA	R (11OCT2020)	N/N	
16-55/ C4591001 1232 12321293	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N	
16-55/ C4591001 1232 12321299	VASC	Hypertension/ Hypertension*		06OCT2020	1/C	2	No	O	NA/W	UNK	N/N	
16-55/ C4591001 1235 12351007	GENRL	Malaise/ General Malaise#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	
		Pyrexia/ Pyrexia#	4	05JAN2021	1/3	1	Yes		NA/TC	R (07JAN2021)	N/N	
16-55/ C4591001	GENRL	Pain/ body aches#	4	25JAN2021	1/2	2	Yes		NA/TC	R (26JAN2021)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351009 16-55/ C4591001	MUSC	Pain in extremity/ Left Arm Pain#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
1235 12351020	MUSC	Arthralgia/ generalized Joint Pain#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Myalgia/ Generalized Myalgia#	4	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001	PSYCH	Depression/ anxiety/depression#	3	DEC2020	1/C	2	No	O	NA/TC	RG	N/N
1235 12351025	GENRL	Fatigue/ Fatigue#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pyrexia/ Pyrexia#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	MUSC	Myalgia/ Myalgia, generalized#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
		Pain in extremity/ Right Arm Pain#	4	13JAN2021	1/3	1	Yes		NA	R (15JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	14JAN2021	2/1	1	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain#	4	04JAN2021	1/3	1	Yes		NA	R (06JAN2021)	N/N
1235 12351029 16-55/ C4591001	RESP	Rhinorrhoea/ Rhinorrhea#	4	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351030 16-55/ C4591001 1235 12351045	MUSC	Myalgia/ Generalized myalgia#	4	05JAN2021	1/2	1	Yes		NA/TC	R (06JAN2021)	N/N
1235 12351045	NERV	Headache/ Headache#	4	05JAN2021	1/1	1	Yes		NA/TC	R (05JAN2021)	N/N
16-55/ C4591001 1235 12351057	GENRL	Chills/ Chills#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
1235 12351057		Pyrexia/ Pyrexia#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
1235 12351057	MUSC	Myalgia/ Myalgia#	4	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1235 12351060	GENRL	Chills/ Chills#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
1235 12351060		Fatigue/ Fatigue#	4	12JAN2021	1/3	2	Yes		NA	RS (14JAN2021)	N/N
1235 12351060		Pyrexia/ Fever#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
1235 12351060	MUSC	Myalgia/ Myalgia#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001 1235 12351074	INFEC	Conjunctivitis/ Conjunctivitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351079	NERV	Pharyngitis/ Pharyngitis	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
		Headache/ cephalgia	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
	RESP	Nasal congestion/ Nasal Congestion	2	16OCT2020	11/6	1	Yes		NA/TC	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes		NA	RS (21JAN2021)	N/N
16-55/ C4591001 1235 12351083	NERV	Headache/ Headache#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Chills/ Chills after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
	MUSC	Fatigue/ Fatigue after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1235 12351084	MUSC	Pain in extremity/ Left arm pain after Vaccine 2	2	07OCT2020	2/4	2	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Rigors	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Cephalgia	2	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Chills/ Rigor	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1235 12351098	NERV	Headache/ Cephalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1235 12351101	GENRL	Pain/ body aches	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
	RESP	Cough/ cough	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
		Nasal congestion/ nasal congestion	2	25OCT2020	18/2	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1235 12351105	GENRL	Chills/ chills	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Pain/ body aches	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
		Pyrexia/ fever	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
	NERV	Headache/ mild headache	2	06OCT2020	1/2	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1235 12351108	GENRL	Injection site pain/ Muscle pain at injection site of left arm#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
16-55/ C4591001 1235 12351110	GENRL	Chills/ chills	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351124	GENRL	Pain/ body aches	2	07OCT2020	1/2	2	Yes		NA/TC	R (08OCT2020)	N/N
		Chills/ Chills#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	MUSC	Fatigue/ Fatigue#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
Myalgia/ Myalgia#		4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N	
16-55/ C4591001 1235 12351130	BLOOD	Lymphadenopathy/ Bilateral swollen mandibular lymph nodes#	4	15JAN2021	4/C	2	Yes		NA	N	N/N
16-55/ C4591001 1235 12351131	MUSC	Myalgia/ Myalgia, generalized	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1235 12351134	GENRL	Chills/ Chills#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
		Fatigue/ Fatigue#	4	07JAN2021	2/1	1	Yes		NA	R (07JAN2021)	N/N
	MUSC	Pain in extremity/ Right Arm Pain#	4	07JAN2021	2/1	1	Yes		NA/TC	R (07JAN2021)	N/N
16-55/ C4591001 1235 12351137	MUSC	Myalgia/ Myalgia	1	15OCT2020	24/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351143	GENRL	Chills/ chills	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ pyrexia	2	12OCT2020	1/4	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1235 12351144	GENRL	Chills/ chills#	4	06JAN2021	1/3	2	Yes		NA/TC	R (08JAN2021)	N/N
		Injection site pain/ injection site soreness#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
		Pyrexia/ pyrexia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	MUSC	Myalgia/ myalgia#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
	NERV	Headache/ headache#	4	06JAN2021	1/3	1	Yes		NA/TC	R (08JAN2021)	N/N
16-55/ C4591001 1235 12351146	GENRL	Injection site pain/ injection site pain#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1235 12351151	GENRL	Pyrexia/ pyrexia	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1235 12351152	MUSC	Pain in extremity/ left arm soreness#	3	18DEC2020	1/2	1	Yes		NA	R (19DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351155	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1235 12351161	GENRL	Injection site pain/ right arm injection site soreness	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
		Pyrexia/ pyrexia	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ cephalalgia	2	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1235 12351162	NERV	Headache/ cephalalgia#	4	08JAN2021	1/6	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1235 12351165	GENRL	Pyrexia/ Pyrexia	2	28OCT2020	2/2	1	Yes		NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1235 12351168	GENRL	Pyrexia/ Febrile	2	31OCT2020	2/2	2	Yes		NA/TC	R (01NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1235 12351169	GENRL	Pyrexia/ PYREXIA*		21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351175	MUSC	Myalgia/ MYALGIA	1	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
		Pain/ Body aches	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Right arm muscle soreness	1	15OCT2020	2/1	2	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ nausea	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
		Vomiting/ emesis	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	GENRL	Chills/ rigor	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	MUSC	Myalgia/ generalized myalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	NERV	Headache/ cephalgia	2	05NOV2020	2/1	2	Yes		NA/TC	R (05NOV2020)	N/N
	16-55/ C4591001 1235 12351180	GENRL	Pyrexia/ fever 38.5 C	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)
	MUSC	Pain in extremity/ left arm soreness	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ pyrexia	2	03NOV2020	1/3	2	Yes		NA	R (05NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351188	MUSC	Pain in extremity/ sore arm#	2	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1235 12351189	MUSC	Pain in extremity/ Arm pain#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1235 12351190	MUSC	Pain in extremity/ Arm soreness, Right#	4	08JAN2021	1/2	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1235 12351191	GENRL	Pyrexia/ pyrexia	2	07NOV2020	2/2	1	Yes		NA/TC	R (08NOV2020)	N/N
	NERV	Headache/ cephalgia	2	09NOV2020	4/1	1	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1235 12351192	GASTR	Diarrhoea/ Diarrhea	1	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	MUSC	Myalgia/ Bilateral Shoulder Myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
		Myalgia/ Right arm myalgia	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	RESP	Upper-airway cough syndrome/ Post-nasal drip	2	09NOV2020	4/1	1	Yes		NA	R (09NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351193	GENRL	Fatigue/ fatigue	1	19OCT2020	1/2	2	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site soreness	2	09NOV2020	1/2	2	Yes		NA	R (10NOV2020)	N/N
	GENRL	Pyrexia/ Pyrexia	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1235 12351195	MUSC	Pain in extremity/ left arm pain	1	19OCT2020	1/3	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1235 12351200	GENRL	Fatigue/ fatigue#	4	05JAN2021	1/2	1	Yes		NA	R (06JAN2021)	N/N
16-55/ C4591001 1235 12351209	GENRL	Fatigue/ fatigue	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Myalgia/ myalgia	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	MUSC	Pain in extremity/ Sore left arm#	3	17DEC2020	1/3	1	Yes		NA/TC	R (19DEC2020)	N/N
	GASTR	Nausea/ nausea#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N
	GENRL	Chills/ chills#	4	05JAN2021	1/3	1	Yes		NA	R (07JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351214	GASTR	Pyrexia/ fever#	4	05JAN2021	1/3	1	Yes	NA	R (07JAN2021)	N/N	
		Nausea/ Nausea	2	11NOV2020	2/3	2	Yes	NA/TC	R (13NOV2020)	N/N	
	GENRL	Chills/ Chills	2	11NOV2020	2/3	2	Yes	NA/TC	R (13NOV2020)	N/N	
16-55/ C4591001 1235 12351215	GENRL	Pyrexia/ Pyrexia	2	11NOV2020	2/3	1	Yes	NA/TC	R (13NOV2020)	N/N	
		Fatigue/ fatigue	2	10NOV2020	1/3	2	Yes	NA	R (12NOV2020)	N/N	
16-55/ C4591001 1235 12351217	MUSC	Pyrexia/ Pyrexia	2	10NOV2020	1/3	2	Yes	NA	R (12NOV2020)	N/N	
		Myalgia/ generalized myalgia#	4	11FEB2021	2/1	1	Yes	NA	R (11FEB2021)	N/N	
16-55/ C4591001 1235 12351218	GENRL	Fatigue/ Fatigue	1	23OCT2020	1/2	2	Yes	NA	R (24OCT2020)	N/N	
	MUSC	Myalgia/ Left arm myalgia	1	23OCT2020	1/2	2	Yes	NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1235 12351223	SKIN	Rash papular/ Rash to right upper arm, raised, tender, 5cm diameter	2	15NOV2020	4/1	1	Yes	NA	R (15NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1235 12351228	GENRL	Pyrexia/ Pyrexia#	4	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20JAN2021	1/2	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1235 12351230	GENRL	Fatigue/ fatigue	1	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	1	03NOV2020	1/2	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001 1241 12411001	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
	GASTR	Nausea/ Nausea#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	2/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		Pyrexia/ Fever#	3	22JAN2021	2/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	10FEB2021	1/3	3	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	3	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411002		Pyrexia/ Fever#	4	10FEB2021	1/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/3	3	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/3	3	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/2	1	Yes		NA	R (08AUG2020)	N/Y
	GENRL	Chills/ Chills	2	26AUG2020	1/1	1	Yes		NA/TC	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1241 12411003	MUSC	Myalgia/ Myalgia	2	26AUG2020	1/2	2	Yes		NA	R (27AUG2020)	N/N
	GASTR	Vomiting/ Vomiting	2	27AUG2020	2/1	1	Yes		NA	R (27AUG2020)	N/N
	NERV	Somnolence/ Somnolence	2	26AUG2020	1/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1241 12411004	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	07AUG2020	1/3	1	Yes		NA	R (09AUG2020)	N/Y
	MUSC	Myalgia/ Myalgia	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411005	NERV	Headache/ Intermittent Headache	2	26AUG2020	1/2	2	No	O	NA/TC	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
		Pyrexia/ Fever	2	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GASTR	Nausea/ Nausea	2	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Chills/ Chills	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
		Injection site pain/ Injection site pain	2	26AUG2020	1/1	1	Yes		NA	R (26AUG2020)	N/Y
			2	26AUG2020	1/1	2	Yes		NA/TC	R (26AUG2020)	N/N
		Pyrexia/ Fever	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	NERV	Headache/ Headache	2	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	18OCT2020	54/1	1	No	O	NA	R (18OCT2020)	N/N
16-55/ C4591001 1241 12411006	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411007	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1241 12411010	GENRL	Injection site erythema/ Injection site erythema	1	07AUG2020	1/1	1	Yes		NA	R (07AUG2020)	N/Y
16-55/ C4591001 1241 12411011	MUSC	Myalgia/ Myalgia	2	27AUG2020	2/3	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1241 12411012	GENRL	Fatigue/ Prostration#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1241 12411013	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y
16-55/ C4591001 1241 12411014	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y
16-55/ C4591001 1241 12411016	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/1	1	Yes		NA	R (10AUG2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411017  16-55/ C4591001 1241 12411018  16-55/ C4591001 1241 12411019  16-55/ C4591001 1241 12411020  16-55/ C4591001 1241 12411021  16-55/ C4591001 1241 12411022	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
	RESP	Rhinitis allergic/ Allergic rhinitis	2	21SEP2020	22/1	1	No	O	NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	10AUG2020	1/3	1	Yes		NA	R (12AUG2020)	N/Y
	NERV	Headache/ headache	1	27AUG2020	18/3	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	1	12AUG2020	3/2	1	Yes		NA	R (13AUG2020)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache	1	28AUG2020	19/1	1	No	O	NA/TC	R (28AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411023	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TCN	R (17FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/1	1	Yes		NA/TC	R (16FEB2021)	N/N
	ENDO	Hypogonadism/ Hypogonadism	1	19AUG2020	10/43	1	No	O	NA/TC	R (30SEP2020)	N/N
	METAB	Dyslipidaemia/ Dyslipidemia	1	19AUG2020	10/93	1	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 1241 12411024	NERV	Headache/ Headache	1	26AUG2020	17/1	2	No	O	NA/TC	R (26AUG2020)	N/N
16-55/ C4591001 1241 12411026	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	2/3	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/3	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ Chills#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ Fatigue#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411027	NERV	Pyrexia/ Fever#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
		Headache/ Headache#	4	11FEB2021	2/1	2	Yes		NA	R (11FEB2021)	N/N
	INFEC	Parasitic gastroenteritis/ Intestinal parasitosis	2	07SEP2020	8/24	1	No	O	NA/TC	R (30SEP2020)	N/N
	METAB	Dyslipidaemia/ Dyslipidemia	2	12SEP2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1241 12411028	METAB	Vitamin D deficiency/ Hypovitaminosis D#	2	07FEB2021	161/C	2	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1241 12411029	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	INFEC	Tonsillitis/ Acute tonsillitis	1	11AUG2020	2/7	1	No	O	NA/TC	R (17AUG2020)	N/N
	INFEC	Tonsillitis/ Acute tonsillitis	2	01SEP2020	2/9	1	No	O	NA/TC	R (09SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411030	INFEC	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Pyrexia/ Fever#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Ear infection/ Otitis	1	20AUG2020	11/4	1	No	O	NA/TC	R (23AUG2020)	N/N
16-55/ C4591001 1241 12411031	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Asthenia/ Asthenia#	3	23JAN2021	3/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	3/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411032	NERV	Dysgeusia/ Bitter taste in mouth	1	11AUG2020	1/1	1	Yes		NA	R (11AUG2020)	N/Y
	NERV	Dysgeusia/ Bitter taste in mouth	2	03SEP2020	1/1	1	Yes		NA	R (03SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
MUSC	Myalgia/ Myalgia#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N	
GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411034	NERV	Injection site pain/ Injection site pain#	4	10FEB2021	2/5	1	Yes		NA	R (14FEB2021)	N/N
		Headache/ Headache#	4	10FEB2021	2/5	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411034	SURG	Sclerotherapy/ Sclerotherapy	2	23SEP2020	22/1	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411037	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411040	NERV	Headache/ Headache	2	28SEP2020	28/1	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1241 12411042	GENRL	Chills/ Chills#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Prostration#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/2	2	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/3	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411043	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411044	GENRL	Injection site pain/ Injection site pain	1	11AUG2020	1/1	2	Yes		NA	R (11AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/6	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
		Nausea/ Nausea#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411045	MUSC	Pyrexia/ Fever#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Myalgia/ Myalgia#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Headache/ Headache#	3	23JAN2021	2/6	2	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411046	INFEC	Oral herpes/ Lip herpes	1	18AUG2020	8/5	1	No	O	NA/TC	R (22AUG2020)	N/N
16-55/ C4591001 1241 12411046	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411047	NERV	Headache/ Headache	1	29AUG2020	19/2	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1241 12411048	GENRL	Fatigue/ Fatigue#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411050	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N	
		Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N	
		SURG	Metabolic surgery/ Bariatric surgery#	2	08MAR2021	188/1	2	No	O	NA/TCN	R (08MAR2021)	N/N
	16-55/ C4591001 1241 12411051	BLOOD	Lymphadenopathy/ Left Axillary lymphadenopathy	2	03SEP2020	2/4	1	Yes		NA	R (06SEP2020)	N/N
		INFEC	Oral candidiasis/ Oral thrush	2	06SEP2020	5/6	1	Yes		NA	R (11SEP2020)	N/N
INFEC		Cystitis/ Cystitis	2	07OCT2020	36/8	2	No	O	NA/TC	R (14OCT2020)	N/N	
16-55/ C4591001 1241 12411053	GASTR	Dyspepsia/ Dyspepsia#	3	31JAN2021	7/13	3	No	O	NA/TC	R (12FEB2021)	N/N	
		Gastroesophageal reflux disease/ Non-erosive reflux esophagitis#	3	31JAN2021	7/C	3	No	O	NA/TC/TCN	RG	Y/N	
16-55/ C4591001 1241 12411059	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/1	1	Yes		NA	R (02FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411060	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411062	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache	2	22SEP2020	21/3	2	No	O	NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411064	GENRL	Fatigue/ FATIGUE#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
Chills/ Chills#		4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
Pyrexia/ Fever#		4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N	
16-55/ C4591001 1241 12411069	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	2	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001	SURG	Gingival operation/ Gingivoplasty	2	21SEP2020	20/1	1	No	O	NA/TC	R (21SEP2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1241 12411070	VASC	Thrombophlebitis superficial/ Left great saphenous thrombophlebitis	2	12OCT2020	41/40	2	No	O	NA/TC	R (20NOV2020)	N/N	
16-55/ C4591001 1241 12411071	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N	
16-55/ C4591001 1241 12411072	MUSC	Neck pain/ Cervicalgia	2	01NOV2020	61/20	2	No	O	NA/TC/TCN	R (20NOV2020)	N/N	
16-55/ C4591001 1241 12411073	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12411073	MUSC	Myalgia/ myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1241 12411075	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	
16-55/ C4591001 1241 12411075	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/1	1	Yes		NA	R (22FEB2021)	N/Y	
16-55/ C4591001 1241 12411077	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/1	1	Yes		NA	R (21JAN2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411078	MUSC	Myalgia/ Myalgia#	3	22JAN2021	2/1	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1241 12411087	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411091	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
	SURG	Hysterectomy/ Hysterectomy#	3	06FEB2021	17/1	1	No	O	NA/TC	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1241 12411093	REPRO	Dysmenorrhoea/ Menstrual cramps	2	30SEP2020	28/3	2	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1241 12411094	INJ&P	Thermal burn/ Burn in right upper limb	2	12DEC2020	101/9	2	No	O	NA/TC	R (20DEC2020)	N/N
16-55/ C4591001 1241 12411098	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411106	INFEC	Otitis media acute/ Acute otitis media	1	21AUG2020	9/10	2	No	O	NA/TC	R (30AUG2020)	N/N
16-55/ C4591001 1241 12411108	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411109	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
16-55/ C4591001 1241 12411111	GENRL	Fatigue/ Fatigue#	3	12FEB2021	2/3	1	Yes		NA/TC	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	12FEB2021	2/3	2	Yes		NA/TC/TCN	R (14FEB2021)	N/N
	NERV	Headache/ Headache#	3	12FEB2021	2/3	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411113	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411114	INFEC	Vaginal infection/ Colpitis	1	28AUG2020	15/68	1	No	O	NA/TC	R (03NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	2/4	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411118	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411120	INFEC	Urinary tract infection/ Urinary tract infection#	2	01MAR2021	179/3	1	No	O	NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 1241 12411122	GENRL	Asthenia/ Asthenia#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411125	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/2	1	Yes		NA	R (15AUG2020)	N/Y
16-55/ C4591001 1241 12411127	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	2	Yes		NA/TC	R (02FEB2021)	N/N
		Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	23FEB2021	2/4	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411131	SURG	Tooth extraction/ Dental extraction#	3	25FEB2021	22/1	1	No	O	NA/TCN	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411132	GENRL	Fatigue/ Intermittent fatigue	1	18OCT2020	66/6	1	No	O	NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12411135	INFEC	Urinary tract infection/ Urinary tract infection	2	05SEP2020	2/10	2	No	O	NA/TC	R (14SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
		Myalgia/ Myalgia	2	05SEP2020	2/8	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411136	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411137	GENRL	Injection site pain/ Injection site pain	1	14AUG2020	1/1	1	Yes		NA	R (14AUG2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411138	GENRL	Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Pyrexia/ Fever#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	15FEB2021	1/1	1	Yes		NA	R (15FEB2021)	N/N
		Pyrexia/ Fever#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411141	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/3	2	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411142	GENRL	Chills/ Chills#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
		Pyrexia/ Fever#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411145	SKIN	Rash/ Generalised Skin rash	2	10DEC2020	93/37	1	No	O	NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1241 12411150	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	09FEB2021	1/2	1	Yes		NA/TC	R (10FEB2021)	N/N
16-55/ C4591001 1241 12411153	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411154	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA/TCN	R (28JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411156	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411157	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411163	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pain/ Body pain#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	2/4	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411165	INV	Blood iron decreased/ Reduction of serum iron	2	JAN2021	116/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411167	GENRL	Chills/ Chills#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411170	NERV	Headache/ Headache#	4	11FEB2021	2/2	2	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411171	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411175	INFEC	Folliculitis/ Folliculitis in the left armpit	1	02SEP2020	17/9	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411178	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411179	GENRL	Asthenia/ Asthenia#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411183	GENRL	Injection site pain/ Injection site plain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411184	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	22JAN2021	1/1	2	Yes		NA/TC	R (22JAN2021)	N/N
		Vomiting/ Vomiting#	3	22JAN2021	1/1	2	Yes		NA/TC	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/2	2	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411188	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411189	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411195	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1241 12411197	INJ&P	Ligament sprain/ Left ankle sprain	2	24SEP2020	17/7	2	No	O	NA/TC	R (30SEP2020)	N/N
	INFEC	Tooth infection/ Dental inflammation	2	28SEP2020	21/15	1	No	O	NA/TC	R (12OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Ipsilateral axillary lymphadenopathy#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Fatigue/ Fatigue#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	1/3	2	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411198	INFEC	Fungal skin infection/ Fungal dermatitis	2	10SEP2020	3/60	1	No	O	NA/TC	R (08NOV2020)	N/N
	INFEC	Folliculitis/ Folliculitis in the armpits	2	15OCT2020	38/25	1	No	O	NA/TC	R (08NOV2020)	N/N
16-55/ C4591001 1241 12411205	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	1/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411206	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N
16-55/ C4591001 1241 12411208	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	10FEB2021	6/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411214	RESP	Cough/ Cough	2	24SEP2020	16/2	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411220		Injection site swelling/ Injection site swelling#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411223	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GASTR	Vomiting/ Vomiting#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/3	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411224	IMMUN	Food allergy/ Worsening Allergic reaction to shrimp	1	19AUG2020	2/1	1	No	O	NA/TC	R (19AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
	NERV	Headache/ Headache#	3	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411226	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/4	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	2	Yes		NA/TC	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411228 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
1241 12411230 16-55/ C4591001	NERV	Headache/ Worsening Recurrent headache	2	02OCT2020	23/5	2	No	O	NA/TC	R (06OCT2020)	N/N
1241 12411231 16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	27JAN2021	1/2	1	Yes		NA/TC	R (28JAN2021)	N/N
1241 12411232	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411236	NERV	Dizziness/ Dizziness	1	08SEP2020	22/2	1	No	O	NA/TC	R (09SEP2020)	N/N
16-55/ C4591001 1241 12411242	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/6	1	Yes		NA	R (14SEP2020)	N/Y
16-55/ C4591001	RESP	Rhinitis allergic/ Allergic rhinitis	2	11SEP2020	3/1	1	No	O	NA/TC	R (11SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411243	GASTR	Diarrhoea/ Diarrhea#	3	01FEB2021	1/3	1	Yes	NA	R	(03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/3	1	Yes	NA	R	(03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes	NA	R	(03FEB2021)	N/N
	GENRL	Asthenia/ Asthenia#	4	22FEB2021	1/2	1	Yes	NA	R	(23FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/1	1	Yes	NA/TC	R	(22FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/2	1	Yes	NA/TC	R	(23FEB2021)	N/N
16-55/ C4591001 1241 12411248	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/4	1	Yes	NA/TC	R	(25JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	1	Yes	NA/TC	R	(23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	1	Yes	NA/TC	R	(11FEB2021)	N/N
16-55/ C4591001 1241 12411250	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes	NA	R	(29JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes	NA/TC	R	(18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411253	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411255	REPRO	Dysmenorrhoea/ Menstrual cramps	1	05SEP2020	19/1	1	No	O	NA/TC	R (05SEP2020)	N/N
16-55/ C4591001 1241 12411257	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411261	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/1	1	Yes		NA	R (19AUG2020)	N/Y
	GENRL	Pyrexia/ Fever#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411262	MUSC	Arthritis/ Right knee arthritis	1	06SEP2020	19/21	2	No	O	NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411263	GENRL	Pyrexia/ Fever	2	14SEP2020	1/6	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Fatigue/ Fatigue#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	04FEB2021	1/4	2	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	1/4	2	Yes		NA/TC	R (07FEB2021)	N/N
	16-55/ C4591001 1241 12411267	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/3	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411268	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411269	SKIN	Hyperhidrosis/ Sweating#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
	INJ&P	Fall/ Fall from own height#	4	06MAR2021	17/1	3	No	O	NA	R (06MAR2021)	Y/N
		Scapula fracture/ Fracture of the anterior border of the right glenoid#	4	06MAR2021	17/C	3	No	O	NA/TCN	N	Y/N
16-55/ C4591001 1241 12411270	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1241 12411272		Pain/ Body pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/3	2	Yes		NA	R (21AUG2020)	N/N
	GENRL	Pyrexia/ Fever	1	20AUG2020	2/2	2	Yes		NA	R (21AUG2020)	N/N
16-55/ C4591001 1241 12411273	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/1	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411274	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/4	2	Yes		NA	R (23AUG2020)	N/N
16-55/ C4591001 1241 12411277	GENRL	Injection site pain/ Injection site pain#	3	26FEB2021	2/3	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1241 12411278	GENRL	Pyrexia/ Fever	2	09SEP2020	2/1	1	Yes		NA/TC	R (09SEP2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	2	12SEP2020	5/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411279	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
	REPRO	Vaginal haemorrhage/ Vaginal bleeding	1	05OCT2020	48/10	1	No	O	NA/TC	R (14OCT2020)	N/N
	PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N
	GENRL	Chills/ Chills#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411280	MUSC	Injection site pain/ Injection site pain#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
		Myalgia/ Myalgia#	3	16FEB2021	1/4	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1241 12411281	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/3	2	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1241 12411282	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
Injection site pain/ Injection site pain#		3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N	
16-55/ C4591001 1241 12411286	GASTR	Diarrhoea/ diarrhea	1	20AUG2020	2/4	1	Yes		NA	R (23AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
	IMMUN	Drug hypersensitivity/ Drug allergy	1	10SEP2020	23/1	3	No	CD	NA	R (10SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411287	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411288	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA/TCN	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411289	NERV	Headache/ Headache#	3	28JAN2021	2/3	2	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411290	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	2/2	1	Yes		NA	R (21AUG2020)	N/N
	RESP	Rhinitis allergic/ Headache due to allergic rhinitis	1	20AUG2020	2/2	1	No	O	NA/TC	R (21AUG2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
		Vomiting/ Vomiting	1	21AUG2020	3/1	1	No	O	NA	R (21AUG2020)	N/N
	NERV	Paraesthesia/ Tingling in the left upper limb	1	21AUG2020	3/1	2	Yes		NA	R (21AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411292	NERV	Headache/ Headache	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
	NERV	Migraine/ Migraine crisis	2	07OCT2020	28/12	2	No	O	NA	R (18OCT2020)	N/N
	GENRL	Chills/ Chills#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411293	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain	1	19AUG2020	1/2	1	Yes		NA	R (20AUG2020)	N/N
16-55/ C4591001 1241 12411294	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411295	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1241 12411299	GENRL	Chills/ Chills#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411300	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411301	REPRO	Dysmenorrhoea/ menstrual cramps*		19AUG2020	1/3	2	No	O	NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1241 12411303	GASTR	Nausea/ Nausea	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		Somnolence/ Drowsiness	2	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411305	GENRL	Chills/ Chills	2	10SEP2020	1/2	1	Yes		NA/TC	R (11SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	11SEP2020	2/1	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1241 12411307	GASTR	Nausea/ Nausea	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site erythema/ Injection site erythema	2	11SEP2020	2/8	1	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411308	NERV	Paraesthesia/ Tingling in the body	2	11SEP2020	2/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache	1	19AUG2020	1/5	1	Yes		NA/TC	R (23AUG2020)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411309	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411311	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	2/2	2	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411312	GENRL	Pyrexia/ Fever	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia	1	20AUG2020	2/1	2	Yes		NA/TC	R (20AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411313	MUSC	Myalgia/ Myalgia	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ Headache	2	10SEP2020	1/3	2	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411314	GENRL	Fatigue/ Prostration#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411315	NERV	Headache/ Headache	1	06SEP2020	19/1	1	No	O	NA/TC	R (06SEP2020)	N/N
16-55/ C4591001 1241 12411317	GENRL	Injection site pain/ Injection site pain	1	19AUG2020	1/3	1	Yes		NA	R (21AUG2020)	N/Y
	INFEC	Varicella/ varicella	1	01SEP2020	14/4	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1241 12411319	INFEC	Gastroenteritis/ Food gastroenteritis	1	10SEP2020	23/1	1	No	O	NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
		Injection site warmth/ Injection site heat	2	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/7	1	Yes		NA	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/7	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1241 12411324	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411326	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/2	2	Yes		NA	R (21AUG2020)	N/N
		Injection site swelling/ Injection site swelling	1	20AUG2020	1/2	2	Yes		NA	R (21AUG2020)	N/N
	NERV	Headache/ Headache	1	21AUG2020	2/1	1	Yes		NA	R (21AUG2020)	N/N
	INJ&P	Animal bite/ Dog bite in the cervical region	2	20DEC2020	103/1	1	No	O	NA/TCN	R (20DEC2020)	N/N
16-55/ C4591001 1241 12411330	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411333	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411334	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	1/2	2	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411335	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1241 12411336	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/3	1	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411337	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12411339	GENRL	Injection site pain/ Injection site pain	2	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ Headache	2	11SEP2020	2/4	2	Yes		NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1241 12411341	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411342	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1241 12411343	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/3	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Back pain/ Backache	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411344		Pain in extremity/ Legs pain	2	12SEP2020	2/3	2	Yes		NA/TC	R (14SEP2020)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	30OCT2020	50/C		No	O	NA	UNK	N/N
	GENRL	Asthenia/ Asthenia	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411345	GENRL	Chills/ chills	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/N
	NERV	Headache/ Headache	1	20AUG2020	1/2	1	Yes		NA/TC	R (21AUG2020)	N/N
16-55/ C4591001 1241 12411346	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411347	NERV	Headache/ Headache	1	09SEP2020	21/1	1	No	O	NA/TC	R (09SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	3	02FEB2021	2/3	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	3/4	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411348	NERV	Headache/ Headache	1	10SEP2020	22/1	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411349	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12411351	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/2	1	Yes		NA	R (25FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411356	GENRL	Pyrexia/ Fever	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411360	GASTR	Nausea/ Nausea#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411362	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411363	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	25JAN2021	1/4	1	Yes		NA	R (28JAN2021)	N/N
16-55/ C4591001 1241 12411367	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	20FEB2021	2/1	1	Yes		NA/TC/TCN	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411368	GENRL	Chills/ Chills	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411369	NERV	Fatigue/ Fatigue	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Headache/ Headache	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411370	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Chills/ Chills	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N
		Fatigue/ Fatigue	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	1/3	2	Yes		NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411372	NERV	Headache/ Headache	1	04SEP2020	16/1	1	No	O	NA/TC	R (04SEP2020)	N/N
16-55/ C4591001 1241 12411373	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411376	GASTR	Toothache/ Toothache	2	18SEP2020	8/1	1	No	O	NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411377	GENRL	Chills/ Chills	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Injection site pain/ Injection site pain	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
		Pain/ Body pain	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
		Pyrexia/ Fever	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Headache/ headache	2	11SEP2020	1/2	2	Yes		NA/TC	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411378	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA/TC	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411379	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411381	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux disease	2	20SEP2020	12/4	1	No	O	NA/TC	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	05FEB2021	4/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411383	GENRL	Injection site pain/ Injection site pain	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ Fever	2	09SEP2020	1/2	2	Yes		NA	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411384	GENRL	Injection site pain/ Injection site pain	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
		Malaise/ Malaise	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411385	NERV	Tension headache/ Tension headache	2	09OCT2020	29/1	1	No	O	NA/TC	R (09OCT2020)	N/N
	REPRO	Dysmenorrhoea/ dysmenorrhea	1	05SEP2020	17/1	1	No	O	NA/TC/TCN	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1241 12411386	BLOOD	Lymphadenopathy/ Lymph node enlargement in the left armpit#	4	11FEB2021	2/3	1	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20AUG2020	1/1	1	Yes		NA	R (20AUG2020)	N/Y
16-55/ C4591001 1241 12411387	GENRL	Fatigue/ Fatigue	2	16SEP2020	1/3	2	Yes		NA/TCN	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411388	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411389	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411390	NERV	Headache/ Headache	1	07SEP2020	19/1	2	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1241 12411393	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12SEP2020	2/1	2	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21AUG2020	1/2	2	Yes		NA/TC	R (22AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11SEP2020	1/1	1	Yes		NA	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411395	GENRL	Pyrexia/ Fever#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411398	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411399	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
	GENRL	Chills/ Chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1241 12411401	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/Y
16-55/ C4591001 1241 12411402	GENRL	Chills/ Chills	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411408	MUSC	Fatigue/ Prostration	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Injection site pain/ Injection site pain	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N	
		Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1241 12411409	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1241 12411410	GENRL	Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N	
		Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
	BLOOD	Injection site swelling/ Injection site swelling#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N	
		Lymphadenopathy/ Left axillary lymph node enlargement#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	
		Injection site pain/ Injection site pain#	3	26JAN2021	2/4	1	Yes		NA	R (29JAN2021)	N/N	
		NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
		GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411411	GENRL	Injection site pruritus/ Injection site itching	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411413	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411415	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	1/3	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411416	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	2	14SEP2020	1/2	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411417	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	2/4	1	Yes		NA/TC	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411418	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411420	GASTR	Nausea/ Nausea#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	3/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	3/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GASTR	Abdominal pain/ Abdominal pain#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N
		Diarrhoea/ Diarrhea#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	5/3	2	Yes		NA	R (31JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411422	GENRL	Fatigue/ Prostration#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411423	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/2	2	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411424	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411426	GENRL	Fatigue/ Fatigue#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/1	1	Yes		NA	R (26JAN2021)	N/N
Fatigue/ Fatigue#		4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
Pyrexia/ Fever#		4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12411431	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/4	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411432	INFEC	Vulvovaginal candidiasis/ Vaginal candidiasis	1	07SEP2020	15/21	1	No	O	NA/TC	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411435	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	NERV	Headache/ Headache	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411437	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411438	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411439	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	2	Yes		NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411440	GENRL	Fatigue/ Prostration#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411441	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
16-55/ C4591001 1241 12411443	GENRL	Injection site erythema/ Erythema at the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
		Injection site swelling/ Swelling the injection site	2	15SEP2020	2/5	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411444	NERV	Tension headache/ Tension headache	1	10SEP2020	18/1	1	No	O	NA/TC	R (10SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411445 16-55/ C4591001 1241 12411447 16-55/ C4591001 1241 12411449 16-55/ C4591001 1241 12411450	MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
	INJ&P	Skin laceration/ Cutting injury in left hand	2	19SEP2020	6/1	2	No	O	NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/3	2	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Injection site pain/ Injection site pain	2	14SEP2020	1/1	1	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Headache/ headache	2	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
	Injection site pain/ Injection site pain#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411451	NERV	Headache/ Headache#	4	11FEB2021	2/1	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	15SEP2020	2/3	2	Yes		NA/TCN	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/1	1	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411452	GENRL	Injection site pain/ Injection site pain*		24AUG2020	1/8	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	26AUG2020	3/6	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ Chills	1	30AUG2020	7/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/6	2	Yes		NA/TC	R (20SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/4	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411453	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411454	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411455	GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/1	1	Yes		NA	R (25JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1241 12411456	GASTR	Nausea/ Nausea	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Fatigue/ Prostration	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411457	NERV	Headache/ headache	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Fatigue/ Prostration#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Pyrexia/ Subfebrile#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
16-55/ C4591001 1241 12411459	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411460	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12411461	GASTR	Nausea/ Nausea	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411462	GENRL	Pyrexia/ Fever	2	15SEP2020	2/2	1	Yes		NA/TC	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411464	MUSC	Fatigue/ Fatigue	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
		Myalgia/ Myalgia	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	GASTR	Injection site swelling/ Injection site swelling	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
		Abdominal pain/ Abdominal pain	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Diarrhoea/ Diarrhea	2	14SEP2020	1/5	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/Y
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/1	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/Y
	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
NERV	Headache/ Headache#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411465	METAB	Food intolerance/ Gastrointestinal food intolerance	1	31AUG2020	8/1	1	No	O	NA/TC	R (31AUG2020)	N/N
	GENRL	Chills/ Chills	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pain/ Body pain	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ Fever	2	17SEP2020	2/1	2	Yes		NA/TC	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	9/1	2	No	O	NA	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411466	GENRL	Injection site pain/ Injection site pain	1	24AUG2020	1/1	1	Yes		NA	R (24AUG2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411467	INFEC	Urinary tract infection/ Urinary tract infection#	2	20FEB2021	158/9	1	No	O	NA/TC	R (28FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411468	GENRL	Chills/ Chills#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	16FEB2021	2/5	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411469	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/4	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411470	GENRL	Chills/ Chills	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/2	2	Yes		NA/TC	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411471	GENRL	Injection site pain/ Injection site pain	1	25AUG2020	1/2	1	Yes		NA	R (26AUG2020)	N/Y
	GASTR	Nausea/ Nausea	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411472		Injection site pain/ Injection site pain	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N	
		Injection site swelling/ Injection site swelling	2	15SEP2020	1/7	2	Yes		NA/TC	R (21SEP2020)	N/N	
		Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N	
		MUSC	Myalgia/ Myalgia	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		BLOOD	Lymphadenopathy/ Reactive axillary lymph node in the left arm	2	16SEP2020	2/11	2	Yes		NA/TC	R (26SEP2020)	N/N
		INFEC	Mumps/ Left mumps#	2	FEB2021	140/C	1	No	O	NA	RG	N/N
		GENRL	Fatigue/ Fatigue#	3	25JAN2021	1/3	2	Yes		NA	R (27JAN2021)	N/N
		MUSC	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
		MUSC	Arthralgia/ Arthralgia#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
		MUSC	Myalgia/ Myalgia#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
		NERV	Headache/ Headache#	3	25JAN2021	1/3	2	Yes		NA/TC	R (27JAN2021)	N/N
GENRL	Pyrexia/ Fever#	3	26JAN2021	2/2	1	Yes		NA/TC	R (27JAN2021)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411473	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/3	1	Yes		NA	R (31JAN2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	2/1	1	Yes		NA/TC	R (29JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		NERV	Headache/ Headache#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)
16-55/ C4591001 1241 12411475	GENRL	Chills/ Chills	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411476	NERV	Dizziness/ Dizziness	1	29AUG2020	5/1	1	No	O	NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/Y
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411477	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	NERV	Headache/ Headache	1	25AUG2020	1/1	2	Yes		NA/TC	R (25AUG2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
		Injection site swelling/ Injection site swelling	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
		Fatigue/ Fatigue	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N
	Injection site pain/ Injection site pain	2	16SEP2020	2/2	1	Yes		NA	R (17SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411478	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	1/1	1	Yes		NA/TC	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	1/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1241 12411480	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/Y
16-55/ C4591001 1241 12411482	NERV	Headache/ headache	1	25AUG2020	1/1	2	Yes		NA/TC	R (25AUG2020)	N/N
	GENRL	Injection site oedema/ Edema at the injection site	1	26AUG2020	2/2	1	Yes		NA	R (27AUG2020)	N/N
		Injection site pain/ injection site pain	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	MUSC	Myalgia/ Myalgia	1	26AUG2020	2/2	2	Yes		NA	R (27AUG2020)	N/N
	GENRL	Fatigue/ Fatigue#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ Injection site pain#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	2	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411483		Fatigue/ Fatigue	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	15SEP2020	1/3	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pain/ Body pain	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	15SEP2020	1/4	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411484	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/3	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411487	NERV	Tension headache/ Tension headache	1	12SEP2020	19/1	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1241 12411488	GASTR	Dyspepsia/ Pyrosis	1	07SEP2020	14/5	1	No	O	NA/TC	R (11SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411489	NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/4	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N	
INJ&P	Limb injury/ Foot injury with nail#	3	15FEB2021	12/1	1	No	O	NA/TCN	R (15FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411495	GENRL	Pyrexia/ Fever	2	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411497	GENRL	Injection site pain/ Injection site pain	2	14SEP2020	1/2	1	Yes		NA/TC	R (15SEP2020)	N/N
	GENRL	Chills/ Chills	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		Fatigue/ Fatigue	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
		Pyrexia/ Fever	2	15SEP2020	2/1	2	Yes		NA/TC	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411499	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/4	2	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411500	GASTR	Diarrhoea/ Diarrhea	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411501	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Malaise/ Malaise	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411502	NERV	Headache/ Headache	2	15SEP2020	2/1	2	Yes		NA	R (15SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411503	GENRL	Injection site pain/ Injection site pain	2	15SEP2020	1/1	1	Yes		NA	R (15SEP2020)	N/Y
16-55/ C4591001 1241 12411504	GASTR	Nausea/ Nausea	2	16SEP2020	2/3	3	Yes		NA	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	16SEP2020	2/3	3	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache	1	10SEP2020	17/1	1	No	O	NA/TC	R (10SEP2020)	N/N
16-55/ C4591001 1241 12411505	GENRL	Chills/ Chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411506	GENRL	Pyrexia/ Fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411509	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/1	2	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411510	NERV	Headache/ Headache	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411512	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
		Injection site swelling/ Injection site swelling	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	1	02SEP2020	2/1	1	Yes		NA/TC	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411513	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1241 12411514	NERV	Headache/ headache	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/2	2	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411515	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	05FEB2021	10/C		No	O	P	UNK	N/N
	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411516	GENRL	Injection site pain/ Injection site pain	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411519	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411520	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/3	2	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/3	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/4	1	Yes		NA/TC	R (25FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411526	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/C	1	Yes		NA	N	N/N
	GENRL	Fatigue/ Fatigue#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411527	NERV	Headache/ Headache#	3	19FEB2021	2/2	2	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	24SEP2020	2/1	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411528	GENRL	Injection site pain/ Injection site pain	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	01SEP2020	1/1	1	Yes		NA	R (01SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/5	1	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/5	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411530	GENRL	Chills/ Chills	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
		Injection site pain/ Injection site pain	2	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411531	MUSC	Myalgia/ Myalgia	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ Prostration#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	16-55/ C4591001 1241 12411532	GENRL	Pyrexia/ Fever	2	22SEP2020	2/2	1	Yes		NA/TC	R (23SEP2020)
16-55/ C4591001 1241 12411535	INFEC	Influenza/ Flu syndrome	1	14SEP2020	13/4	1	No	O	NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411536	NERV	Headache/ Headache#	3	28JAN2021	2/1	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411538	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/2	1	Yes	NA	NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411542	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/2	1	Yes	NA	NA	R (04SEP2020)	N/N
		Injection site pain/ Injection site pain	1	03SEP2020	2/4	2	Yes	NA/TC	NA/TC	R (06SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	24SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	2/2	2	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N
		Fatigue/ Fatigue	2	24SEP2020	2/2	2	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N
		Pyrexia/ Fever	2	24SEP2020	2/2	2	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/2	1	Yes	NA/TC	NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411544	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes	NA	NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411546	MUSC	Myalgia/ Myalgia#	3	22JAN2021	1/5	1	Yes	NA/TC	NA/TC	R (26JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	1/5	1	Yes	NA/TC	NA/TC	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411547	GENRL	Chills/ Chills#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
		Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N
16-55/ C4591001 1241 12411548	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	1	Yes		NA	R (24SEP2020)	N/Y
16-55/ C4591001 1241 12411552	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	NERV	Headache/ Headache#	3	01FEB2021	1/2	1	Yes		NA/TC	R (02FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/2	2	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411555	GASTR	Diarrhoea/ Diarrhea#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411556	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	2/2	2	Yes		NA	R (04SEP2020)	N/N
	NERV	Headache/ Headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411557	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411558	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Prostration	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411561	MUSC	Pyrexia/ Fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
		Myalgia/ Myalgia	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	25SEP2020	4/6	1	Yes		NA/TC	R (30SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	26SEP2020	5/1	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/5	1	Yes		NA	R (05FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement#	4	22FEB2021	1/5	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411562	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
		Myalgia/ Myalgia#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411563	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/5	1	Yes		NA	R (27FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411564	GENRL	Injection site pain/ Injection site pain	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	SURG	Mammoplasty/ Breast implant prosthesis	2	15DEC2020	85/1	1	No	O	NA/TC	R (15DEC2020)	N/N
16-55/ C4591001 1241 12411565	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411566	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/4	1	Yes		NA	R (31JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411567	GENRL	Chills/ Chills#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
		Fatigue/ Fatigue#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/4	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	2	Yes		NA/TC/TCN	R (02FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/2	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411568		Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TCN	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	3/1	1	Yes		NA	R (04SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Right axillary lymph node enlargement#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/3	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	4	18FEB2021	2/3	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411569	GENRL	Injection site erythema/ Injection site redness	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Injection site pain	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1241 12411570	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	INFEC	Cystitis/ Cystitis	2	24OCT2020	31/11	1	No	O	NA/TC	R (03NOV2020)	N/N
16-55/ C4591001 1241 12411572	GENRL	Chills/ Chills	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411574	GASTR	Odynophagia/ Odynophagia	1	03SEP2020	1/1	1	No	O	NA	R (03SEP2020)	N/Y
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411575	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	2	Yes		NA	R (23SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411576	EYE	Eye pain/ Pain in the eyes	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Chills/ Chills	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1241 12411577	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411578	GENRL	Pyrexia/ Fever	2	03OCT2020	2/1	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1241 12411580	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411581	GENRL	Chills/ Chills#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411582	NERV	Pyrexia/ Fever#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
		Headache/ Headache#	3	23FEB2021	1/4	1	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1241 12411583	MUSC	Myalgia/ myalgia	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Tension headache/ Tension headache	2	21OCT2020	29/1	1	No	O	NA/TCN	R (21OCT2020)	N/N
	GENRL	Chills/ Chills#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411586	NERV	Headache/ Headache#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	04SEP2020	2/1	2	Yes		NA/TC	R (04SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N
Vomiting/ Vomiting		2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue	2	22SEP2020	1/4	2	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411587	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/4	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1241 12411589	INFEC	Tinea cruris/ Ringworm in the inguinal region	1	04SEP2020	2/4	1	No	O	NA/TCN	R (07SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12411590	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411592	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411595	GENRL	Fatigue/ Fatigue	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411596	METAB	Decreased appetite/ Inapetence	2	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/3	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411599	GENRL	Chills/ Chills	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Fatigue/ Fatigue	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411600	NERV	Injection site pain/ Injection site pain	2	22SEP2020	1/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
		Headache/ Headache	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
	INFEC	Rhinitis/ Worsening Recurrent rhinitis	1	21SEP2020	19/2	1	No	O	NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411601	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12411603	GENRL	Injection site pain/ Injection site pain	2	22SEP2020	1/4	1	Yes		NA	R (25SEP2020)	N/Y
16-55/ C4591001 1241 12411604	GENRL	Fatigue/ Fatigue#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes		NA/TC/TCN	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Injection site erythema/ Injection site redness#	4	23FEB2021	2/2	1	Yes		NA/TC/TCN	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411605	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N
16-55/ C4591001 1241 12411607	GENRL	Chills/ Chills	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/4	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 1241 12411608	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411610		Injection site pain/ Injection site pain#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/4	2	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001 1241 12411611	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411613	GENRL	Chills/ Chills	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
		Injection site pain/ Injection site pain	1	05SEP2020	2/1	2	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	25SEP2020	1/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411616	NERV	Sciatica/ Left sciatic nerve inflammation	2	16OCT2020	24/39	2	No	O	NA/TC/TCN	R (23NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411617		Fatigue/ Prostration#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ Chills#	4	13FEB2021	2/2	1	Yes		NA/TC	R (14FEB2021)	N/N
		Fatigue/ Fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1241 12411619	GENRL	Injection site pain/ Injection site pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411624	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411625	GASTR	Pyrexia/ Fever#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		Diarrhoea/ Diarrhea	1	21SEP2020	18/2	1	No	O	NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA/TC	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411626	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
		GENRL	Injection site pain/ Injection site pain	1	05SEP2020	2/2	2	Yes		NA/TC	R (06SEP2020)
16-55/ C4591001 1241 12411630	MUSC	Pyrexia/ Fever	1	05SEP2020	2/2	2	Yes		NA/TC/TCN	R (06SEP2020)	N/N
		Myalgia/ Myalgia#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	NERV	Headache/ Headache#	3	23JAN2021	2/2	1	Yes		NA/TC	R (24JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N
NERV	Headache/ Headache#	4	15FEB2021	1/3	1	Yes		NA	R (17FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411632	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411633	INFEC	Furuncle/ Furunculosis in buttocks	2	07OCT2020	14/8	1	No	O	NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	2/4	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411635	NERV	Headache/ Headache	1	20SEP2020	17/2	1	No	O	NA/TC	R (21SEP2020)	N/N
	GENRL	Fatigue/ Prostration#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411636	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Injection site pruritus/ Injection site itching	2	24SEP2020	1/3	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411637		Fatigue/ Fatigue	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	24SEP2020	1/2	1	Yes		NA	R (25SEP2020)	N/N
	NERV	Somnolence/ Drowsiness	2	24SEP2020	1/2	2	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411638	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/1	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1241 12411639	GENRL	Pyrexia/ Fever	2	26SEP2020	3/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1241 12411640	RESP	Nasal congestion/ Nasal congestion	2	06OCT2020	13/2	1	No	O	NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411641	INJ&P	Skin laceration/ Second left finger cut	2	11OCT2020	19/1	2	No	O	NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411645	GENRL	Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411646	NERV	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		Somnolence/ Drowsiness	2	25SEP2020	2/2	1	Yes		NA/TC	R (26SEP2020)	N/N
	GENRL	Chills/ Chills#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411648	GENRL	Myalgia/ Myalgia#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/1	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1241 12411650	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411651	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/Y
	INFEC	Pelvic inflammatory disease/ Pelvic inflammatory disease	1	14SEP2020	11/26	2	No	O	NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411653	MUSC	Pyrexia/ Fever#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
		Myalgia/ Myalgia#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	MUSC	Pyrexia/ Fever#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
		Myalgia/ Myalgia#	4	24FEB2021	2/3	2	Yes		NA/TC	R (26FEB2021)	N/N
	GENRL	Injection site rash/ Injection site macular papular rash	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/2	2	Yes		NA/TC	R (09SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	09SEP2020	2/2	2	Yes		NA	R (10SEP2020)	N/N
	16-55/ C4591001 1241 12411654	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)
16-55/ C4591001 1241 12411655	GENRL	Fatigue/ Fatigue#	3	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/2	2	Yes		NA	R (05FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411656	GENRL	Injection site pain/ Injection site pain	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
		Pyrexia/ Fever	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	NERV	Headache/ Headache	1	10SEP2020	1/1	2	Yes		NA/TC	R (10SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1241 12411657	EYE	Eye pain/ Retroorbital pain#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Fatigue/ Prostration#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411658	GENRL	Chills/ Chills	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1241 12411659	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	3	02FEB2021	1/3	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411661	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411663	GENRL	Pyrexia/ Fever	2	01OCT2020	3/1	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1241 12411664	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411665	NERV	Headache/ Headache	1	11SEP2020	2/3	1	Yes		NA/TC	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411666	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1241 12411667	GENRL	Chills/ Chills	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	METAB	Decreased appetite/ Hyporexia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	30SEP2020	2/1	2	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1241 12411672	GASTR	Diarrhoea/ Diarrhea	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
		Vomiting/ Vomiting	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
	NERV	Headache/ Headache	1	15SEP2020	2/1	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1241 12411673	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411674	MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411678	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411679	REPRO	Uterine inflammation/ Uterine inflammation	1	01OCT2020	18/5	2	No	O	NA/TCN	R (05OCT2020)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	01NOV2020	28/C		No	O	NA	UNK	N/N
	MUSC	Back pain/ Backache	2	15NOV2020	42/2	2	No	O	NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 1241 12411680	GENRL	Asthenia/ Asthenia	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/N
		Chills/ Chills	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	05OCT2020	1/4	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411681		Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Pyrexia/ Fever	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411683	GENRL	Fatigue/ Fatigue	1	15SEP2020	1/2	2	Yes		NA	R (16SEP2020)	N/N
		Injection site pain/ Injection site pain	1	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	2/1	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411684	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411685	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	15SEP2020	1/3	2	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Fatigue/ fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y
	MUSC	Myalgia/ Muscle pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/4	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA	R (06OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411694	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411695	NERV	Headache/ Headache#	3	30JAN2021	2/1	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411696	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	2/2	2	Yes		NA	R (17SEP2020)	N/N
16-55/ C4591001 1241 12411697	GENRL	Injection site pain/ Injection site paIN#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411698	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411699	GENRL	Chest discomfort/ Chest discomfort	1	25SEP2020	11/2	1	No	O	NA/TC	R (26SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411700	GENRL	Pyrexia/ Fever	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411701	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411702	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/2	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411707	NERV	Headache/ headache	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1241 12411708	INJ&P	Injury/ Injury secondary to trauma	1	04OCT2020	19/23	1	No	O	NA/TC	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/1	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1241 12411709	GENRL	Pyrexia/ Fever	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06OCT2020	2/3	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411710	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411713	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411714	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	2/4	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/1	1	Yes		NA	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411715	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes	NA	R (04FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	22FEB2021	1/2	1	Yes	NA/TCN	R (23FEB2021)	N/N	
16-55/ C4591001 1241 12411716	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/1	1	Yes	NA	R (16SEP2020)	N/N	
	NERV	Headache/ Headache	1	16SEP2020	1/1	1	Yes	NA/TC	R (16SEP2020)	N/N	
	NERV	Headache/ headache	2	06OCT2020	2/1	1	Yes	NA/TC	R (06OCT2020)	N/N	
16-55/ C4591001 1241 12411719	GASTR	Aphthous ulcer/ Oral aphthae	1	17SEP2020	2/4	1	Yes	NA/TC	R (20SEP2020)	N/N	
		Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes	NA/TC	R (17SEP2020)	N/N	
	GENRL	Asthenia/ Asthenia	1	17SEP2020	2/2	1	Yes	NA/TC	R (18SEP2020)	N/N	
		Injection site pain/ Injection site pain	1	17SEP2020	2/1	1	Yes	NA/TC	R (17SEP2020)	N/N	
	NERV	Headache/ Headache	1	17SEP2020	2/2	1	Yes	NA/TC	R (18SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	05OCT2020	1/4	1	Yes	NA	R (08OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411720	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411724	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411725	GENRL	Asthenia/ Asthenia	2	06OCT2020	2/1	1	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1241 12411726	GENRL	Fatigue/ Prostration#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411727	SKIN	Rash/ Skin rash	1	16SEP2020	1/4	2	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	1	17SEP2020	2/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411730	MUSC	Myalgia/ Myalgia	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	4/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411731	GENRL	Fatigue/ Fatigue	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
		Injection site pain/ Injection site pain	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	05OCT2020	1/2	1	Yes		NA/TC	R (06OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache#	4	18FEB2021	1/2	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1241 12411733	MUSC	Back pain/ Backache	2	01NOV2020	27/5	1	No	O	NA/TC	R (05NOV2020)	N/N
16-55/ C4591001 1241 12411735	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411736	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N
		Vomiting/ Vomiting	1	16SEP2020	1/3	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	2	05OCT2020	1/4	1	Yes		NA	R (08OCT2020)	N/Y
16-55/ C4591001 1241 12411740	GASTR	Diarrhoea/ Diarrhea	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pyrexia/ Fever#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411741	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1241 12411744	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411747	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12411750	MUSC	Back pain/ Backache	1	21SEP2020	6/4	1	No	O	NA/TC	R (24SEP2020)	N/N
	GENRL	Chills/ Chills#	3	03FEB2021	2/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	23FEB2021	1/2	2	Yes		NA	R (24FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411756	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411757	GENRL	Pyrexia/ fever	2	07OCT2020	2/1	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1241 12411758	GENRL	Chills/ Chills	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	2/2	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411760	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12411762	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	29JAN2021	2/1	2	Yes		NA/TC	R (29JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/1	2	Yes		NA/TC	R (29JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/4	1	Yes		NA/TC	R (06FEB2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
			Pyrexia/ Fever#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N	
	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	17SEP2020	2/C		No	O	P	UNK	N/N	
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411769	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain	1	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		Fatigue/ Fatigue	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1241 12411771	GENRL	Pyrexia/ Fever	2	07OCT2020	2/1	1	Yes		NA/TC	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection site pain	2	06OCT2020	1/2	2	Yes		NA/TC	R (07OCT2020)	N/N
16-55/ C4591001 1241 12411774	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411775	GENRL	Fatigue/ Fatigue	1	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411776		Injection site pain/ Injection site pain#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	02FEB2021	1/3	2	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	12FEB2021	2/1	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	4	12FEB2021	2/1	1	Yes		NA/TC	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	12FEB2021	2/1	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
	16-55/ C4591001 1241 12411777	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)
16-55/ C4591001 1241 12411779	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/2	2	Yes		NA	R (17SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411781	GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	20FEB2021	2/2	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12411782	GENRL	Pyrexia/ Fever	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411784	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411784	GENRL	Chills/ Chills#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411785	GENRL	Chills/ Chills#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/3	1	Yes		NA/TCN	R (18SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	17SEP2020	2/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	IMMUN	Drug hypersensitivity/ Allergic reaction to dipyrone	1	17SEP2020	2/1	3	No	CD	NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411790	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411792	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411793	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411797	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411798	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411799	GENRL	Chills/ Chills	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Fatigue/ Fatigue	1	17SEP2020	1/1	2	Yes		NA	R (17SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411800	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411801	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411803	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Fatigue/ Fatigue	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411804	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411805	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411806	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411807	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411808	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12411809	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	NERV	Headache/ Headache#	3	22JAN2021	2/2	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1241 12411810	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411812	NERV	Headache/ Headache	1	18SEP2020	2/2	3	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pain/ Body pain	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411813	MUSC	Myalgia/ Myalgia	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	1/1	1	Yes		NA/TC	R (17SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411814	INJ&P	Limb injury/ Right foot trauma	1	05OCT2020	19/14	1	No	O	NA/TC	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411815	NERV	Headache/ Headache#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12411816	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411817	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/2	2	Yes		NA/TC	R (19SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Asthenia/ Asthenia	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411818	MUSC	Chills/ Chills	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Myalgia/ Myalgia	2	09OCT2020	2/12	2	Yes		NA	R (20OCT2020)	N/N
		Headache/ Headache	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411820	GENRL	Pyrexia/ fever	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411820	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411823	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411824	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
		Fatigue/ Prostration#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411827		Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	2/5	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411828	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411830	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411834	GENRL	Injection site pain/ injection site pain	1	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ Prostration	2	09OCT2020	2/3	2	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411835	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411837	MUSC	Pyrexia/ Fever#	4	23FEB2021	1/3	1	Yes		NA/TC	R (25FEB2021)	N/N
		Myalgia/ Myalgia#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	MUSC	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
		Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N	
16-55/ C4591001 1241 12411839	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA/TC/TCN	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411845	GENRL	Pyrexia/ Fever	2	09OCT2020	2/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	INJ&P	Limb injury/ Left hand injury#	3	12MAR2021	15/1	2	No	O	NA/TC	R (12MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411846	GENRL	Fatigue/ Fatigue#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411847	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411849	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411850	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411854	NERV	Headache/ Headache	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/5	1	Yes		NA/TCN	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1241 12411855	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
16-55/ C4591001 1241 12411856	NERV	Headache/ Headache#	3	29JAN2021	2/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site bruising/ Injection site bruise	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	1/5	2	Yes		NA	R (13OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411857	GENRL	Fatigue/ Prostration	2	09OCT2020	2/1	2	Yes		NA	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	2/1	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411858	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411860	GENRL	Pyrexia/ Fever#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	2/3	1	Yes		NA/TC	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411861	GENRL	Injection site pain/ Injection site pain#	4	15FEB2021	1/3	1	Yes		NA/TC	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Chills/ Chills	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Fever	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411862	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Axillary lymph nodes enlargement in left arm	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/4	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411863	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/1	2	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411864	NERV	Headache/ Headache#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
16-55/ C4591001 1241 12411865	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411866	NERV	Headache/ Headache	1	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	1/1	1	Yes		NA	R (08OCT2020)	N/Y
16-55/ C4591001 1241 12411867	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001 1241 12411868	SKIN	Erythema nodosum/ Erythema nodosum on the inner face of the right thigh#	4	16FEB2021	1/21	1	Yes		NA/TC	R (08MAR2021)	N/N
16-55/ C4591001 1241 12411869	GENRL	Chills/ chills	2	09OCT2020	2/1	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411872		Pyrexia/ Fever	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411873	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411874	GENRL	Injection site pain/ Injection site pain#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	1/2	1	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411875	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411877	GENRL	Asthenia/ Asthenia	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ Injection site pain and burning sensation	1	18SEP2020	1/1	1	Yes		NA	R (18SEP2020)	N/Y
16-55/ C4591001 1241 12411878	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411879	GENRL	Chills/ Chills	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411881	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411882	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Fatigue/ Fatigue	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411884	GENRL	Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411886	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA/TC	R (19SEP2020)	N/N
		Asthenia/ Asthenia	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411887	GENRL	Pyrexia/ Fever	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		Fatigue/ Prostration	2	10OCT2020	2/1	2	Yes		NA	R (10OCT2020)	N/N
		Teratoma/ High grade immature teratoma	2	18JAN2021	102/10	3	No	O	NA	R (27JAN2021)	Y/N
16-55/ C4591001 1241 12411888	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ Fatigue	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411889	NERV	Injection site pain/ Injection site pain	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
		Headache/ Headache	1	19SEP2020	2/3	1	Yes		NA/TC	R (21SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/1	2	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411892	GENRL	Chills/ Chills	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1241 12411892	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
16-55/ C4591001 1241 12411893	GENRL	Asthenia/ Asthenia	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/5	2	Yes		NA	R (22SEP2020)	N/N
		Chills/ Chills	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
		Fatigue/ Fatigue	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411894	NERV	Injection site pain/ Injection site pain	2	09OCT2020	1/3	1	Yes		NA/TC	R (11OCT2020)	N/N
		Pyrexia/ Fever	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Headache/ Headache	2	09OCT2020	1/2	2	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/4	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12411895	NERV	Pyrexia/ Fever#	4	17FEB2021	1/2	2	Yes		NA/TC	R (18FEB2021)	N/N
		Headache/ Headache#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411897	GENRL	Fatigue/ Prostration	2	16OCT2020	3/1	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	3/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12411897	GENRL	Chills/ Chills#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Fatigue#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001	RESP	Injection site pain/ Injection site pain#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N
		Rhinorrhoea/ Rhinorrhea	1	07OCT2020	20/2	1	No	O	NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411898 16-55/ C4591001 1241 12411899	GENRL	Chills/ Chills	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411900	GENRL	Fatigue/ Fatigue#	3	06FEB2021	3/2	1	Yes		NA/TC	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	3/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411904	GENRL	Chills/ Chills	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
		Fatigue/ Fatigue	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N
		Fatigue/ Prostration	2	10OCT2020	2/6	2	Yes		NA	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	10OCT2020	2/3	1	Yes		NA	R (12OCT2020)	N/N
16-55/ C4591001 1241 12411906	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411911	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411912	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/2	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411914		Injection site pain/ Injection site pain#	4	10FEB2021	1/2	1	Yes		NA/TC/TCN	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chills	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue	1	22SEP2020	5/4	1	Yes		NA	R (25SEP2020)	N/N
GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411915	MUSC	Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411915	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	15DEC2020	68/C		No	O	NA	UNK	N/N
16-55/ C4591001 1241 12411917	GENRL	Chills/ Chills#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411919	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	1/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12411920	GENRL	Chills/ Chills	1	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/1	1	Yes		NA/TC/TCN	R (19SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ chills	2	09OCT2020	1/1	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411921	GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes	NA	R	(11OCT2020)	N/N
	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes	NA	R	(11OCT2020)	N/N
16-55/ C4591001 1241 12411924	GENRL	Pyrexia/ Fever	2	09OCT2020	1/2	1	Yes	NA/TC	R	(10OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/1	2	Yes	NA/TCN	R	(10OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	10OCT2020	2/1	2	Yes	NA/TCN	R	(10OCT2020)	N/N
16-55/ C4591001 1241 12411925	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes	NA/TC	R	(05FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes	NA/TC	R	(05FEB2021)	N/N
16-55/ C4591001 1241 12411926	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes	NA	R	(07FEB2021)	N/N
16-55/ C4591001 1241 12411927	GENRL	Chills/ Chills	2	10OCT2020	2/2	1	Yes	NA/TC	R	(11OCT2020)	N/N
		Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes	NA/TC	R	(11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411930	NERV	Headache/ Headache	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
	NERV	Headache/ Headache#	4	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	2/2	1	Yes		NA	R (17FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	17FEB2021	3/3	1	Yes		NA/TC	R (19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411936	GENRL	Axillary pain/ Left armpit pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411937	NERV	Injection site pain/ Injection site pain	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
		Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA/TC	R (08OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/3	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411939	GASTR	Diarrhoea/ Diarrhea	2	09OCT2020	3/3	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12411940	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411942	GENRL	Pyrexia/ fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411943	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411944	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/Y
16-55/ C4591001 1241 12411945	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1241 12411947	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/Y
16-55/ C4591001 1241 12411948	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1241 12411949		Injection site swelling/ Injection site swelling	1	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	2/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	15FEB2021	1/2	2	Yes		NA/TCN	R (16FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411950	GENRL	Asthenia/ Asthenia	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
		Pyrexia/ Fever	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411951	GENRL	Injection site pain/ Injection site pain	1	18SEP2020	1/3	2	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ Chill	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411952	INFEC	Helicobacter gastritis/ Helicobacter pylori gastritis	2	13OCT2020	7/25	1	No	O	NA/TC	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/4	2	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/4	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411953	NERV	Headache/ Headache#	3	27JAN2021	2/1	1	Yes		NA/TC	R (27JAN2021)	N/N
16-55/ C4591001 1241 12411954	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411956	GENRL	Injection site pain/ Injection site pain	2	07OCT2020	1/4	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1241 12411957	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08OCT2020	2/2	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1241 12411958	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411960	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12411961	GENRL	Fatigue/ Prostration	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1241 12411962	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
	RESP	Nasal obstruction/ Nasal obstruction	1	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
		Rhinorrhoea/ Runny nose	1	19SEP2020	2/3	2	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1241 12411965	GASTR	Vomiting/ Vomiting due to medication	1	25SEP2020	5/2	1	No	CD	NA	R (26SEP2020)	N/N
	MUSC	Back pain/ Backache (Exacerbation of pre- existing condition)	1	25SEP2020	5/9	2	No	O	NA/TC	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	1/4	1	Yes		NA	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	3	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	23JAN2021	2/1	2	Yes		NA	R (23JAN2021)	N/N
	GENRL	Chills/ Chills#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12411967	GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Reactional Left axillary lymph node	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411968 16-55/ C4591001 1241 12411969	GENRL	Chills/ Chills#	3	01FEB2021	1/2	1	Yes	NA	NA	R (02FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	01FEB2021	1/4	1	Yes	NA	NA	R (04FEB2021)	N/Y
	GENRL	Pyrexia/ Fever#	3	03FEB2021	3/1	1	Yes	NA/TC	NA/TC	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	22FEB2021	1/5	1	Yes	NA/TC	NA/TC	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	22FEB2021	1/5	1	Yes	NA	NA	R (26FEB2021)	N/Y
		Pyrexia/ Fever#	4	22FEB2021	1/5	1	Yes	NA/TC	NA/TC	R (26FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	22FEB2021	1/5	1	Yes	NA/TC	NA/TC	R (26FEB2021)	N/N
	NERV	Headache/ Headache#	4	22FEB2021	1/5	1	Yes	NA	NA	R (26FEB2021)	N/Y
16-55/ C4591001 1241 12411970	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	2	Yes	NA	NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes	NA	NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes	NA/TC	NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411972	GASTR	Nausea/ Nausea	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
		Vomiting/ Vomiting	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/3	2	Yes		NA/TC	R (24SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Pyrexia/ Fever#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GASTR	Nausea/ Nausea#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12411973	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411974	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411978	NERV	Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
		Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 1241 12411980	INFEC	Cellulitis/ Cellulitis on the right foot	2	27DEC2020	76/C	2	No	O	NA/TC	N	Y/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12411982	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	16-55/ C4591001	Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
GENRL		Fatigue/ Fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12411983	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
1241 12411984	GENRL	Pyrexia/ Fever#	3	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
1241 12411987	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
1241 12411991	GENRL	Pyrexia/ Fever#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411993	NERV	Headache/ Headache#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N
	GENRL	Fatigue/ Prostration	1	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
		Pyrexia/ Fever	1	21SEP2020	1/1	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1241 12411994	GENRL	Fatigue/ fatigue	2	04NOV2020	2/2	1	Yes		NA	R (05NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1241 12411996	NERV	Headache/ Headache	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411997	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411998	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/3	2	Yes		NA	R (13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1241 12412002	NERV	Headache/ Headache#	4	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
	NERV	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
16-55/ C4591001 1241 12412003	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/Y
	GENRL	Asthenia/ Asthenia#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/1	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1241 12412004	GENRL	Injection site pain/ Injection site pain	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412006	GENRL	Injection site pain/ Injection site tenderness#	3	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412007	GENRL	Pyrexia/ Fever#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412008	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	14OCT2020	2/3	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412009	GENRL	Pain/ Body pain	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412010	SKIN	Skin lesion/ Hypochromic skin lesions	1	30SEP2020	10/21	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412013	GASTR	Nausea/ Nausea	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	1	22SEP2020	2/2	2	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/Y
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412015	GENRL	Pyrexia/ Fever#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/2	1	Yes		NA/TC	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412016	GENRL	Pyrexia/ Fever	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412018	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	04FEB2021	1/5	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412020	GENRL	Injection site pain/ Injection Site pain	1	28SEP2020	1/3	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1241 12412022	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412023	GENRL	Chills/ Chills#	3	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
		Fatigue/ Prostration#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/3	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412024	GENRL	Chills/ Chills#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412025	GENRL	Chills/ Chills	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	2	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412026	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	2	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	2	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	3/8	1	Yes		NA	R (19NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	NERV	Headache/ Headache#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Pyrexia/ Fever#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Myalgia/ Myalgia#	4	16FEB2021	1/3	1	Yes		NA/TC	R (18FEB2021)	N/N
		Headache/ Headache#	4	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412027	GENRL	Injection site pain/ Injection site pain	2	24OCT2020	2/3	2	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1241 12412028	GENRL	Fatigue/ Fatigue	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	22OCT2020	1/6	2	Yes		NA/TC	R (27OCT2020)	N/N
		Headache/ Headache	2	22OCT2020	1/6	2	Yes		NA/TC	R (27OCT2020)	N/N
		Injection site pain/ Injection site pain	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412029	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Pain/ Body pain	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412031	GASTR	Pyrexia/ Fever	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
		Diarrhoea/ Diarrhea#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412032	SKIN	Fatigue/ Prostration#	3	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
		Pruritus/ Itching in the body	1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Rash/ Left elbow rash	1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412034	GENRL	Rash/ Right trunk rash	1	02OCT2020	3/19	1	Yes		NA	R (20OCT2020)	N/N
		Fatigue/ Fatigue#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Injection site pain	2	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412035	GASTR	Odynophagia/ Odinophagy	1	13OCT2020	14/4	1	No	O	NA	R (16OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	25OCT2020	3/3	1	Yes		NA	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412037	GASTR	Nausea/ Nausea	1	30SEP2020	1/3	2	Yes		NA/TC	R (02OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Injection site pain	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	2	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412038	GENRL	Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412041	MUSC	Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N	
	16-55/ C4591001 1241 12412043	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N	
		Pyrexia/ Fever	2	22OCT2020	1/2	1	Yes		NA/TC	R (23OCT2020)	N/N	
	16-55/ C4591001 1241 12412045	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	05FEB2021	1/3	1	Yes		NA/TC	R (07FEB2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	01FEB2021	1/2	1	Yes		NA	R (02FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412046 16-55/ C4591001 1241 12412048	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
1241 12412048 16-55/ C4591001 1241 12412049	GENRL	Fatigue/ Fatigue	2	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
1241 12412049 16-55/ C4591001 1241 12412050	GENRL	Pyrexia/ Fever	2	21OCT2020	1/1	1	Yes		NA/TC	R (21OCT2020)	N/N
1241 12412050 16-55/ C4591001 1241 12412051	GASTR	Diarrhoea/ Diarrhea	2	22OCT2020	2/7	1	Yes		NA	R (28OCT2020)	N/N
1241 12412051 16-55/ C4591001 1241 12412052	INJ&P	Injury/ Blunt trauma#	2	30JAN2021	102/25	2	No	O	NA	R (23FEB2021)	N/N
1241 12412052 16-55/ C4591001 1241 12412053	GENRL	Chills/ Chills	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
1241 12412053 16-55/ C4591001 1241 12412054	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
1241 12412054 16-55/ C4591001 1241 12412055	GENRL	Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
1241 12412055 16-55/ C4591001	SKIN	Rash/ Skin rash in arms	2	12NOV2020	23/2	1	No	O	NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412053	INJ&P	Clavicle fracture/ Fracture of right clavicle#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
		Rib fracture/ Fracture of ribs#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
		Road traffic accident/ Motor Vehicle Accident#	2	31JAN2021	103/1	3	No	O	NA	R (31JAN2021)	Y/N
16-55/ C4591001 1241 12412055	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy#	4	26FEB2021	3/6	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1241 12412056	GENRL	Chills/ Chills	1	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Injection site pain/ Injection site pain	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	NERV	Headache/ Headache	1	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GASTR	Toothache/ Toothache	1	02OCT2020	3/1	1	No	O	NA/TC	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412057	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412059	MUSC	Myalgia/ Myalgia	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	NERV	Headache/ Headache	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412060	GENRL	Injection site pain/ Injection site pain	1	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/Y
	GASTR	Nausea/ Nausea	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	MUSC	Arthralgia/ Polyarthralgia	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Chills/ Chills#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Fatigue/ Fatigue#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N
	NERV	Headache/ Headache#	4	24FEB2021	2/2	1	Yes		NA/TC	R (25FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412061	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412062	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	2/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/3	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412063	GENRL	Chills/ Chills	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		Fatigue/ Prostration	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
		Injection site pain/ Injection site pain	2	20OCT2020	1/4	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	2	20OCT2020	1/3	2	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412064		Injection site pain/ Injection site pain#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	1/3	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412067	GENRL	Injection site pain/ Injection site burning	1	30SEP2020	1/1	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	01OCT2020	2/1	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412070	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/4	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	GENRL	Chills/ Chills	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
		Fatigue/ Fatigue	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
		Pyrexia/ Fever	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412071	NERV	Headache/ Headache	2	20OCT2020	1/2	1	Yes		NA/TC	R (21OCT2020)	N/N
	NERV	Headache/ Headache	1	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Headache/ Headache	2	23OCT2020	2/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/4	1	Yes		NA	R (28FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	NERV	Headache/ Headache#	4	25FEB2021	2/4	1	Yes		NA/TC	R (28FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	22OCT2020	2/3	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412074	MUSC	Myalgia/ Myalgia	2	22OCT2020	2/3	2	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412078	GENRL	Injection site pain/ Injection site pain	2	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412080	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412081	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412081	GASTR	Nausea/ Nausea	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Injection site erythema/ Injection site redness	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
		Injection site pain/ Injection site pain	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
		Injection site swelling/ Injection site swelling	2	22OCT2020	1/5	2	Yes		NA/TC	R (26OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	1/2	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412083	GENRL	Fatigue/ Fatigue	2	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412084	GENRL	Pain/ Body pain	2	31OCT2020	2/2	1	Yes	NA	R	(01NOV2020)	N/N
	INV	Body temperature increased/ Subfebrile temperature	2	31OCT2020	2/2	1	Yes	NA	R	(01NOV2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/2	1	Yes	NA	R	(01NOV2020)	N/N
16-55/ C4591001 1241 12412086	GENRL	Pyrexia/ Fever#	3	06FEB2021	2/1	1	Yes	NA/TC	R	(06FEB2021)	N/N
16-55/ C4591001 1241 12412087	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/6	1	Yes	NA	R	(14FEB2021)	N/N
16-55/ C4591001 1241 12412088	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes	NA	R	(05FEB2021)	N/N
16-55/ C4591001 1241 12412091	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes	NA	R	(06FEB2021)	N/N
16-55/ C4591001 1241 12412093	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes	NA	R	(07FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	03OCT2020	3/3	1	Yes	NA/TC	R	(05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412094	GASTR	Diarrhoea/ Diarrhea	1	06OCT2020	6/1	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ Headache	2	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412095	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412096	GENRL	Chills/ Chills	2	23OCT2020	2/2	2	Yes		NA/TC	R (24OCT2020)	N/N
		Injection site pain/ Injection site pain	2	23OCT2020	2/2	1	Yes		NA/TC	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412097	GENRL	Fatigue/ Fatigue#	4	11FEB2021	1/2	1	Yes		NA/TC/TCN	R (12FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412098	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412099	GENRL	Injection site pain/ Injection site pain	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N
		Pyrexia/ Fever	2	24OCT2020	2/1	1	Yes		NA/TCN	R (24OCT2020)	N/N
		Fatigue/ Prostration#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Subfebrile#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Fatigue/ Prostration#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12412100	GENRL	Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
		Myalgia/ Myalgia#	4	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
		Urinary tract infection/ Urinary tract infection	1	20OCT2020	20/9	2	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1241 12412101	GENRL	Injection site pain/ Injection site pain	2	31OCT2020	2/2	1	Yes		NA	R (01NOV2020)	N/N
		Injection site pain/ Injection site pain#	3	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
		Myalgia/ Myalgia#	4	10FEB2021	1/2	1	Yes		NA/TC	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412102	GENRL	Asthenia/ Asthenia	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	22OCT2020	2/2	2	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412103	MUSC	Myalgia/ Myalgia#	3	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412104	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		Injection site pain/ Injection site pain	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412105	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Chills/ Chills	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412107	MUSC	Injection site pain/ Injection site pain	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
		Myalgia/ Myalgia	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	21OCT2020	1/3	2	Yes		NA/TC	R (23OCT2020)	N/N
	GASTR	Dyspepsia/ Dyspepsia	1	20OCT2020	19/1	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412108	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
		Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412108	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412109	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412110	BLOOD	Lymphadenopathy/ Left axillary lymph node enlargement	2	28OCT2020	3/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412111	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/2	2	Yes		NA/TC	R (27OCT2020)	N/N
	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Left armpit linfoadenomegaly#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412112	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412113		Injection site pain/ Injection site pain	1	02OCT2020	1/2	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	NERV	Headache/ Headache	1	03OCT2020	2/1	1	Yes		NA/TC	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
		Pyrexia/ Fever	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
	NERV	Headache/ Headache	2	22OCT2020	2/2	1	Yes		NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412117	GENRL	Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes		NA/TC	R (08FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412117	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412118	GENRL	Chills/ Chills	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412121	NERV	Pain/ Body pain	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Headache/ Headache	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1241 12412122	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12412123	NERV	Headache/ Headache	2	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412128		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412133	GENRL	Fatigue/ Fatigue	2	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001 1241 12412134	GENRL	Asthenia/ Asthenia#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412135	GENRL	Pain/ Body pain	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
		Pyrexia/ Fever	1	03OCT2020	2/2	1	Yes		NA/TC	R (04OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
		Pyrexia/ Fever	2	21OCT2020	1/2	1	Yes		NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412137	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412138	NERV	Headache/ Headache	2	27OCT2020	2/1	2	Yes		NA/TC	R (27OCT2020)	N/N
	GENRL	Chills/ Chills	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N
		Pyrexia/ Feeling of fever	1	07OCT2020	3/1	1	Yes		NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/5	2	Yes		NA/TC	R (30OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1241 12412139	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	05OCT2020	1/3	2	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1241 12412140	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/8	2	Yes		NA/TC	R (02NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/1	1	Yes		NA	R (06OCT2020)	N/Y
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412141	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	1	Yes	NA	NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412142	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	1	Yes	NA	NA	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412143	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/2	1	Yes	NA	NA	R (07OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	26OCT2020	1/2	1	Yes	NA	NA	R (27OCT2020)	N/N
16-55/ C4591001 1241 12412149	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	2	Yes	NA	NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	26OCT2020	1/5	2	Yes	NA/TC	NA/TC	R (30OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	26OCT2020	1/5	2	Yes	NA/TC	NA/TC	R (30OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	27OCT2020	2/3	2	Yes	NA/TC	NA/TC	R (29OCT2020)	N/N
16-55/ C4591001 1241 12412150	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/2	1	Yes	NA	NA	R (04FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/4	2	Yes	NA	NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412151	GENRL	Chills/ Chills	2	28OCT2020	1/2	1	Yes	NA/TC	R (29OCT2020)	N/N	
		Fatigue/ Fatigue	2	28OCT2020	1/2	1	Yes	NA/TC	R (29OCT2020)	N/N	
		Pyrexia/ Fever	2	28OCT2020	1/2	1	Yes	NA/TC	R (29OCT2020)	N/N	
16-55/ C4591001 1241 12412152	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/2	1	Yes	NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	30OCT2020	2/3	2	Yes	NA	R (01NOV2020)	N/N	
16-55/ C4591001 1241 12412154	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes	NA	R (10FEB2021)	N/N	
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes	NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412155	GENRL	Injection site pain/ Injection site pain	1	08OCT2020	2/1	1	Yes	NA	R (08OCT2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes	NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412156	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes	NA	R (10FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412157	GENRL	Injection site pain/ Injection site pain	2	29OCT2020	1/2	1	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1241 12412159	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 1241 12412160	NERV	Headache/ Headache	1	09OCT2020	3/1	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	31OCT2020	2/1	2	Yes		NA	R (31OCT2020)	N/N
16-55/ C4591001 1241 12412162	SURG	Dental implantation/ Dental implant unit 44	1	28OCT2020	22/1	1	No	O	NA/TC	R (28OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412163	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/4	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412165	GENRL	Injection site pain/ Injection site pain	1	09OCT2020	1/3	2	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412167	NERV	Headache/ Headache	2	28OCT2020	1/2	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	13OCT2020	1/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1241 12412168		Injection site pain/ Injection site pain	1	13OCT2020	1/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA/TCN	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412169	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	13OCT2020	1/2	1	Yes		NA/TCN	R (14OCT2020)	N/N
16-55/ C4591001 1241 12412171	INFEC	Sinusitis bacterial/ Sinusitis of bacterial etiology	2	13NOV2020	11/12	1	No	O	NA/TC	R (24NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412172	GENRL	Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412173	GENRL	Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412174	GENRL	Injection site swelling/ Injection site swelling	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412175	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/Y
16-55/ C4591001 1241 12412176	GENRL	Fatigue/ Prostration	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ Injection site pain	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	2/3	2	Yes		NA	R (07NOV2020)	N/N
		Injection site pain/ Injection site pain	2	05NOV2020	2/3	2	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	2/3	2	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412177	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412179	GENRL	Chills/ Chills#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Fatigue/ Fatigue#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Pyrexia/ Fever	1	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	16-55/ C4591001 1241 12412180	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)
16-55/ C4591001 1241 12412180	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Pyrexia/ Fever#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412181	GENRL	Injection site pain/ Injection site pain	1	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/3	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412182	GENRL	Injection site pain/ Injection site paijn#	3	09FEB2021	2/5	1	Yes		NA/TC	R (13FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	2/3	1	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412183	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412186	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412187	GENRL	Pyrexia/ Fever	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	3/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412188 16-55/ C4591001 1241 12412190	BLOOD	Lymphadenopathy/ Left armpit lymph node enlargement	1	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Medical device pain/ Pain in prosthesis in the left hand	1	15OCT2020	2/16	1	Yes		NA	R (30OCT2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ Fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Medical device pain/ Pain in prosthesis in the left hand	2	05NOV2020	2/3	1	Yes		NA	R (07NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412193	GENRL	Injection site erythema/ Injection site redness	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412194	GENRL	Chills/ Chills	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		Fatigue/ Fatigue	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	1	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412195	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/1	1	Yes		NA	R (26JAN2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412197	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	1	Yes		NA/TCN	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412198	GENRL	Pyrexia/ Fever	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1241 12412201	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ Fever	1	16OCT2020	2/2	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412202	GASTR	Diarrhoea/ Diarrhea	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
		Pyrexia/ Fever	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N	
	GASTR	Nausea/ Nausea	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N	
	16-55/ C4591001 1241 12412203	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		NERV	Headache/ Headache#	4	17FEB2021	2/1	1	Yes		NA/TC	R (17FEB2021)	N/N
	16-55/ C4591001 1241 12412204	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/1	1	Yes		NA	R (16OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	04NOV2020	1/2	1	Yes		NA	R (05NOV2020)	N/N
	16-55/ C4591001 1241 12412206	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/2	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	2/2	2	Yes		NA/TCN	R (17FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	2/2	2	Yes		NA/TCN	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412207	GENRL	Injection site pain/ Injection site pain	1	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412208	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	5/3	2	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412209	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	2/3	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/1	1	Yes		NA/TCN	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412211	GENRL	Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
	NERV	Headache/ Headache	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412212		Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412215	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/2	1	Yes		NA	R (05FEB2021)	N/N
		Pyrexia/ Fever#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
	NERV	Headache/ Headache#	3	04FEB2021	2/1	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1241 12412216	GENRL	Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412217	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	08FEB2021	1/4	2	Yes		NA/TC	R (11FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412218	INFEC	Conjunctivitis/ Conjunctivitis in the right eye	1	17OCT2020	3/8	1	No	O	NA/TC	R (24OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INFEC	Appendicitis/ APPENDICITIS	2	23NOV2020	18/3	3	No	O	NA/TC/TCN	R (25NOV2020)	Y/N
	GENRL	Chills/ Chills#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Chills/ Chills#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
16-55/ C4591001 1241 12412221	MUSC	Myalgia/ Myalgia	1	16OCT2020	2/1	2	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	08NOV2020	3/1	2	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1241 12412222	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412223	GENRL	Pyrexia/ Fever	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/3	1	Yes		NA/TC	R (08NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412225	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes		NA/TC	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/7	1	Yes		NA/TCN	R (23FEB2021)	N/N
16-55/ C4591001 1241 12412227	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N
	GENRL	Chills/ Chills	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	2	Yes		NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412229	GENRL	Pyrexia/ Fever#	3	05FEB2021	1/2	1	Yes		NA/TCN	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	1	Yes		NA/TCN	R (06FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TCN	R (07FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412232	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Chills/ chills	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412233	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA/TC	R (26FEB2021)	N/N
		Pyrexia/ Fever#	4	25FEB2021	2/1	1	Yes		NA/TC	R (25FEB2021)	N/N
16-55/ C4591001 1241 12412235	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1241 12412236	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	1/4	2	Yes		NA/TC	R (09NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	1/2	1	Yes		NA/TC	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412237	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412239	GENRL	Fatigue/ Fatigue	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/2	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412244	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412245	GENRL	Fatigue/ Fatigue	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Chills/ Chills#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12412247	GENRL	Fatigue/ Fatigue#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412248	NERV	Pyrexia/ Fever#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N	
		Headache/ Headache#	3	29JAN2021	1/4	1	Yes		NA/TC	R (01FEB2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N	
		Pyrexia/ Fever#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N	
	NERV	Headache/ Headache#	4	19FEB2021	1/3	1	Yes		NA/TC	R (21FEB2021)	N/N	
		GENRL	Fatigue/ Fatigue	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	16-55/ C4591001 1241 12412249		Injection site pain/ Injection site pain	1	17OCT2020	2/3	2	Yes		NA/TC	R (19OCT2020)	N/N
		RESP	Oropharyngeal discomfort/ Throat discomfort	2	05NOV2020	1/5	1	Yes		NA/TC	R (09NOV2020)	N/N
		GENRL	Chills/ Chills	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
			Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1241 12412252	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N	
	NERV	Tremor/ Leg tremors	1	20OCT2020	5/3	1	Yes		NA	R (22OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412254	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		Fatigue/ Prostration	1	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
	EYE	Asthenopia/ Weight in the eyes	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
		Eye irritation/ Eye burning	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	GENRL	Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	1/4	1	Yes		NA	R (09NOV2020)	N/N
16-55/ C4591001 1241 12412255	GASTR	Nausea/ Nausea	1	17OCT2020	2/4	2	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412256	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412258	INV	Body temperature increased/ Subfebrile temperature	2	06NOV2020	1/1	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412259	GENRL	Chills/ Chills#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Fatigue/ Fatigue#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412261	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412264	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA/TC	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412267	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412270	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	2/1	1	Yes		NA/TC	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	24FEB2021	1/3	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1241 12412271	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	06NOV2020	1/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412274	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412275	GENRL	Injection site pain/ Injection site pain	1	17OCT2020	2/2	2	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412276	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/2	1	Yes	NA	R (28JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	17FEB2021	2/1	2	Yes	NA	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12412277	GENRL	Chills/ Chills#	3	26JAN2021	1/1	1	Yes	NA/TC	R (26JAN2021)	N/N	
		Pyrexia/ Fever#	3	26JAN2021	1/1	1	Yes	NA/TC	R (26JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	2/2	2	Yes	NA/TCN	R (28JAN2021)	N/N	
	MUSC	Myalgia/ Myalgia#	3	27JAN2021	2/2	2	Yes	NA	R (28JAN2021)	N/N	
	NERV	Headache/ Headache#	3	27JAN2021	2/2	2	Yes	NA/TC	R (28JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	16FEB2021	1/2	1	Yes	NA	R (17FEB2021)	N/N	
		Pyrexia/ Fever#	4	16FEB2021	1/2	1	Yes	NA	R (17FEB2021)	N/N	
	NERV	Headache/ Headache#	4	16FEB2021	1/2	1	Yes	NA	R (17FEB2021)	N/N	
16-55/ C4591001 1241 12412278	GENRL	Injection site erythema/ Injection site redness	1	16OCT2020	1/4	1	Yes	NA	R (19OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ Injection site pain	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site swelling/ Injection site swelling	1	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Pyrexia/ Fever	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	18OCT2020	3/1	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1241 12412279	GENRL	Injection site pain/ Injection site pain#	3	25JAN2021	1/3	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12412280	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
		Fatigue/ Prostration	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Injection site pain	2	06NOV2020	2/1	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412281	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412282	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412284	GENRL	Asthenia/ Asthenia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	23FEB2021	2/1	1	Yes		NA/TC	R (23FEB2021)	N/N
16-55/ C4591001 1241 12412285	GENRL	Injection site pain/ Injection site pain	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/Y
		Malaise/ Malaise	2	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/Y
	MUSC	Myalgia/ Myalgia	2	05NOV2020	1/2	1	Yes		NA/TC	R (06NOV2020)	N/Y
16-55/ C4591001 1241 12412288	INFEC	Syphilis/ Syphilis	1	23OCT2020	8/C	1	No	O	NA	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412290	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412291	GENRL	Asthenia/ Asthenia#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/1	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412293	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	2	Yes		NA	R (07NOV2020)	N/N
16-55/ C4591001 1241 12412294	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12412295	GENRL	Injection site pain/ Injection site pain	1	16OCT2020	1/4	2	Yes		NA	R (19OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412296	MUSC	Myalgia/ Myalgia	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	NERV	Headache/ Headache	2	06NOV2020	2/2	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1241 12412301		Injection site pain/ Injection site pain#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412303	NERV	Headache/ Headache#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA/TCN	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	2	Yes		NA/TC	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412304 16-55/ C4591001	NERV	Headache/ Headache#	3	03FEB2021	1/1	1	Yes		NA/TC	R (03FEB2021)	N/N
1241 12412306 16-55/ C4591001	GASTR	Nausea/ Nausea	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
1241 12412307	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
	NERV	Headache/ Headache	2	09NOV2020	1/1	1	Yes		NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 1241 12412312	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA/TCN	R (20OCT2020)	N/N
	EYE	Conjunctivitis allergic/ Allergic conjunctivitis	1	25OCT2020	7/3	1	No	O	NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412314	NERV	Headache/ Headache	2	09NOV2020	1/1	2	Yes		NA/TC	R (09NOV2020)	N/N
	GENRL	Injection site erythema/ Injection site hyperemia	2	10NOV2020	2/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Injection site pain/ Injection site burning	2	09NOV2020	1/7	2	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/7	2	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Headache/ Headache#	4	02MAR2021	2/3	1	Yes		NA	R (04MAR2021)	N/N
	NERV	Dizziness/ Dizziness#	4	04MAR2021	4/4	2	No	O	NA	R (07MAR2021)	N/N
	RENAL	Dysuria/ Difficulty urinating#	4	04MAR2021	4/4	2	No	O	NA	R (07MAR2021)	N/N
	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412317	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	02FEB2021	1/3	1	Yes		NA	R (04FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
		Pyrexia/ Fever#	4	23FEB2021	1/2	1	Yes		NA/TC	R (24FEB2021)	N/N
16-55/ C4591001 1241 12412320	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA/TCN	R (22OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412321	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412322	GENRL	Chills/ Chills	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412323	GENRL	Injection site pain/ Injection site pain#	3	03FEB2021	2/5	1	Yes		NA	R (07FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	24FEB2021	2/5	1	Yes		NA	R (28FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412324	GENRL	Chills/ Chills#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412330	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412333	MUSC	Arthralgia/ Polyarthralgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
		Myalgia/ Myalgia	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412334	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/4	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412336	NERV	Headache/ Headache	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412337	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412338	GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	1	Yes		NA	R (21OCT2020)	N/N
		Injection site pain/ Injection site pain	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	2/2	2	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412339	GENRL	Chills/ Chills	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
		Pyrexia/ Fever	1	20OCT2020	2/2	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412341	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	2/3	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412342	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412343	GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12412345	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12412346	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA	R (22OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Injection site pain/ Injection site pain	2	09NOV2020	1/4	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
		Dizziness/ Dizziness	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N
	Headache/ Headache	2	09NOV2020	1/3	2	Yes		NA/TC	R (11NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412347	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412348	GENRL	Injection site swelling/ Injection site swelling	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/3	1	Yes		NA	R (18NOV2020)	N/N
16-55/ C4591001 1241 12412351	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412352	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/2	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Prostration	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412353	GENRL	Chills/ Chills	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
		Fatigue/ Fatigue	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
		Pyrexia/ Fever	1	21OCT2020	3/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412354	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	1	Yes		NA	R (22OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Prostration	1	20OCT2020	2/2	2	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412355	GENRL	Fatigue/ Fatigue#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
		Pyrexia/ Fever#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1241 12412357	GENRL	Fatigue/ Fatigue#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412360	GENRL	Injection site pain/ Injection site pain#	4	25FEB2021	2/2	1	Yes		NA	R (26FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	08FEB2021	1/2	1	Yes		NA	R (09FEB2021)	N/Y
16-55/ C4591001 1241 12412361	GENRL	Injection site pain/ Injection site pain	1	19OCT2020	1/4	2	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Chills/ Chills	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		Fatigue/ Fatigue	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
		Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA/TC	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	2/1	1	Yes		NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412362	GENRL	Injection site erythema/ Injection site redness#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/Y
		Injection site swelling/ Injection site swelling#	3	27JAN2021	1/1	1	Yes		NA	R (27JAN2021)	N/Y
16-55/ C4591001 1241 12412363	NERV	Headache/ Headache	1	19OCT2020	1/2	1	Yes		NA/TC	R (20OCT2020)	N/Y

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412365	GENRL	Pyrexia/ Fever	1	19OCT2020	1/1	1	Yes		NA/TC	R (19OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412366	GENRL	Chills/ Chills#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	20FEB2021	2/1	1	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1241 12412367	GENRL	Fatigue/ Fatigue	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412368	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412369	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	21JAN2021	72/C		No	O	P	UNK	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12412370	GASTR	Diarrhoea/ Diarrhea	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412371	INV	Body temperature increased/ Subfebrile temperature	2	10NOV2020	2/1	1	Yes		NA	R (10NOV2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Fatigue/ Fatigue	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	10NOV2020	1/4	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412373	MUSC	Myalgia/ Myalgia	2	10NOV2020	1/2	2	Yes		NA/TC	R (11NOV2020)	N/N
	NERV	Presyncope/ Lipothymia (Presyncope)	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/3	1	Yes		NA/TC	R (24JAN2021)	N/N
16-55/ C4591001 1241 12412375	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	GENRL	Pyrexia/ Fever	1	20OCT2020	2/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412377	MUSC	Myalgia/ Myalgia	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	2	10NOV2020	2/2	1	Yes		NA	R (11NOV2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	2/1	2	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412378	GENRL	Fatigue/ Fatigue	2	09NOV2020	1/2	2	Yes		NA/TCN	R (10NOV2020)	N/N
		Injection site pain/ Injection site pain	2	09NOV2020	1/2	1	Yes		NA	R (10NOV2020)	N/N
16-55/ C4591001 1241 12412379	GENRL	Fatigue/ Fatigue#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
16-55/ C4591001 1241 12412380	GASTR	Nausea/ Nausea	1	20OCT2020	1/3	1	Yes		NA/TC	R (22OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	1/3	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Injection site pain/ Injection site pain	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412381	NERV	Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Headache/ Headache	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA/TCN	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412382	SKIN	Pityriasis rosea/ Pityriasis rosea	1	25OCT2020	6/23	2	Yes		NA/TC	R (16NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	15DEC2020	1/2	2	Yes		NA	R (16DEC2020)	N/N
16-55/ C4591001 1241 12412385	GENRL	Injection site pain/ Injection site pain#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	19FEB2021	2/3	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1241 12412387	GENRL	Fatigue/ Fatigue	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412389	MUSC	Myalgia/ Myalgia#	4	19FEB2021	2/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412390	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412391	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA	R (11NOV2020)	N/N
	GENRL	Chills/ Chills	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
		Fatigue/ Fatigue	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412392		Nausea/ Nausea	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412395	MUSC	Injection site pain/ Injection site pain	2	11NOV2020	2/3	1	Yes		NA	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
		Myalgia/ Myalgia	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	2/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412395	GENRL	Injection site pain/ Injection site pain#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412397	GASTR	Diarrhoea/ Diarrhea#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Pyrexia/ Fever#	3	26JAN2021	1/3	1	Yes		NA/TC	R (28JAN2021)	N/N
16-55/ C4591001 1241 12412398	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/5	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	11NOV2020	2/3	1	Yes		NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412399	GENRL	Fatigue/ Prostration	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412400	GENRL	Injection site pain/ Injection site pain#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412401	SKIN	Urticaria/ Chest region Urticaria	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
	NERV	Headache/ Headache#	3	10FEB2021	1/3	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1241 12412402	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412403	GENRL	Pain/ Body pain	2	11NOV2020	2/2	1	Yes		NA/TC	R (12NOV2020)	N/N
		Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412404	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Chills/ Chills	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
16-55/ C4591001 1241 12412405	MUSC	Injection site pain/ Injection site pain	2	10NOV2020	1/3	2	Yes		NA	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Myalgia/ Myalgia	2	10NOV2020	1/2	1	Yes		NA/TC	R (11NOV2020)	N/N
		Headache/ Headache	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412406	INJ&P	Rib fracture/ Fracture of two ribs on the right#	2	26FEB2021	109/1	2	No	O	NA/TC	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Road traffic accident/ Motor vehicle accident#	2	26FEB2021	109/1	2	No	O	NA	R (26FEB2021)	N/N
		Fatigue/ Fatigue	1	21OCT2020	2/2	1	Yes		NA	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412407	GENRL	Pyrexia/ Fever	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412409	METAB	Decreased appetite/ Hyporexia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	1	21OCT2020	2/1	1	Yes		NA	R (21OCT2020)	N/N
16-55/ C4591001 1241 12412410	GASTR	Nausea/ Nausea	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	NERV	Headache/ Headache	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 1241 12412411	NEOPL	Fibroadenoma of breast/ Right breast fibroadenoma	2	NOV2020	1/C	1	No	O	NA	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	NERV	Headache/ Headache#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
	INJ&P	Maternal exposure during pregnancy/	3	12FEB2021	5/C		No	O	P	UNK	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412413	GASTR	Maternal exposure during pregnancy# Vomiting/ Vomiting	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	10NOV2020	1/3	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412414	GENRL	Injection site pain/ Injection site pain	1	20OCT2020	1/2	1	Yes		NA	R (21OCT2020)	N/Y
	GENRL	Chills/ Chills	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
		Fatigue/ Fatigue	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain	2	11NOV2020	2/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412415	GENRL	Chills/ Chills	1	20OCT2020	1/1	1	Yes		NA	R (20OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	1/2	2	Yes		NA	R (06FEB2021)	N/N
	EYE	Keratitis/ Right eye keratitis#	3	22FEB2021	18/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	11FEB2021	3/1	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412416		Fatigue/ Prostration#	3	11FEB2021	3/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412424	GENRL	Fatigue/ Prostration	1	22OCT2020	2/1	1	Yes		NA	R (22OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	1/2	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412425	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
16-55/ C4591001 1241 12412426	NERV	Headache/ Headache	1	21OCT2020	1/2	1	Yes		NA	R (22OCT2020)	N/N
	NERV	Headache/ Headache	2	16NOV2020	1/2	2	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1241 12412427	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/3	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Prostration#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever	1	22OCT2020	2/1	1	Yes		NA/TC	R (22OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412429	GENRL	Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes	NA	R (12NOV2020)	N/N	
16-55/ C4591001 1241 12412430	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/2	1	Yes	NA	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12412432	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes	NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12412432	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/2	1	Yes	NA/TC	R (05FEB2021)	N/N	
16-55/ C4591001 1241 12412438	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes	NA	R (23OCT2020)	N/N	
16-55/ C4591001 1241 12412439	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/4	1	Yes	NA	R (25OCT2020)	N/N	
	NERV	Headache/ Headache	1	22OCT2020	1/4	1	Yes	NA	R (25OCT2020)	N/N	
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/4	1	Yes	NA/TC	R (15NOV2020)	N/N	
	NERV	Headache/ Headache	2	12NOV2020	2/4	1	Yes	NA/TC	R (15NOV2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes	NA	R (12NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412440	GASTR	Diarrhoea/ Diarrhea#	3	19FEB2021	2/2	1	Yes	NA	R	(20FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	19FEB2021	2/1	1	Yes	NA/TC	R	(19FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	19FEB2021	2/1	1	Yes	NA/TC	R	(19FEB2021)	N/N
16-55/ C4591001 1241 12412441	GENRL	Injection site pain/ Injection site pain#	3	23JAN2021	2/2	1	Yes	NA	R	(24JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	11FEB2021	2/3	1	Yes	NA/TC	R	(13FEB2021)	N/N
		Pyrexia/ Fever#	4	11FEB2021	2/3	1	Yes	NA/TC	R	(13FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/3	1	Yes	NA/TC	R	(13FEB2021)	N/N
16-55/ C4591001 1241 12412442	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes	NA	R	(23OCT2020)	N/N
	GENRL	Chills/ Chills	2	11NOV2020	1/3	2	Yes	NA/TC	R	(13NOV2020)	N/N
	NERV	Headache/ Headache	2	11NOV2020	1/3	2	Yes	NA/TC	R	(13NOV2020)	N/N
16-55/ C4591001 1241 12412443	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	2	Yes	NA/TC	R	(12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412444	GENRL	Pyrexia/ Fever	2	11NOV2020	1/2	2	Yes		NA/TC	R (12NOV2020)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412445	EYE	Eye irritation/ Eye burning	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
		Fatigue/ Fatigue	1	23OCT2020	2/2	2	Yes		NA	R (24OCT2020)	N/N
		Injection site pain/ Injection site pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N
		Pain/ Body pain	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/3	2	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	1	Yes		NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412448	MUSC	Myalgia/ Myalgia#	4	11FEB2021	2/1	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412449	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/2	2	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412450	NERV	Headache/ Headache	2	12NOV2020	2/5	1	Yes		NA	R (16NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/3	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/2	2	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412451	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/3	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412452	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	2	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412456	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA/TC	R (23OCT2020)	N/N
	GENRL	Pyrexia/ fever	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412457	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	05FEB2021	2/3	1	Yes		NA/TC	R (07FEB2021)	N/N
	NERV	Headache/ Headache#	3	05FEB2021	2/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412458	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	2/2	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1241 12412459	GENRL	Injection site pain/ Injection site pain#	3	05FEB2021	1/3	1	Yes		NA/TCN	R (07FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1241 12412460	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	2	Yes		NA	R (12NOV2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412461 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain#	3	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N
1241 12412462 16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	22OCT2020	1/2	1	Yes		NA	R (23OCT2020)	N/N
1241 12412463	GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Fatigue/ Fatigue	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Injection site pain/ Injection site pain	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412464	MUSC	Myalgia/ Myalgia#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1241 12412465	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412466	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412468	GENRL	Pyrexia/ Fever	2	12NOV2020	2/1	1	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412470	GENRL	Chills/ Chills	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
		Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412471	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412472	GENRL	Fatigue/ Fatigue	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
		Pyrexia/ Fever	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	2/3	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412475	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes		NA	R (11NOV2020)	N/Y
	GENRL	Injection site pain/ Injection site pain#	3	30JAN2021	2/2	2	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1241 12412477	NERV	Headache/ Headache	2	12NOV2020	2/11	2	Yes		NA	R (22NOV2020)	N/N
16-55/ C4591001 1241 12412478	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	2/5	2	Yes		NA	R (27OCT2020)	N/N
	GENRL	Chills/ Chills	1	24OCT2020	3/1	1	Yes		NA	R (24OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection site pain	2	16NOV2020	1/4	1	Yes		NA/TCN	R (19NOV2020)	N/N
16-55/ C4591001 1241 12412479	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412480	GENRL	Asthenia/ Asthenia	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	NERV	Headache/ Headache	1	23OCT2020	2/1	1	Yes		NA	R (23OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/3	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
		Pyrexia/ Fever	2	12NOV2020	2/1	2	Yes		NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1241 12412482	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412485	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache	1	23OCT2020	1/1	1	Yes		NA/TC	R (23OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412486	GASTR	Nausea/ Nausea	1	27OCT2020	5/1	1	Yes		NA	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412491	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/6	1	Yes		NA/TC	R (22FEB2021)	N/N
		Injection site swelling/ Injection site swelling#	4	17FEB2021	1/6	1	Yes		NA	R (22FEB2021)	N/N
	GENRL	Injection site erythema/ Injection site hyperemia#	4	18FEB2021	2/5	2	Yes		NA	R (22FEB2021)	N/N
		Injection site pruritus/ Injection site itching#	4	18FEB2021	2/5	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1241 12412494	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TC	R (24OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	12NOV2020	1/2	1	Yes		NA/TC	R (13NOV2020)	N/N
	NERV	Headache/ Headache	2	12NOV2020	1/6	1	Yes		NA/TC	R (17NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1241 12412495	INFEC	Nail infection/ Nail infection in the first left toe	2	20NOV2020	9/8	1	No	O	NA/TC	R (27NOV2020)	N/N	
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N	
		Pyrexia/ Fever#	4	18FEB2021	1/2	1	Yes		NA/TC	R (19FEB2021)	N/N	
16-55/ C4591001 1241 12412498	NERV	Headache/ Headache	1	24OCT2020	2/1	1	Yes		NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1241 12412501	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	
	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
		Pyrexia/ Fever	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N	
16-55/ C4591001 1241 12412505	NERV	Headache/ Headache	2	12NOV2020	1/3	1	Yes		NA	R (14NOV2020)	N/N	
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412507	GENRL	Chills/ Chills#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
		Fatigue/ Prostration#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	17FEB2021	1/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412509	GENRL	Chills/ Chills#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	NERV	Headache/ Headache#	3	29JAN2021	1/4	1	Yes		NA	R (01FEB2021)	N/N
	GASTR	Diarrhoea/ Diarrhea#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
	GENRL	Fatigue/ Prostration#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
		Pyrexia/ Fever#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/6	2	Yes		NA/TC	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412510	GASTR	Nausea/ Nausea	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412512	GASTR	Abdominal pain/ Abdominal pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
		Diarrhoea/ diarrhea	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GASTR	Abdominal pain/ Abdominal pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
		Diarrhoea/ Diarrhea	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001 1241 12412515	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Chills/ Chills	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Injection site pain/ Injection site pain	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412516	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
	GENRL	Injection site pruritus/ Injection site itching	2	16NOV2020	5/10	2	Yes		NA	R (25NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/1	2	Yes		NA/TCN	R (13NOV2020)	N/N
16-55/ C4591001 1241 12412517		Injection site pain/ Injection site pain	2	13NOV2020	2/3	2	Yes		NA/TCN	R (15NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/3	2	Yes		NA/TC	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/3	2	Yes		NA	R (14NOV2020)	N/N
	GENRL	Fatigue/ Prostration	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412518		Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412525	INJ&P	Ligament injury/ Injury to ligaments in the right ankle	1	06NOV2020	15/63	2	No	O	NA/TC/TCN	R (07JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412527	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/1	1	Yes		NA	R (18FEB2021)	N/N
	NERV	Headache/ Headache#	4	18FEB2021	2/1	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412528	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	1	Yes		NA	R (13NOV2020)	N/N
	GENRL	Chills/ Chills	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N
		Pyrexia/ Fever	1	24OCT2020	2/3	3	Yes		NA/TC	R (26OCT2020)	N/N
	NERV	Headache/ Headache	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
	VASC	Hypotension/ Hypotension	1	24OCT2020	2/6	3	Yes		NA/TC	R (29OCT2020)	N/N
GENRL	Chills/ Chills	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N	
	Injection site pain/ Injection site pain	2	12NOV2020	2/1	1	Yes		NA	R (12NOV2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412529	NERV	Pyrexia/ Fever	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
		Headache/ Headache	2	12NOV2020	2/3	2	Yes		NA/TC	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/4	2	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
	NERV	Somnolence/ Somnolence	1	24OCT2020	2/1	2	Yes		NA/TCN	R (24OCT2020)	N/N
16-55/ C4591001 1241 12412530	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	2/3	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
16-55/ C4591001 1241 12412535	GENRL	Pyrexia/ Fever#	3	04FEB2021	1/2	1	Yes		NA/TC	R (05FEB2021)	N/N
		Pyrexia/ Fever	2	13NOV2020	2/2	1	Yes		NA/TC	R (14NOV2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412537	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13NOV2020	2/2	2	Yes		NA/TC	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412539	GENRL	Injection site pain/ Injection site pain#	3	26JAN2021	1/2	1	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	2/2	1	Yes		NA	R (18FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1241 12412540	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/2	1	Yes		NA	R (12NOV2020)	N/N
	GENRL	Chills/ Chills#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	2/1	2	Yes		NA/TC	R (28JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	18FEB2021	2/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1241 12412543	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA/TCN	R (24OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412544	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/5	1	Yes		NA/TC	R (17NOV2020)	N/N
		Injection site pain/ Injection site pain	2	13NOV2020	2/5	1	Yes		NA/TC	R (17NOV2020)	N/N
16-55/ C4591001 1241 12412546	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	2	26DEC2020	45/C		No	O	NA	UNK	N/N
16-55/ C4591001 1241 12412548	GENRL	Fatigue/ Fatigue	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ Injection site pain	2	13NOV2020	2/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1241 12412549	GENRL	Pyrexia/ Fever#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	10FEB2021	1/2	2	Yes		NA/TC	R (11FEB2021)	N/N
16-55/ C4591001 1241 12412552	GENRL	Fatigue/ Fatigue	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
		Injection site pain/ Injection site pain	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412553	MUSC	Myalgia/ Myalgia	2	14NOV2020	2/2	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
		Injection site pain/ Injection site pain#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
		Pyrexia/ Fever#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
	MUSC	Myalgia/ Myalgia#	3	06FEB2021	2/3	1	Yes		NA	R (08FEB2021)	N/N
16-55/ C4591001 1241 12412554	GENRL	Fatigue/ Fatigue#	4	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
		Injection site pain/ Injection site pain#	4	01MAR2021	1/3	1	Yes		NA	R (03MAR2021)	N/N
	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/2	1	Yes		NA	R (24OCT2020)	N/N
	INJ&P	Fall/ Skates falling	2	22NOV2020	11/1	1	No	O	NA	R (22NOV2020)	N/N
		Joint injury/ Left knee trauma	2	22NOV2020	11/1	1	No	O	NA	R (22NOV2020)	N/N
16-55/ C4591001 1241 12412556	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12412557	GENRL	Pyrexia/ Fever	2	13NOV2020	2/1	2	Yes		NA/TC	R (13NOV2020)	N/N
		Fatigue/ Fatigue	1	24OCT2020	2/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1241 12412559	GENRL	Injection site pain/ Injection site pain#	3	04FEB2021	1/5	2	Yes		NA/TC	R (08FEB2021)	N/N
	GENRL	Chills/ Chills#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1241 12412560	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		Pyrexia/ Fever#	3	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N
		Myalgia/ Myalgia#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
		MUSC	Injection site pain/ Injection site pain#	4	19FEB2021	2/C	1	Yes		NA	N
16-55/ C4591001 1241 12412560	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/1	1	Yes		NA	R (19FEB2021)	N/N
		Injection site pain/ Injection site pain	1	24OCT2020	2/2	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001	INFEC	Pulmonary tuberculosis/ Pulmonary Tuberculosis	2	17NOV2020	6/C	1	No	O	NA/TC	RG	N/N
	GENRL	Injection site pain/ Injection site pain#	3	28JAN2021	2/1	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412561	GENRL	Fatigue/ Fatigue#	4	17FEB2021	1/2	1	Yes	NA	R (18FEB2021)	N/N	
		Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes	NA	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12412563	GENRL	Injection site pain/ Injection site pain#	3	27JAN2021	1/1	1	Yes	NA	R (27JAN2021)	N/N	
	GENRL	Injection site pain/ Injection site pain#	4	17FEB2021	1/2	1	Yes	NA/TC	R (18FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	18FEB2021	2/1	1	Yes	NA/TC	R (18FEB2021)	N/N	
16-55/ C4591001 1241 12412564	GENRL	Injection site pain/ Injection site pain	1	24OCT2020	2/1	1	Yes	NA/TC	R (24OCT2020)	N/N	
16-55/ C4591001 1241 12412565	GENRL	Injection site pain/ Injection site pain	2	11NOV2020	1/1	1	Yes	NA	R (11NOV2020)	N/Y	
	GENRL	Injection site pain/ Injection site pain#	3	09FEB2021	1/2	1	Yes	NA	R (10FEB2021)	N/N	
16-55/ C4591001 1241 12412566†	GENRL	Injection site erythema/ Injection site erythema#	3	22JAN2021	1/4	1	Yes	NA	R (25JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	11FEB2021	2/2	1	Yes	NA	R (12FEB2021)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1246 12461004	GENRL	Fatigue/ Prostration#	4	11FEB2021	2/2	1	Yes		NA/TC	R (12FEB2021)	N/N
16-55/ C4591001 1246 12461004	GENRL	Injection site pain/ Painful Left arm IP injection site.#	3	11FEB2021	1/3	2	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1246 12461008	MUSC	Muscle spasms/ Back Muscle Spasm	2	11NOV2020	27/17	2	No	O	NA/TC	R (27NOV2020)	N/N
16-55/ C4591001 1246 12461020	MUSC	Pain in extremity/ Painful Left Arm#	3	27FEB2021	1/3	1	Yes		NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1246 12461025	SKIN	Urticaria/ urticaria generalized	1	29SEP2020	2/4	3	Yes		NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 1246 12461026	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N
16-55/ C4591001 1246 12461026	INFEC	Sinusitis/ Sinusitis	2	27OCT2020	9/15	2	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 1246 12461028	MUSC	Pain in extremity/ Painful Left arm#	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Painful Left Arm injection site#	3	24FEB2021	1/3	1	Yes		NA/TC	R (26FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1246 12461030 16-55/ C4591001	GENRL	Injection site pain/ Pain in left arm injection site#	3	10FEB2021	1/5	1	Yes		NA/TC	R (14FEB2021)	N/N
1246 12461037 16-55/ C4591001	MUSC	Pain in extremity/ Painful Left Arm#	3	01MAR2021	1/3	1	Yes		NA/TC	R (03MAR2021)	N/N
1246 12461043 16-55/ C4591001	GENRL	Injection site pain/ Painful left arm at injection site#	3	11FEB2021	1/2	1	Yes		NA/TC	R (12FEB2021)	N/N
1246 12461045 16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	28OCT2020	7/6	1	No	O	NA	R (02NOV2020)	N/N
1246 12461050 16-55/ C4591001	RESP	Rhinitis allergic/ Worsening of Allergic Rhinitis	2	15NOV2020	25/7	2	No	O	NA/TC	R (21NOV2020)	N/N
1246 12461052 16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N
1246 12461060		Injection site pain/ Painful Right arm injection site.#	3	26FEB2021	1/3	1	Yes		NA/TC	R (28FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1246 12461070	INFEC	Urinary tract infection/ Urine tract Infection-pathogen unknown	2	15NOV2020	23/4	2	No	O	NA/TC	R (18NOV2020)	N/N	
	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N	
16-55/ C4591001 1246 12461072	GENRL	Malaise/ Malaise#	3	20FEB2021	2/4	2	Yes		NA	R (23FEB2021)	N/N	
		Pain/ Body pains (generalized)#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N	
		Pyrexia/ Low grade fever#	3	20FEB2021	2/4	2	Yes		NA/TC	R (23FEB2021)	N/N	
16-55/ C4591001 1246 12461078	GENRL	Injection site pain/ Painfull Left arm at injection site#	3	11FEB2021	1/5	1	Yes		NA	R (15FEB2021)	N/N	
	GENRL	Pyrexia/ Fever#	4	09MAR2021	6/3	2	Yes		NA/TC/TCN	R (11MAR2021)	N/N	
	GASTR	Stomatitis/ Stomatitis of mouth#	4	12MAR2021	9/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1246 12461082	GENRL	Injection site pain/ Painful Left Arm injection area#	3	11FEB2021	1/2	1	Yes		NA	R (12FEB2021)	N/N	
16-55/ C4591001 1246 12461084	GENRL	Injection site pain/ Painful left arm injection site.#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1246 12461087	GENRL	Injection site pain/ Painful left arm injection site#	3	16FEB2021	1/3	1	Yes		NA	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	09MAR2021	1/3	2	Yes		NA/TC	R (11MAR2021)	N/N
		Pyrexia/ Fever#	4	09MAR2021	1/3	2	Yes		NA/TC	R (11MAR2021)	N/N
	GASTR	Stomatitis/ Stomatitis mouth#	4	12MAR2021	4/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1246 12461088	GASTR	Constipation/ Constipation	1	08OCT2020	3/20	2	No	O	NA/TC	R (27OCT2020)	N/N
	GENRL	Injection site pain/ Painful left arm at injection side#	3	16FEB2021	1/4	2	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1246 12461092	GENRL	Injection site pain/ Painful left arm injection site#	3	12FEB2021	1/3	1	Yes		NA/TC	R (14FEB2021)	N/N
16-55/ C4591001 1246 12461094	GENRL	Injection site pain/ Painful left arm at injection side#	3	12FEB2021	1/4	2	Yes		NA/TC	R (15FEB2021)	N/N
16-55/ C4591001 1246 12461104	GENRL	Injection site pain/ Painful Left arm at injection side#	3	15FEB2021	1/4	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Painful left arm at injection site#	3	16FEB2021	1/4	1	Yes		NA/TC	R (19FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1246 12461114 16-55/ C4591001 1246 12461115	GENRL	Injection site pain/ Painful left arm injection site#	3	15FEB2021	1/2	1	Yes		NA/TC	R (16FEB2021)	N/N
1246 12461116	GASTR	Irritable bowel syndrome/ Irritable bowel syndrome#	3	05MAR2021	19/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1246 12461116	GENRL	Injection site pain/ Painful left arm at injection site#	3	16FEB2021	1/4	1	Yes		NA/TC	R (19FEB2021)	N/N
16-55/ C4591001 1246 12461117	INFEC	Tinea versicolour/ Pityriasis Versicolor on thorax	2	16NOV2020	20/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1246 12461119	GENRL	Injection site pain/ Painful Left Arm injection site.#	3	27FEB2021	1/3	1	Yes		NA/TC	R (01MAR2021)	N/N
16-55/ C4591001 1246 12461131	REPRO	Endometriosis/ Worsening of Endometriosis left ovary	2	06JAN2021	68/15	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N
16-55/ C4591001 1246 12461136	MUSC	Pain in extremity/ Painful Left Arm#	3	27FEB2021	1/2	1	Yes		NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 1246 12461136	GENRL	Injection site pain/ Painful Left Arm injection side#	3	15FEB2021	1/4	1	Yes		NA/TC	R (18FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1246 12461139	GENRL	Injection site pain/ Painful left Arm injection side#	3	15FEB2021	1/8	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1247 12471016	INFEC	Vaginal infection/ Vaginitis	1	12OCT2020	19/11	2	No	O	NA	R (22OCT2020)	N/N
16-55/ C4591001 1247 12471019	INFEC	Tinea versicolour/ Tinea Versicolor (upper limbs)	2	28OCT2020	14/C	2	No	O	NA	RG	N/N
16-55/ C4591001 1247 12471040	INFEC	Blister infected/ Infected Fever Blister	2	10NOV2020	27/3	2	No	O	NA/TC	R (12NOV2020)	N/N
16-55/ C4591001 1247 12471053	INFEC	Nasopharyngitis/ Common cold	1	08OCT2020	14/3	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1247 12471058	INFEC	Otitis media/ Otitis Media Right Ear	2	20JAN2021	98/4	2	No	O	NA/TC	R (23JAN2021)	N/N
16-55/ C4591001 1247 12471089	RESP	Allergic sinusitis/ Allergic Sinusitis	1	01OCT2020	3/5	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001	INFEC	Escherichia urinary tract infection/ Acute E.coli UTI	1	18OCT2020	20/8	2	No	O	NA/TC	R (25OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1247 12471092 16-55/ C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1247 12471137	MUSC	Road traffic accident/ Motorcycle accident Back pain/ Worsening back pain	2	30OCT2020	10/1	2	No	O	NA	R (30OCT2020)	N/N
16-55/ C4591001 1247 12471142	INFEC	Intervertebral disc protrusion/ Worsening pain related to L5/S1 and L4/L5 disc protrusion Escherichia urinary tract infection/ Uncomplicated E.coli urinary tract infection	2	09NOV2020	20/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1247 12471147	VASC	Hypertension/ Exacerbation of hypertension	1	12OCT2020	12/15	1	No	O	NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 1247 12471168	GENRL	Chest pain/ Chest pain	1	13OCT2020	13/10	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001	BLOOD	Lymphadenopathy/ Left axilla Lymphadenopathy	2	12NOV2020	18/2	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C4591001			2	27OCT2020	2/9	1	Yes		NA	R (04NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1247 12471172 16-55/ C4591001 1247 12471181	GENRL	Injection site pain/ Local injection site pain#	3	05FEB2021	2/1	1	Yes		NA	R (05FEB2021)	N/N
1247 12471181	GENRL	Malaise/ Malaise#	4	26FEB2021	2/1	1	Yes		NA	R (26FEB2021)	N/N
16-55/ C4591001 1247 12471183	GENRL	Injection site pain/ Injection site pain	1	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site swelling/ Injection site swelling	1	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	27OCT2020	1/2	2	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	28OCT2020	2/2	1	Yes		NA	R (29OCT2020)	N/N
		Fatigue/ Fatigue	2	28OCT2020	2/1	2	Yes		NA	R (28OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29OCT2020	3/2	1	Yes		NA	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	2	29OCT2020	3/2	1	Yes		NA	R (30OCT2020)	N/N
	NERV	Headache/ Headache	2	29OCT2020	3/2	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1247 12471184	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	2	Yes		NA	R (14OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471185	MUSC	Injection site pain/ Local injection site pain	1	06OCT2020	1/3	2	Yes		NA	R (08OCT2020)	N/N
		Myalgia/ Muscle pain-general	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	27OCT2020	1/3	1	Yes		NA	R (29OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/9	1	Yes		NA	R (14OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ Headache	1	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Injection site pain/ Injection site pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
		Myalgia/ Muscle Pain	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ Injection pain	1	08OCT2020	3/2	1	Yes		NA	R (09OCT2020)	N/N
GENRL	Pyrexia/ Fever	2	27OCT2020	1/3	2	Yes		NA	R (29OCT2020)	N/N	
16-55/ C4591001 1247 12471186	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471193	NERV	Headache/ Headache	1	06OCT2020	1/4	1	Yes		NA	R (09OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	4/2	2	Yes		NA	R (10OCT2020)	N/N
	NERV	Headache/ Headache	1	06OCT2020	1/2	1	Yes		NA	R (07OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	07OCT2020	2/4	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Chills/ Chills	1	10OCT2020	5/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1247 12471196	MUSC	Arthralgia/ Joint pain	1	10OCT2020	5/2	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Injection site pain/ Local injection pain	1	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
	GASTR	Nausea/ Nausea	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ Headache	1	08OCT2020	3/5	1	Yes		NA	R (12OCT2020)	N/N
	MUSC	Arthralgia/ Joint pain	1	10OCT2020	5/5	2	Yes		NA	R (14OCT2020)	N/N
MUSC	Myalgia/ Muscle pain Generalised	1	11OCT2020	6/4	1	Yes		NA	R (14OCT2020)	N/N	
GASTR	Nausea/ Nausea	2	28OCT2020	2/3	1	Yes		NA	R (30OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471197	GENRL	Fatigue/ Fatigue	1	07OCT2020	2/7	2	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ Headache	1	07OCT2020	2/2	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1247 12471199	GENRL	Fatigue/ Fatigue	1	06OCT2020	1/1	2	Yes		NA	R (06OCT2020)	N/N
		Injection site erythema/ Injection site redness	1	06OCT2020	1/2	3	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Injection site pain	1	06OCT2020	1/2	2	Yes		NA	R (07OCT2020)	N/N
		Injection site swelling/ Injection site swelling	1	06OCT2020	1/1	3	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1247 12471201	NERV	Headache/ Headache	1	10OCT2020	4/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1247 12471203	NERV	Headache/ Headache	1	12OCT2020	6/3	1	Yes		NA	R (14OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	13OCT2020	7/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	28OCT2020	1/2	2	Yes		NA/TC	R (29OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471205	VASC	Hypertension/ newly diagnosed hypertension (permanent)	2	24NOV2020	28/C	1	No	O	NA/TC/TCN	N	N/N
	GASTR	Diarrhoea/ Diarrhea	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
	INJ&P	Injection site pain/ Local injection site pain	1	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1247 12471209	INJ&P	Stab wound/ Left arm stab	1	17OCT2020	11/16	1	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	07OCT2020	1/2	2	Yes		NA	R (08OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	28OCT2020	1/4	2	Yes		NA/TC	R (31OCT2020)	N/N
16-55/ C4591001 1247 12471215	NERV	Headache/ Headache	2	28OCT2020	1/11	2	Yes		NA/TC	R (07NOV2020)	N/N
	INFEC	Nasopharyngitis/ Common Cold*		07OCT2020	-5/3	1	No	O	NA	R (09OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1247 12471220	GENRL	Fatigue/ Fatigue	1	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N
		Injection site pain/ Injection Pain	1	13OCT2020	6/2	1	Yes		NA	R (14OCT2020)	N/N
	BLOOD	Lymphadenopathy/ Left axillary lymphadenopathy	2	29OCT2020	2/5	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Arthralgia/ Generalized Joint pain	2	29OCT2020	2/1	2	Yes		NA	R (29OCT2020)	N/N
	NERV	Headache/ Headaches	2	29OCT2020	2/1	2	Yes		NA/TC	R (29OCT2020)	N/N
	MUSC	Arthralgia/ Generalized Joint pain	2	30OCT2020	3/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1247 12471222	GENRL	Chills/ Chills	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
		Injection site pain/ Injection site pain	1	08OCT2020	1/4	1	Yes		NA	R (11OCT2020)	N/N
	MUSC	Myalgia/ New muscle pain (general)	1	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Chills/ Chills	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
	MUSC	Myalgia/ Muscle pains generalized	2	30OCT2020	1/3	2	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	30OCT2020	1/4	2	Yes		NA/TC	R (02NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471223	GENRL	Injection site pain/ Local injection site pain	2	30OCT2020	1/3	1	Yes		NA	R (01NOV2020)	N/N
	NERV	Headache/ Headache	2	30OCT2020	1/3	1	Yes		NA	R (01NOV2020)	N/N
	PSYCH	Irritability/ Irritable mood	2	30OCT2020	1/1	1	No	O	NA	R (30OCT2020)	N/N
	GENRL	Oedema peripheral/ Bilateral ankle edema	2	04NOV2020	6/23	2	No	O	NA	R (26NOV2020)	N/N
	SKIN	Urticaria/ Urticarial rash (upper body and bilateral arms)#	4	03MAR2021	3/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 1247 12471226	PSYCH	Depression/ Severe depressive episode	2	04FEB2021	98/5	2	No	O	NA	R (08FEB2021)	Y/N
16-55/ C4591001 1247 12471232	NERV	Headache/ Headache	1	08OCT2020	1/2	2	Yes		NA/TC	R (09OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	30OCT2020	2/4	1	Yes		NA	R (02NOV2020)	N/N
	NERV	Headache/ Headache	2	30OCT2020	2/4	1	Yes		NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 1247 12471236	NERV	Headache/ Headache	1	09OCT2020	2/2	1	Yes		NA	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1247 12471240	GENRL	Injection site pain/ Injection Pain	1	09OCT2020	2/3	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001 1247 12471244	NERV	Facial paralysis/ Recurrence of Left Bells Palsy Left facial hemipareses#	3	11FEB2021	9/C	2	Yes		NA/TC	RG	N/N
16-55/ C4591001 1247 12471245	GENRL	Injection site pain/ Local Injection site pain	2	30OCT2020	1/3	1	Yes		NA	R (01NOV2020)	N/N
16-55/ C4591001 1247 12471258	GENRL	Injection site pain/ Local injection site pain	2	30OCT2020	1/4	1	Yes		NA	R (02NOV2020)	N/N
	MUSC	Myalgia/ Muscle pains (generalised)	2	30OCT2020	1/4	2	Yes		NA	R (02NOV2020)	N/N
16-55/ C4591001 1248 12481001	GENRL	Chills/ Chills	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ Fever	2	18SEP2020	2/1	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1248 12481004	GENRL	Fatigue/ fatigue#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Pain/ body aches#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481005	EYE	Pyrexia/ mild fever#	3	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Photophobia/ Light Sensitivity (Eyes)	1	29AUG2020	4/5	1	Yes		NA	R (02SEP2020)	N/N
	INFEC	Ear infection/ Right Ear Infection	1	29AUG2020	4/1	2	No	O	NA/TC	R (29AUG2020)	N/N
16-55/ C4591001 1248 12481012	EAR	Vertigo/ Vertigo	1	30AUG2020	5/4	1	No	O	NA	R (02SEP2020)	N/N
	INJ&P	Foot fracture/ Right Foot Fracture	2	28SEP2020	12/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1248 12481017	GENRL	Injection site pain/ Local Soreness at Injection Site Left Arm	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
16-55/ C4591001 1248 12481019	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1248 12481023	GASTR	Pyrexia/ Fever	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Diarrhoea/ Diarrhea	1	30AUG2020	3/1	1	No	O	NA	R (30AUG2020)	N/N
	RESP	Cough/ Cough	1	01SEP2020	5/4	1	Yes		NA/TC	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481024	SKIN	Hyperhidrosis/ Sweats	1	01SEP2020	5/4	1	Yes		NA	R (04SEP2020)	N/N
	RESP	Sputum discoloured/ Green Phlegm	2	06JAN2021	111/34	1	No	O	NA	R (08FEB2021)	N/N
16-55/ C4591001 1248 12481038	GENRL	Injection site pain/ Left Arm Pain Injection Site	1	30AUG2020	1/4	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Reaction Pain*		31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
16-55/ C4591001 1248 12481056	GENRL	Chest pain/ Chest Pain	1	12SEP2020	12/2	1	No	O	NA	R (13SEP2020)	N/N
16-55/ C4591001 1248 12481061	NERV	Dizziness/ Light-headedness	1	02SEP2020	1/1	1	Yes		NA	R (02SEP2020)	N/Y
16-55/ C4591001 1248 12481065	GASTR	Abdominal pain upper/ Stomachache	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
		Diarrhoea/ Diarrhea	1	07SEP2020	4/3	1	No	O	NA	R (09SEP2020)	N/N
	INFEC	Tooth abscess/ Abscess (tooth)	2	07OCT2020	14/7	2	No	O	NA/TC/TCN	R (13OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481068	GENRL	Fatigue/ Tiredness	1	05SEP2020	1/3	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1248 12481075	GENRL	Fatigue/ Mild Fatigue	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
	MUSC	Myalgia/ Generalized Mild Muscle Aches	1	05SEP2020	1/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1248 12481076	GENRL	Influenza like illness/ Flu Like Symptoms	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001 1248 12481077	GENRL	Injection site pain/ Pain Injection Site	1	05SEP2020	1/2	2	Yes		NA	R (06SEP2020)	N/N
	GENRL	Pyrexia/ Fever	1	06SEP2020	2/2	2	Yes		NA	R (07SEP2020)	N/N
	MUSC	Myalgia/ Muscle Ache	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ Headache Mild	1	06SEP2020	2/1	2	Yes		NA	R (06SEP2020)	N/N
16-55/ C4591001 1248 12481081	GENRL	Injection site pain/ Injection site Reaction (Pain)	1	06SEP2020	2/2	1	Yes		NA	R (07SEP2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle soreness#	4	09FEB2021	1/2	1	Yes		NA	R (10FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1248 12481086 16-55/ C4591001	NERV	Headache/ Headache	1	20SEP2020	13/5	1	No	O	NA	R (24SEP2020)	N/N
1248 12481098 16-55/ C4591001	GENRL	Chills/ Chills#	3	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
1248 12481099 16-55/ C4591001	GENRL	Pyrexia/ Fever Temperature (Unknown Temperature)	1	08SEP2020	1/3	2	Yes		NA	R (10SEP2020)	N/N
1248 12481103 16-55/ C4591001	INJ&P	Procedural pain/ Tooth Ache (after root canal procedure)	1	01OCT2020	20/7	1	No	O	NA	R (07OCT2020)	N/N
1248 12481123 16-55/ C4591001	GENRL	Chills/ Chills	1	12SEP2020	1/1	1	Yes		NA	R (12SEP2020)	N/N
1248 12481131	GASTR	Diarrhoea/ Diarrhea	1	17SEP2020	6/1	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	3	09JAN2021	2/2	1	Yes		NA	R (10JAN2021)	N/N
16-55/ C4591001 1248 12481145	GENRL	Injection site pain/ Injection site Reaction (mild pain right upper arm)	1	13SEP2020	1/3	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481146	GENRL	Injection site pain/ Injection Site Pain	1	14SEP2020	2/3	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1248 12481158	GENRL	Injection site pain/ Injection Site Reaction Pain	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	NERV	Lethargy/ Lethargy	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1248 12481159	GENRL	Chills/ Chills	1	16SEP2020	3/15	1	Yes		NA	R (30SEP2020)	N/N
		Fatigue/ Fatigue	1	16SEP2020	3/21	2	Yes		NA	R (06OCT2020)	N/N
16-55/ C4591001 1248 12481170	GENRL	Pain/ Body Aches#	4	06FEB2021	2/1	2	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1248 12481176	GENRL	Pain/ Body Aches	1	19SEP2020	5/2	2	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	19SEP2020	5/2	3	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1248 12481187	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/3	2	Yes		NA	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	2/1	2	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1248 12481188	GENRL	Injection site pain/ Injection Site Reaction Pain	1	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1248 12481193	GENRL	Influenza like illness/ Flu-Like Symptoms	1	18SEP2020	2/2	2	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1248 12481194	MUSC	Myalgia/ Muscle Aches	1	17SEP2020	1/17	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1248 12481195	GENRL	Exercise tolerance decreased/ Mild Decrease in Exercise Tolerance	1	17SEP2020	1/21	1	Yes		NA	R (07OCT2020)	N/N
16-55/ C4591001 1248 12481200	NERV	Dizziness/ dizziness	1	07OCT2020	21/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1248 12481204	GENRL	Chills/ chills#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Fatigue/ fatigue#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481205	NERV	Pain/ body aches#	4	10FEB2021	2/2	1	Yes		NA	R (11FEB2021)	N/N
		Headache/ headache#	4	10FEB2021	2/1	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Fatigue/ Tiredness	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
	MUSC	Pain in extremity/ Left Arm Pain	1	19SEP2020	2/3	2	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001 1248 12481210	GENRL	Fatigue/ fatigue#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
	MUSC	Injection site pain/ Injection site soreness#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
		Myalgia/ muscle aches#	4	01FEB2021	1/4	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1248 12481212	GASTR	Nausea/ Nausea	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Chills/ Chills	2	08OCT2020	2/2	1	Yes		NA/TC	R (09OCT2020)	N/N
	PSYCH	Disorientation/ disoriented	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1248 12481213	SKIN	Rash/ Skin Rash on Face and Abdomen	1	20SEP2020	3/5	1	No	O	NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1248 12481215	GENRL	Chills/ chills#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
		Pain/ body aches#	4	09FEB2021	1/1	1	Yes		NA	R (09FEB2021)	N/N
16-55/ C4591001 1248 12481218	GASTR	Vomiting/ Vomiting*		20SEP2020	/2	1	No	O	NA/TCN	R (21SEP2020)	N/N
	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N
16-55/ C4591001 1251 12511003	GASTR	Diarrhoea/ Diarrhea#	3	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1251 12511013	GENRL	Pain/ Body Aches	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ Headache	2	09SEP2020	1/3	1	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1251 12511031	METAB	Diabetes mellitus inadequate control/ worsening diabetes type 11#	4	25FEB2021	14/C	4	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1251 12511033	NERV	Idiopathic intracranial hypertension/ Pseudotumor Cerebri	2	JAN2021	114/C	3	No	O	NA/TC	N	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1251 12511046	GENRL	Injection site pain/ upper left arm pain at injection site	1	14SEP2020	22/18	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1251 12511058	INFEC	Otitis externa/ swimmers ear Left	1	08SEP2020	14/5	1	No	O	NA/TC	R (12SEP2020)	N/N
16-55/ C4591001 1251 12511060	RESP	Nasal congestion/ Nasal Congestion	1	02SEP2020	8/3	1	Yes		NA	R (04SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ exposure during pregnancy subjects wife is pregnant	2	JAN2021	108/C	1	No	O	NA	N	N/N
16-55/ C4591001 1251 12511068	GASTR	Vomiting/ Vomiting	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Chills/ Chills	2	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/N
	INJ&P	Foot fracture/ Jones Fracture#	2	11FEB2021	149/29	3	No	O	NA/TC/TCN	R (11MAR2021)	N/N
16-55/ C4591001 1251 12511081	RESP	Sinus congestion/ sinus congestion	1	30SEP2020	31/44	1	No	O	NA/TC	R (12NOV2020)	N/N
		Wheezing/ Wheezing	1	30SEP2020	31/44	1	No	O	NA/TC	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1251 12511082	GENRL	Chills/ chills	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
	INJ&P	Contusion/ head contusion	2	09DEC2020	80/C	1	No	O	NA	RG	N/N
		Muscle strain/ cervical strain	2	09DEC2020	80/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1251 12511093	GASTR	Diarrhoea/ Diarrhea	1	05SEP2020	5/1	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1251 12511124	NERV	Headache/ headache intermittent	2	12OCT2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1251 12511127	MUSC	Plantar fasciitis/ Plantar Fasciitis	2	09OCT2020	11/C	1	No	O	NA	N	N/N
16-55/ C4591001 1251 12511131	REPRO	Ovarian cyst/ ovarian cyst	1	10SEP2020	3/C	2	No	O	NA	N	N/N
16-55/ C4591001 1251 12511141	GENRL	Chills/ Chills	2	30SEP2020	1/1	1	Yes		NA/TC	R (30SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Right deltoid pain at injection site#	4	13MAR2021	2/C	1	Yes		NA	N	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1251 12511147 16-55/ C4591001	GENRL	Injection site pain/ Pain at Injection Site Left Deltoid	2	30SEP2020	1/11	1	Yes		NA	R (10OCT2020)	N/N
1251 12511155 16-55/ C4591001	GENRL	Chills/ Chills	2	07OCT2020	1/1	1	Yes		NA	R (07OCT2020)	N/N
1251 12511161		Pyrexia/ Fever	2	07OCT2020	1/3	1	Yes		NA/TC	R (09OCT2020)	N/N
16-55/ C4591001	MUSC	Myalgia/ Muscle Aches (Body)	2	07OCT2020	2/2	1	Yes		NA/TC	R (08OCT2020)	N/N
1251 12511171 16-55/ C4591001	GENRL	Pain/ body aches	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
1251 12511191		Pyrexia/ fever of 101.4	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ Fever greater than 100.4 (101.8)	2	15OCT2020	2/1	2	Yes		NA/TC	R (15OCT2020)	N/N
1251 12511218 16-55/ C4591001	GENRL	Injection site pain/ Muscle Pain at Injection Site	1	30SEP2020	2/4	1	Yes		NA	R (03OCT2020)	N/N
1251 12511221											

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ Intermittent Muscle Pain Left Deltoid	2	19OCT2020	1/38	1	Yes		NA	R (25NOV2020)	N/N
16-55/ C4591001 1251 12511223	MUSC	Muscle discomfort/ Intermittent Muscle Discomfort Right Upper Arm	1	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/Y
16-55/ C4591001 1251 12511232	GENRL	Pain/ Body Aches	2	28OCT2020	1/1	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1251 12511233	GENRL	Fatigue/ fatigue	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
	RESP	Nasal congestion/ nasal congestion	1	10OCT2020	4/5	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1251 12511239	CARD	Myocardial ischaemia/ Myocardial ischemia	2	13NOV2020	12/4	4	No	O	NA/TC	R (16NOV2020)	Y/N
16-55/ C4591001 1251 12511245	GENRL	Injection site pain/ pain at injection site left arm	1	15OCT2020	1/4	1	Yes		NA/TC	R (18OCT2020)	N/N
	GENRL	Pain/ Bodyaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
		Pyrexia/ Fever	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headaches	2	04NOV2020	2/2	1	Yes		NA/TC	R (05NOV2020)	N/N
	SKIN	Hidradenitis/ Hidradenitis Suppurative	2	01DEC2020	29/C	3	No	O	NA/TC	N	N/N
16-55/ C4591001 1251 12511259	SKIN	Pruritus/ itching-left arm	2	16DEC2020	29/7	1	No	O	NA	RS (22DEC2020)	N/N
	SKIN	Urticaria/ welts-left arm#	2	17DEC2020	30/6	1	No	O	NA	R (22DEC2020)	N/N
16-55/ C4591001 1251 12511262	NERV	Seizure/ seizure	2	15DEC2020	29/1	3	No	O	NA/TC	R (15DEC2020)	N/N
	NERV	Dizziness/ moderate dizziness	2	18DEC2020	32/1	1	No	O	NA/TCN	R (18DEC2020)	N/N
16-55/ C4591001 1254 12541003	GENRL	Injection site pain/ Soreness at injection site#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1254 12541005	GENRL	Injection site pain/ Soreness at the injection site	1	26AUG2020	1/3	1	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001 1254 12541008	MUSC	Myalgia/ generalized Muscle Aches	1	27AUG2020	2/2	2	Yes		NA	R (28AUG2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection Site Soreness#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541020	MUSC	Myalgia/ Muscle aches#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541027	GENRL	Injection site pain/ PAIN AT INJECTION SITE	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
16-55/ C4591001 1254 12541030	GENRL	Injection site pain/ INJECTION SITE PAIN	1	29AUG2020	1/2	1	Yes		NA	R (30AUG2020)	N/N
	GASTR	Diarrhoea/ DIARRHEA	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Chills/ CHILLS	2	19SEP2020	1/2	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ FATIGUE	2	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Pain/ BODYACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
	NERV	Headache/ HEADACHE	2	20SEP2020	2/2	1	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1254 12541031	GENRL	Chills/ chills#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Injection site pain/ soreness at injection site#	3	08JAN2021	2/2	1	Yes		NA	R (09JAN2021)	N/N
		Pain/ body aches#	3	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541032	GENRL	Injection site pain/ Injection Site Soreness#	4	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Pain/ Body ache#	4	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	03FEB2021	1/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1254 12541033	GENRL	Injection site pain/ Soreness at injection site#	4	25FEB2021	2/3	1	Yes		NA	R (27FEB2021)	N/N
	NERV	Headache/ headache	1	30AUG2020	2/2	2	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001 1254 12541034	GENRL	Pyrexia/ FEVER TEMPERATURE AT 101.5F	2	20SEP2020	2/1	1	Yes		NA/TC	R (20SEP2020)	N/N
	GENRL	Chills/ Chills#	4	21JAN2021	2/1	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	21JAN2021	2/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection#	4	21JAN2021	2/3	1	Yes		NA	R (23JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541035	GENRL	Pyrexia/ FEVER OF 100.9F	1	30AUG2020	2/1	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1254 12541036	GENRL	Injection site pain/ Soreness at the Injection Site#	3	30JAN2021	1/3	2	Yes		NA	R (01FEB2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	20FEB2021	1/3	1	Yes		NA	R (22FEB2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	21FEB2021	2/2	1	Yes		NA	R (22FEB2021)	N/N
16-55/ C4591001 1254 12541038	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Chills/ CHILLS	2	20SEP2020	2/1	1	Yes		NA	R (20SEP2020)	N/N
		Injection site pain/ pain at injection site	2	20SEP2020	2/3	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1254 12541039	GENRL	Fatigue/ fatigue	1	03SEP2020	6/3	2	No	O	NA	R (05SEP2020)	N/N
	RESP	Pulmonary pain/ lungs burning sensation	1	12SEP2020	15/1	1	No	O	NA	R (12SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Body temperature increased/ Elevated temperature of 99.8F	2	21SEP2020	3/2	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ Pain at Injection Site#	3	28JAN2021	1/3	1	Yes		NA	R (30JAN2021)	N/N
	INV	Body temperature increased/ Elevated temperature of 99.9F#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541040	MUSC	Myalgia/ generalized muscle soreness	1	30AUG2020	2/2	1	Yes		NA	R (31AUG2020)	N/N
16-55/ C4591001 1254 12541041	GENRL	Injection site pain/ Injection Site Soreness#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1254 12541042	GENRL	Injection site pain/ Soreness at Injection Site#	3	20DEC2020	2/2	1	Yes		NA	R (21DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	07JAN2021	1/2	2	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Soreness at Injection Site#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ Myalgia#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1254 12541049	GENRL	Injection site pain/ soreness at injection site#	3	23JAN2021	1/4	1	Yes		NA	R (26JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Injection Site Soreness#	4	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
	GENRL	Chills/ Chills#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
		Pyrexia/ Fever of 100.5F#	4	14FEB2021	2/1	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1254 12541050	GENRL	Fatigue/ Fatigue#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
		Injection site pain/ Soreness at Injection Site#	3	12JAN2021	1/3	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	02FEB2021	1/31	2	Yes		NA	R (04MAR2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
		Pyrexia/ Fever of 100.5F#	4	02FEB2021	1/3	2	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1254 12541051	GENRL	Pyrexia/ fever of 100.5F	2	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1254 12541052	GENRL	Injection site pain/ Injection site soreness#	3	03FEB2021	1/4	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1254 12541053	GENRL	Fatigue/ fatigue	1	31AUG2020	1/3	2	Yes		NA	R (02SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541054	GENRL	Injection site pain/ Left arm injection site soreness	1	31AUG2020	1/4	1	Yes		NA	R (03SEP2020)	N/N
		Injection site pain/ pain at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
	METAB	Pain/ bodyache	2	24SEP2020	2/3	2	Yes		NA/TC	R (26SEP2020)	N/N
		Decreased appetite/ loss of appetite	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
		Fatigue/ Fatigue#	3	10FEB2021	1/4	2	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1254 12541056	GENRL	Injection site pain/ Injection Site Soreness#	3	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
		Pyrexia/ Fever of 101.9F#	3	11FEB2021	2/3	2	Yes		NA/TC	R (13FEB2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GASTR	Nausea/ nausea	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Dizziness/ lightheadedness	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Headache/ headache	2	21SEP2020	1/3	1	Yes		NA/TC	R (23SEP2020)	N/N
		Pyrexia/ fever of 102F	2	22SEP2020	2/1	2	Yes		NA/TC	R (22SEP2020)	N/N
		Pyrexia/ fever of 104.9	2	22SEP2020	2/1	3	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1254 12541057	RESP	Cough/ Cough	1	10SEP2020	11/1	1	No	O	NA	R (10SEP2020)	N/N
16-55/ C4591001 1254 12541058	GENRL	Injection site pain/ Site Injection Soreness#	3	26JAN2021	1/2	2	Yes		NA/TC	R (27JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	17FEB2021	2/2	1	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001 1254 12541061	GENRL	Injection site pain/ Injection Site Soreness#	3	26JAN2021	1/2	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1254 12541062	MUSC	Musculoskeletal chest pain/ Rib cage pain	1	06SEP2020	6/9	2	Yes		NA	R (14SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1254 12541063	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541064	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/4	1	Yes		NA/TC	R (25SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Pain/ bodyache	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Soreness of Injection Site#	3	20DEC2020	2/1	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	07JAN2021	1/3	1	Yes		NA	R (09JAN2021)	N/N
	GENRL	Chills/ Intermittent Chills#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	08JAN2021	2/2	2	Yes		NA	R (09JAN2021)	N/N
	GENRL	Pain/ Body ache#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	NERV	Headache/ Headache#	4	08JAN2021	2/2	2	Yes		NA/TC	R (09JAN2021)	N/N
	16-55/ C4591001 1254 12541066	NERV	Somnolence/ drowsiness	1	09SEP2020	8/10	2	No	O	NA	R (18SEP2020)
	VASC	Hot flush/ worsening hot flashes	1	09SEP2020	8/C	1	No	O	NA	RG	N/N
	GENRL	Fatigue/ Fatigue#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541067	GENRL	Injection site pain/ Injection Site Soreness#	4	16FEB2021	1/2	1	Yes		NA	R (17FEB2021)	N/N
		Injection site pain/ injection site pain	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
	GASTR	Nausea/ nausea	1	03SEP2020	2/1	1	No	O	NA	R (03SEP2020)	N/N
16-55/ C4591001 1254 12541068	GENRL	Injection site pain/ Injection Site Soreness	2	24SEP2020	2/3	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ muscle pain at injection site	1	02SEP2020	1/3	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1254 12541069	GENRL	Injection site pain/ Injection Site Arm Soreness#	3	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
	GENRL	Chills/ Chills#	4	03MAR2021	1/2	2	Yes		NA	R (04MAR2021)	N/N
	INV	Injection site pain/ Injection Site Soreness#	4	03MAR2021	1/3	2	Yes		NA	R (05MAR2021)	N/N
Body temperature increased/ Elevated Body Temperature#		4	04MAR2021	2/1	2	Yes		NA	R (04MAR2021)	N/N	
16-55/ C4591001 1254 12541071	NERV	Headache/ Moderate Headache#	4	04MAR2021	2/2	2	Yes		NA	R (05MAR2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Soreness at injection site#	3	31JAN2021	2/3	1	Yes		NA	R (02FEB2021)	N/N
		Fatigue/ Fatigue#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
	NERV	Injection site pain/ Soreness at injection site#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
		Headache/ Headache#	4	20FEB2021	1/5	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1254 12541072	GENRL	Injection site pain/ INJECTION SITE PAIN	1	03SEP2020	2/3	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Pain in extremity/ RIGHT ARM SORENESS	1	02SEP2020	1/2	1	Yes		NA	R (03SEP2020)	N/N
	METAB	Type 2 diabetes mellitus/ worsening of diabetes mellitus type 2	1	11SEP2020	10/68	2	No	O	NA/TC	R (17NOV2020)	N/N
	GENRL	Injection site pain/ soreness pf injection site	2	22SEP2020	2/3	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Pyrexia/ fever of 100.4F	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
		Back pain/ low back pain	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
	16-55/ C4591001	GENRL	Injection site pain/ Site Injection Soreness#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541075	GENRL	Injection site pain/ Site Injection Soreness#	4	12JAN2021	1/3	1	Yes	NA	R	(14JAN2021)	N/N
16-55/ C4591001 1254 12541077	GENRL	Pain/ body aches generalized	1	03SEP2020	2/2	1	Yes	NA	R	(04SEP2020)	N/N
	GENRL	Chills/ chills	2	24SEP2020	2/2	1	Yes	NA	R	(25SEP2020)	N/N
		Fatigue/ fatigue	2	24SEP2020	2/2	1	Yes	NA	R	(25SEP2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	2	24SEP2020	2/2	1	Yes	NA	R	(25SEP2020)	N/N
	NERV	Headache/ headache	2	24SEP2020	2/2	1	Yes	NA	R	(25SEP2020)	N/N
16-55/ C4591001 1254 12541079	GENRL	Injection site pain/ Soreness at Injection Site#	3	29DEC2020	1/1	1	Yes	NA	R	(29DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	1/2	1	Yes	NA	R	(21JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	20JAN2021	1/3	2	Yes	NA/TC	R	(22JAN2021)	N/N
16-55/ C4591001 1254 12541080	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	1	Yes	NA	R	(05SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	25SEP2020	2/7	1	Yes	NA	R	(01OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1254 12541081	GENRL	Pyrexia/ fever 100.4F	2	25SEP2020	2/1	2	Yes		NA/TC	R (25SEP2020)	N/N	
		Injection site erythema/ REDNESS AT INJECTION SITE	2	28SEP2020	5/2	1	Yes		NA	R (29SEP2020)	N/N	
		Injection site pruritus/ ITCHY AT INJECTION SITE	2	28SEP2020	5/2	1	Yes		NA	R (29SEP2020)	N/N	
	GENRL	Injection site pain/ injection site pain	1	03SEP2020	1/3	2	Yes		NA	R (05SEP2020)	N/N	
	16-55/ C4591001 1254 12541082	GENRL	Injection site pain/ Soreness at injection site#	3	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
		GENRL	Injection site pain/ Soreness at Injection Site#	4	09FEB2021	1/30	1	Yes		NA	R (10MAR2021)	N/N
		NERV	Headache/ Mild Headache#	4	10FEB2021	2/1	2	Yes		NA	R (10FEB2021)	N/N
	16-55/ C4591001 1254 12541083	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
		INV	Body temperature increased/ ELEVATED BODY TEMPERATURE 99.6F/36.6C	1	04SEP2020	2/2	1	Yes		NA	R (05SEP2020)	N/N
	16-55/ C4591001 1254 12541086	GENRL	Injection site pain/ Injection site pain	1	04SEP2020	2/4	1	Yes		NA	R (07SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/2	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1254 12541087	GENRL	Injection site pain/ LEFT ARM SORENESS AT INJECTION SITE	1	03SEP2020	1/5	1	Yes		NA	R (07SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1254 12541089	GENRL	Injection site pain/ Injection site soreness#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541090	GASTR	Diarrhoea/ diarrhea	1	05SEP2020	2/1	1	Yes		NA	R (05SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	2/1	2	Yes		NA	R (20FEB2021)	N/N
		Fatigue/ Fatigue#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
	INV	Body temperature increased/ Elevated body temperature of 99.9F#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001	NERV	Headache/ Headache#	3	29JAN2021	1/1	1	Yes		NA	R (29JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541091	GENRL	Fatigue/ Fatigue#	4	20FEB2021	1/3	1	Yes	NA	R (22FEB2021)	N/N	
16-55/ C4591001 1254 12541094	EYE	Eye irritation/ mild burning sensation in both eyes	1	04SEP2020	1/2	1	Yes	NA	R (05SEP2020)	N/N	
	GENRL	Injection site pain/ Injection site tenderness	1	04SEP2020	1/3	1	Yes	NA	R (06SEP2020)	N/N	
		Pain/ Body ache	1	04SEP2020	1/3	1	Yes	NA	R (06SEP2020)	N/N	
	NERV	Headache/ headache	1	04SEP2020	1/3	1	Yes	NA/TC	R (06SEP2020)	N/N	
	GENRL	Chills/ chills	2	27SEP2020	2/1	1	Yes	NA	R (27SEP2020)	N/N	
		Pain/ bodyache	2	27SEP2020	2/2	2	Yes	NA/TC	R (28SEP2020)	N/N	
		Pyrexia/ Fever at 100.4F	2	27SEP2020	2/1	2	Yes	NA/TC	R (27SEP2020)	N/N	
	NERV	Headache/ headache	2	27SEP2020	2/2	1	Yes	NA	R (28SEP2020)	N/N	
16-55/ C4591001 1254 12541099	GENRL	Injection site pain/ left arm injection site soreness	1	04SEP2020	1/4	1	Yes	NA	R (07SEP2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	05SEP2020	2/2	1	Yes	NA	R (06SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Weight increased/ WEIGHT GAIN	1	10SEP2020	7/	1	No	O	NA/TC	R	N/N
	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	1	Yes		NA	R (28SEP2020)	N/N
	GENRL	Chills/ chills	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ fatigue	2	26SEP2020	2/1	1	Yes		NA	R (26SEP2020)	N/N
		Pain/ bodyache	2	26SEP2020	2/1	1	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1254 12541100	GENRL	Injection site pain/ Injection Site Soreness#	2	27JAN2021	125/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	2	28JAN2021	126/2	1	Yes		NA	R (29JAN2021)	N/N
16-55/ C4591001 1254 12541101	GENRL	Fatigue/ Fatigue#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
		Injection site pain/ Injection site soreness#	3	28JAN2021	2/4	2	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1254 12541102	PSYCH	Insomnia/ Insomnia	1	14SEP2020	10/2	2	No	O	NA	R (15SEP2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	09JAN2021	1/1	1	Yes		NA	R (09JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541104		Injection site pain/ Soreness at Injection Site#	4	09JAN2021	1/3	2	Yes		NA	R (11JAN2021)	N/N
		Pyrexia/ Fever of 101F#	4	09JAN2021	1/2	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	10JAN2021	2/3	2	Yes		NA	R (12JAN2021)	N/N
		Pain/ Body Ache#	4	10JAN2021	2/2	2	Yes		NA	R (11JAN2021)	N/N
16-55/ C4591001 1254 12541105	GENRL	Chills/ CHILLS	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
		Pain/ bodyache	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
16-55/ C4591001 1254 12541107	GENRL	Injection site pain/ Soreness at injection site	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	PSYCH	Depression/ worsening of depression	2	OCT2020	3/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1254 12541109	GENRL	Injection site pain/ Soreness at injection site#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	BLOOD	Lymphadenopathy/ Bilateral swollen lymph nodes#	4	21FEB2021	2/2	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site bruising/ Injection Site Bruising#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541110		Injection site pain/ Injection Site Soreness#	3	29JAN2021	2/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20FEB2021	2/1	1	Yes		NA	R (20FEB2021)	N/N
	INV	Body temperature increased/ Elevated body temperature of 99.7F#	4	20FEB2021	2/1	2	Yes		NA/TC	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541111	GENRL	Chills/ chills	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ generalized body ache	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1254 12541114	INJ&P	Limb injury/ Finger Puncture Injury	1	17SEP2020	10/1	1	No	O	NA/TC	R (17SEP2020)	N/N
	GENRL	Injection site pain/ Soreness of Injection Site#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	13JAN2021	1/1	2	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ Headache#	4	13JAN2021	1/2	2	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	2/2	2	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ pain at injection site	2	30SEP2020	1/17	2	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541115	RESP	Productive cough/ INCREASED PHELM	1	14SEP2020	5/45	1	Yes		NA	R (28OCT2020)	N/N
16-55/ C4591001 1254 12541117	INFEC	Chlamydial infection/ Chlamydia infection	2	21DEC2020	83/8	2	No	O	NA/TC	R (28DEC2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	25JAN2021	3/6	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
		Pain/ Body ache#	4	18FEB2021	2/4	2	Yes		NA	R (21FEB2021)	N/N
	INFEC	Chlamydial infection/ Chlamydia Infection#	4	13MAR2021	25/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1254 12541119	GASTR	Abdominal distension/ abdominal bloating	1	10SEP2020	1/4	1	Yes		NA	R (13SEP2020)	N/N
		Diarrhoea/ diarrhea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Nausea/ nausea	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Headache/ headache	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541120	GENRL	Injection site pain/ LEFT ARM INJECTION SITE SORENESS	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1254 12541121	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/Y
	GENRL	Fatigue/ MILD FATIGUE	1	11SEP2020	2/3	1	Yes		NA	R (13SEP2020)	N/N
16-55/ C4591001 1254 12541123	GENRL	Fatigue/ Fatigue#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Soreness at the Injection Site#	3	27JAN2021	2/2	1	Yes		NA	R (28JAN2021)	N/N
		Pain/ Body ache#	3	27JAN2021	2/2	1	Yes		NA/TC	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	4	16FEB2021	1/3	2	Yes		NA/TC	R (18FEB2021)	N/N
	GENRL	Chills/ Chills#	4	17FEB2021	2/1	1	Yes		NA	R (17FEB2021)	N/N
		Pain/ Generalized Body Ache#	4	17FEB2021	2/1	2	Yes		NA/TC	R (17FEB2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature of 100.0F#	4	17FEB2021	2/2	2	Yes		NA/TC	R (18FEB2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	1/2	2	Yes		NA/TC	R (20SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541124	GENRL	Fatigue/ fatigue	1	20SEP2020	2/1	2	Yes		NA	R (20SEP2020)	N/N
	MUSC	Myalgia/ muscle bodyaches	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	2/1	2	Yes		NA/TC	R (20SEP2020)	N/N
	MUSC	Pain in extremity/ pain right index finger	1	27SEP2020	9/2	1	No	O	NA	R (28SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	10OCT2020	1/3	2	Yes		NA/TC	R (12OCT2020)	N/N
	GENRL	Chills/ chills	2	11OCT2020	2/1	1	Yes		NA	R (11OCT2020)	N/N
		Pain/ body aches	2	11OCT2020	2/1	2	Yes		NA/TC	R (11OCT2020)	N/N
	INV	Heart rate increased/ elevated heart rate	2	11OCT2020	2/8	2	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	11OCT2020	2/2	2	Yes		NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 1254 12541126	GENRL	Injection site pain/ injection site pain	1	11SEP2020	1/3	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Injection site pain/ tenderness at injection site	2	02OCT2020	1/3	1	Yes		NA	R (04OCT2020)	N/N
	NERV	Somnolence/ drowsiness	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541131	GENRL	Injection site pain/ Injection Site Soreness#	3	17FEB2021	1/2	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1254 12541133	GENRL	Injection site pain/ Injection Site Pain#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
16-55/ C4591001 1254 12541134	GENRL	Chills/ chills	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	SKIN	Hyperhidrosis/ SWEATING	1	11SEP2020	1/4	2	Yes		NA	R (14SEP2020)	N/N
	GASTR	Nausea/ NAUSEA	1	14SEP2020	4/2	1	Yes		NA	R (15SEP2020)	N/N
	SKIN	Hyperhidrosis/ sweating	2	02OCT2020	1/15	2	Yes		NA	R (16OCT2020)	N/N
	GASTR	Nausea/ nausea	2	03OCT2020	2/3	2	Yes		NA	R (05OCT2020)	N/N
	GENRL	Chills/ chills	2	04OCT2020	3/13	1	Yes		NA	R (16OCT2020)	N/N
	GENRL	Injection site pain/ Injection site soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541135	NERV	Headache/ Headache	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GASTR	Nausea/ nausea	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Lethargy/ Lethargy	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GASTR	Abdominal pain upper/ stomach pain	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
		Nausea/ nausea	2	03OCT2020	2/1	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	3	29JAN2021	1/6	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
		Pain/ Body ache#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
	GENRL	Chills/ Chills#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
	GENRL	Pain/ Body aches#	4	20FEB2021	2/3	2	Yes		NA	R (22FEB2021)	N/N
	NERV	Headache/ Headaches#	4	20FEB2021	2/2	2	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541140	GENRL	Injection site pain/ injection site pain	1	12SEP2020	1/15	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site erythema/ erythema at injection site	1	13SEP2020	2/14	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541142	EYE	Eye irritation/ left eye irritation	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N
		Ocular hyperaemia/ left eye redness	1	12SEP2020	1/3	1	No	O	NA	R (14SEP2020)	N/N
	GENRL	Chills/ intermittent chills	1	12SEP2020	1/14	1	Yes		NA	R (25SEP2020)	N/N
	INJ&P	Maternal exposure during pregnancy/ Maternal Exposure During Pregnancy	1	12SEP2020	1/C		No	O	P	UNK	N/N
	INV	Body temperature increased/ elevated body temperature at 100.0F	1	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Pyrexia/ fever at 102.0F	1	14SEP2020	3/1	2	Yes		NA/TC	R (14SEP2020)	N/N
	INV	Body temperature increased/ elevated body temperature at 100.0F	1	14SEP2020	3/2	2	Yes		NA/TC	R (15SEP2020)	N/N
	GASTR	Abdominal pain upper/ stomach pain	1	15SEP2020	4/1	2	No	O	NA/TC	R (15SEP2020)	N/N
	NERV	Headache/ headache intermittent	1	15SEP2020	4/11	2	Yes		NA/TC	R (25SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	26SEP2020	15/C	1	No	O	NA	RG	N/N
	INV	Weight decreased/ weight loss	1	OCT2020	20/C	1	No	O	NA	N	N/N
	SKIN	Alopecia/ hair loss	1	OCT2020	20/C	1	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541144	GASTR	Nausea/ worsening of Nausea	1	12SEP2020	1/3	1	Yes		NA	R (14SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	1/6	1	Yes		NA	R (17SEP2020)	N/N
		Injection site pain/ Injection Site Tenderness	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	1/5	1	Yes		NA	R (07OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	03OCT2020	1/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Pyrexia/ fever 100.6F	2	04OCT2020	2/3	1	Yes		NA/TC	R (06OCT2020)	N/N
	GASTR	Diarrhoea/ diarrhea	2	06OCT2020	4/1	3	Yes		NA/TC	R (06OCT2020)	N/N
		Vomiting/ vomiting	2	06OCT2020	4/1	2	Yes		NA/TC	R (06OCT2020)	N/N
	RESP	Pharyngeal swelling/ Throat Swollen Internal	2	22JAN2021	112/1	2	No	O	NA/TC	R (22JAN2021)	N/N
16-55/ C4591001 1254 12541145	GENRL	Injection site pain/ Injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N
	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	22SEP2020	11/C		No	O	NA	UNK	N/N
16-55/ C4591001 1254 12541147	GENRL	Injection site pain/ injection site pain	1	12SEP2020	1/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541148	GENRL	Injection site pain/ Injection Site Soreness#	3	29JAN2021	1/2	1	Yes		NA	R (30JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	21FEB2021	2/1	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Fatigue/ fatigue	1	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
	REPRO	Premenstrual syndrome/ worsening of premenstrual syndrome symptoms	1	14SEP2020	3/4	1	Yes		NA	R (17SEP2020)	N/N
	PSYCH	Insomnia/ Worsening of Insomnia	2	15DEC2020	74/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1254 12541150	GENRL	Injection site pain/ Injection Site Soreness#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
	INFEC	Chlamydial infection/ Chlamydia infection	2	05JAN2021	92/9	2	No	O	NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1254 12541151		Gonorrhoea/ Gonorrhea	2	05JAN2021	92/9	2	No	O	NA/TC	R (13JAN2021)	N/N
	NERV	Headache/ headache	1	14SEP2020	1/1	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Injection site pain/ INJECTION SITE PAIN	1	15SEP2020	2/3	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541152		Pain/ body ache	1	15SEP2020	2/2	1	Yes		NA	R (16SEP2020)	N/N
	GENRL	Pain/ body aches	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1254 12541153	GENRL	Fatigue/ FATIGUE	1	16SEP2020	3/25	2	Yes		NA	R (10OCT2020)	N/N
	PSYCH	Irritability/ IRRITABILITY	1	16SEP2020	3/42	2	No	O	NA	R (27OCT2020)	N/N
16-55/ C4591001 1254 12541155	GENRL	Injection site pain/ Injection site pain	1	16SEP2020	1/1	1	Yes		NA	R (16SEP2020)	N/Y
	GENRL	Injection site pain/ Injection Site Soreness#	3	16JAN2021	1/2	1	Yes		NA	R (17JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	05FEB2021	1/3	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1254 12541157	GENRL	Injection site pain/ Injection Site Soreness#	3	13FEB2021	1/3	1	Yes		NA	R (15FEB2021)	N/N
16-55/ C4591001 1254 12541158	GENRL	Injection site pain/ Injection site Soreness#	3	30DEC2020	2/2	1	Yes		NA	R (31DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541159	GENRL	Chills/ Chills#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
		Injection site pain/ Injection Site Soreness#	4	20JAN2021	1/2	1	Yes		NA	R (21JAN2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site	1	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ bodyache	1	17SEP2020	2/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	07OCT2020	1/3	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	08OCT2020	2/2	1	Yes		NA	R (09OCT2020)	N/N
	INV	Body temperature increased/ elevated body temperature of 99.9F	2	08OCT2020	2/1	1	Yes		NA	R (08OCT2020)	N/N
	SKIN	Pruritus/ generalized itching	1	20SEP2020	3/53	1	No	O	NA	R (11NOV2020)	N/N
	16-55/ C4591001 1254 12541162	GENRL	Fatigue/ fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)
16-55/ C4591001 1254 12541163		Injection site pain/ injection site soreness	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Pain at the Injection Site#	3	20DEC2020	2/2	1	Yes		NA	R (21DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541164	GENRL	Injection site pain/ Pain at the Injection Site#	4	07JAN2021	1/2	1	Yes		NA	R (08JAN2021)	N/N
16-55/ C4591001 1254 12541165	GENRL	Injection site pain/ injection site pain	1	19SEP2020	1/4	1	Yes		NA	R (22SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	11OCT2020	2/2	1	Yes		NA	R (12OCT2020)	N/N
	NERV	Headache/ headache	2	11OCT2020	2/1	1	Yes		NA/TC	R (11OCT2020)	N/N
16-55/ C4591001 1254 12541166	GENRL	Injection site pain/ Injection site pain	1	19SEP2020	1/3	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	10OCT2020	1/4	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1254 12541168†	INFEC	Abscess limb/ abscess left thigh	2	28OCT2020	14/10	2	No	O	NA/TC	R (06NOV2020)	N/N
16-55/ C4591001 1254 12541169	MUSC	Back pain/ back pain	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N
	NERV	Headache/ headache	1	25SEP2020	2/5	2	Yes		NA/TC	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Alopecia/ Hair Loss	1	01OCT2020	8/125	1	No	O	NA	R (02FEB2021)	N/N
	GENRL	Chills/ chills	2	15OCT2020	1/2	1	Yes		NA	R (16OCT2020)	N/N
		Fatigue/ fatigue	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
		Injection site swelling/ swelling at injection site	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
	RESP	Rhinorrhoea/ runny nose	2	15OCT2020	1/3	1	Yes		NA	R (17OCT2020)	N/N
	GENRL	Injection site swelling/ Left Arm Swelling at Injection Site.#	3	28JAN2021	2/4	2	Yes		NA/TC	R (31JAN2021)	N/N
		Pain/ Body aches#	3	28JAN2021	2/3	2	Yes		NA	R (30JAN2021)	N/N
	GENRL	Chills/ Chills#	3	29JAN2021	3/2	2	Yes		NA	R (30JAN2021)	N/N
	GASTR	Gastritis/ Gastritis#	4	20FEB2021	2/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1254 12541170	GENRL	Injection site pain/ left injection site pain	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N
		Injection site pain/ SORENESS AT INJECTION SITE	2	14OCT2020	1/3	1	Yes		NA	R (16OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541172	GENRL	Injection site pain/ Site Injection Soreness#	3	30JAN2021	2/2	1	Yes		NA	R (31JAN2021)	N/N
16-55/ C4591001 1254 12541173	GENRL	Injection site pain/ injection site soreness	1	23SEP2020	1/5	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Chills/ chills	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
		Pyrexia/ fever at 100.6F	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle ache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 1254 12541174	GENRL	Injection site pain/ Injection Site Pain#	3	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
	GENRL	Pyrexia/ Fever of 101.0F#	3	25FEB2021	2/1	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1254 12541175	GENRL	Injection site pain/ Injection Site Soreness#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
16-55/ C4591001 1254 12541176	GENRL	Injection site pain/ INJECTION SITE SORENESS LEFT ARM	1	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ HEADACHE	1	24SEP2020	2/4	1	Yes		NA/TC	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1254 12541177	GENRL	Injection site pain/ soreness at injection site	2	15OCT2020	1/4	2	Yes		NA/TC	R (18OCT2020)	N/N	
	GENRL	Fatigue/ fatigue	2	16OCT2020	2/2	2	Yes		NA	R (17OCT2020)	N/N	
	NERV	Headache/ headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N	
	GENRL	Fatigue/ FATIGUE	1	23SEP2020	1/4	1	Yes		NA	R (26SEP2020)	N/N	
	GENRL	Chills/ CHILLS	1	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N	
	16-55/ C4591001 1254 12541179	GENRL	Fatigue/ Fatigue#	3	08JAN2021	2/1	1	Yes		NA	R (08JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	3	08JAN2021	2/3	1	Yes		NA	R (10JAN2021)	N/N	
	GENRL	Injection site pain/ Soreness at Injection Site#	4	30JAN2021	1/2	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Chills/ Chills#	4	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N	
	GENRL	Fatigue/ Fatigue#	4	31JAN2021	2/1	1	Yes		NA	R (31JAN2021)	N/N	
16-55/ C4591001 1254 12541180	GENRL	Injection site pain/ pain at injection site	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	
		Pain/ bodyache	1	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ fatigue	2	17OCT2020	2/3	2	Yes		NA	R (19OCT2020)	N/N
	MUSC	Myalgia/ generalized muscle pain	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	GASTR	Aphthous ulcer/ canker sore	2	18OCT2020	3/13	2	Yes		NA	R (30OCT2020)	N/N
16-55/ C4591001 1254 12541181	GENRL	Injection site pain/ Injection site soreness	1	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection Site#	3	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Injection site pain/ Soreness at Injection Site#	4	11FEB2021	2/2	1	Yes		NA	R (12FEB2021)	N/N
	INV	Body temperature increased/ Elevated Body Temperature of 100F#	4	11FEB2021	2/2	2	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1254 12541182	GENRL	Injection site pain/ INJECTION SITE SORENESS	1	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1254 12541184	GENRL	Injection site pain/ Injection site soreness#	3	28FEB2021	2/1	1	Yes		NA	R (28FEB2021)	N/N
16-55/ C4591001	EYE	Vitreous floaters/ vision changes eye floaters right eye	1	17OCT2020	4/20	1	No	O	NA	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1254 12541185	NERV	Headache/ headache	1	18OCT2020	5/17	2	No	O	NA	R (03NOV2020)	N/N
	GASTR	Abdominal pain lower/ right lower quadrant pain	1	02NOV2020	20/5	1	No	O	NA	R (06NOV2020)	N/N
	GENRL	Injection site pain/ Left Arm Sore at Injection Site#	3	22JAN2021	2/6	2	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1254 12541187	GENRL	Fatigue/ fatigue	1	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
16-55/ C4591001 1254 12541188	NERV	Headache/ intermittent headaches	2	05NOV2020	1/4	1	Yes		NA	R (08NOV2020)	N/N
	GENRL	Fatigue/ fatigue	2	06NOV2020	2/3	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1254 12541189	GENRL	Injection site pain/ Soreness at the Injection Site#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	18FEB2021	2/7	2	Yes		NA/TC	R (24FEB2021)	N/N
		Pain/ bodyaches#	4	18FEB2021	2/3	2	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541193		Pyrexia/ fever of 100.7F#	4	18FEB2021	2/2	2	Yes		NA	R (19FEB2021)	N/N
	MUSC	Arthralgia/ generalized joint pain#	4	18FEB2021	2/7	2	Yes		NA/TC	R (24FEB2021)	N/N
	NERV	Headache/ headache#	4	18FEB2021	2/2	2	Yes		NA/TC/W	R (19FEB2021)	N/N
16-55/ C4591001 1254 12541193	GENRL	Injection site pain/ soreness of injection site	2	07NOV2020	1/2	1	Yes		NA	R (08NOV2020)	N/N
16-55/ C4591001 1254 12541194	NERV	Headache/ mild headache	1	17OCT2020	1/3	1	Yes		NA	R (19OCT2020)	N/N
	GENRL	Fatigue/ fatigue	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
	PSYCH	Anxiety/ worsening of anxiety	1	18OCT2020	2/2	1	Yes		NA	R (19OCT2020)	N/N
	SKIN	Pruritus/ body itch	1	18OCT2020	2/2	1	No	O	NA/TCN	R (19OCT2020)	N/N
	GENRL	Fatigue/ Fatigue#	2	28JAN2021	84/2	1	Yes		NA	R (29JAN2021)	N/N
		Injection site pain/ Soreness at injection site#	3	28JAN2021	1/2	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site soreness#	4	19FEB2021	1/2	1	Yes		NA	R (20FEB2021)	N/N
16-55/ C4591001 1254 12541199	GENRL	Injection site pain/ pain at injection site	1	21OCT2020	1/18	1	Yes		NA	R (07NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1254 12541201	NERV	Headache/ headache	1	21OCT2020	1/18	1	Yes		NA/TC	R (07NOV2020)	N/N
	MUSC	Myalgia/ generalized muscle aches	1	23OCT2020	3/16	1	Yes		NA	R (07NOV2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	02DEC2020	2/2	1	Yes		NA	R (03DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	22OCT2020	2/2	1	Yes		NA	R (23OCT2020)	N/N
16-55/ C4591001 1254 12541202	GENRL	Injection site pain/ Soreness of injection site	2	12NOV2020	1/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 1254 12541202	GENRL	Injection site pain/ injection site soreness	1	24OCT2020	1/3	1	Yes		NA	R (26OCT2020)	N/N
16-55/ C4591001 1254 12541204	METAB	Hyperlipidaemia/ worsening hyperlipidemia	1	26OCT2020	3/C	2	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Soreness of Injection Site	2	14NOV2020	1/2	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Fatigue/ Fatigue	2	15NOV2020	2/1	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Pain/ Body Aches	2	15NOV2020	2/1	1	Yes		NA/TC	R (15NOV2020)	N/N
	GENRL	Pyrexia/ Fever of 100.5 F	2	15NOV2020	2/1	1	Yes		NA	R (15NOV2020)	N/N
	GENRL	Injection site erythema/ redness at injection site	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ pain at injection site	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N
	MUSC	Myalgia/ bilateral sore neck muscles	2	14NOV2020	1/2	1	No	O	NA	R (15NOV2020)	N/N
	NERV	Headache/ headache	2	14NOV2020	1/1	1	Yes		NA	R (14NOV2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness#	3	02FEB2021	1/2	1	Yes		NA	R (03FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	23FEB2021	1/3	1	Yes		NA	R (25FEB2021)	N/N
		Pyrexia/ Fever 100.4F#	4	23FEB2021	1/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Soreness at injection site#	4	24FEB2021	2/4	2	Yes		NA/TC	R (27FEB2021)	N/N
16-55/ C4591001 1254 12541208	GENRL	Pain/ Body Aches#	4	10FEB2021	1/3	1	Yes		NA	R (12FEB2021)	N/N
16-55/ C4591001 1254 12541211	GENRL	Injection site pain/ Injection site soreness#	3	30JAN2021	1/3	1	Yes		NA	R (01FEB2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	31JAN2021	2/2	1	Yes		NA	R (01FEB2021)	N/N
	GASTR	Nausea/ Nausea#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N
	GENRL	Chills/ Chills#	4	20FEB2021	1/2	1	Yes		NA	R (21FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1258 12581004	MUSC	Myalgia/ Muscle aches#	4	20FEB2021	1/2	2	Yes		NA/TC	R (21FEB2021)	N/N
	GASTR	Nausea/ nausea#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Chills/ chills#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
16-55/ C4591001 1258 12581016	GENRL	Pyrexia/ Fever#	4	23FEB2021	2/2	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Fatigue/ fatigue	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 1258 12581044		Malaise/ Malaise	2	03OCT2020	10/6	1	No	O	NA	R (08OCT2020)	N/N
	INFEC	Otitis media/ right otitis media	1	30SEP2020	7/7	1	No	O	NA/TC	R (06OCT2020)	N/N
16-55/ C4591001 1258 12581046	INFEC	Otitis media/ right otitis media	1	08OCT2020	11/5	1	No	O	NA/TC	R (12OCT2020)	N/N
	RESP	Cough/ cough	1	08OCT2020	11/3	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1260 12601002	GASTR	Vomiting/ vomiting	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601004	GENRL	Fatigue/ fatigue	1	27AUG2020	2/5	1	Yes		NA	R (31AUG2020)	N/N
		Injection site pain/ soreness at the injection site	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Migraine without aura/ increased intensity of migraine without aura	1	27AUG2020	2/1	2	Yes		NA/TC	R (27AUG2020)	N/N
	GENRL	Fatigue/ fatigue	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	16SEP2020	2/3	2	Yes		NA	R (18SEP2020)	N/N
		Pain/ generalized body aches	2	16SEP2020	2/3	2	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	26AUG2020	1/7	2	Yes		NA	R (01SEP2020)	N/N
	MUSC	Myalgia/ muscle pain	1	31AUG2020	6/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
		Malaise/ MALAISE	2	05OCT2020	19/2	1	No	O	NA	R (06OCT2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	08JAN2021	1/3	1	Yes		NA	R (10JAN2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	MUSC	Myalgia/ general muscle aches#	4	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601005	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
		Pain/ generalized body aches	2	17SEP2020	2/2	2	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1260 12601006	GENRL	Injection site pain/ Soreness at injection site	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	MUSC	Arthralgia/ Left hand joint pain	1	27AUG2020	2/2	1	Yes		NA/TC	R (28AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	16SEP2020	1/6	1	Yes		NA/TC	R (21SEP2020)	N/N
16-55/ C4591001 1260 12601007	MUSC	Arthralgia/ joint pain left wrist/hand	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
	NERV	Headache/ headache	1	27AUG2020	2/2	1	Yes		NA	R (28AUG2020)	N/N
	GASTR	Constipation/ constipation	2	15OCT2020	31/8	1	No	O	NA/TC/TCN	R (22OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	29DEC2020	1/2	1	Yes		NA	R (30DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
		Injection site pain/ soreness at the injection site#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601009	NERV	Headache/ headache#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N
	GASTR	Diarrhoea/ diarrhea	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Injection site pain/ Soreness at Injection site	1	27AUG2020	1/4	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site swelling/ swelling at injection site	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	16SEP2020	1/3	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1260 12601010	GENRL	Fatigue/ fatigue	2	17SEP2020	2/1	1	Yes		NA	R (17SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgias	2	17SEP2020	2/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	22JAN2021	1/3	1	Yes		NA	R (24JAN2021)	N/N
	GENRL	Chills/ chills#	4	13FEB2021	2/1	1	Yes		NA	R (13FEB2021)	N/N
	GENRL	Fatigue/ fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
16-55/ C4591001 1260 12601010	GENRL	Injection site pain/ soreness at the injection site#	4	13FEB2021	2/5	1	Yes		NA	R (17FEB2021)	N/N
	NERV	Headache/ headache#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601011	GENRL	Injection site pain/ injection site pain	1	29AUG2020	3/2	1	Yes		NA	R (30AUG2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	24DEC2020	2/3	1	Yes		NA/TC	R (26DEC2020)	N/N
	MUSC	Pain in extremity/ bilateral arm soreness#	4	14JAN2021	2/3	1	Yes		NA/TC	R (16JAN2021)	N/N
16-55/ C4591001 1260 12601012	GENRL	Injection site pain/ soreness at injection site	1	27AUG2020	1/2	1	Yes		NA	R (28AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	28AUG2020	2/1	1	Yes		NA	R (28AUG2020)	N/N
	NERV	Headache/ Headache	2	07OCT2020	20/2	1	Yes		NA	R (08OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	16JAN2021	2/2	2	Yes		NA/TC	R (17JAN2021)	N/N
		Pyrexia/ low grade temp 100.0#	3	16JAN2021	2/2	1	Yes		NA/TC	R (17JAN2021)	N/N
	NERV	Headache/ headache#	3	16JAN2021	2/2	2	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	04FEB2021	1/3	1	Yes		NA	R (06FEB2021)	N/N
	GASTR	Nausea/ severe nausea#	4	05FEB2021	2/2	1	Yes		NA	R (06FEB2021)	N/N
16-55/ C4591001 1260 12601013	GENRL	Fatigue/ fatigue	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Injection site pain/ injection site pain	1	29AUG2020	2/3	2	Yes		NA	R (31AUG2020)	N/N
	NERV	Headache/ intermittent episodes of headaches	1	29AUG2020	2/2	2	Yes		NA/TC	R (30AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	7/2	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Injection site pain/ Injection Site Soreness	2	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Malaise/ Malaise	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
		Pyrexia/ Low Grade Fever (100.2 max)	2	18SEP2020	2/32	1	Yes		NA	R (19OCT2020)	N/N
	NERV	Headache/ Headache	2	18SEP2020	2/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1260 12601014	GENRL	Injection site pain/ soreness at injection site	1	28AUG2020	1/4	1	Yes		NA/TC	R (31AUG2020)	N/N
	NERV	Headache/ headache	1	31AUG2020	4/2	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Injection site pain/ Arm soreness at injection site	2	18SEP2020	1/4	1	Yes		NA	R (21SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	2/3	1	Yes		NA	R (21SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ fatigue	1	28AUG2020	1/3	1	Yes		NA	R (30AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601016	GENRL	Chills/ chills	1	29AUG2020	2/2	1	Yes		NA	R (30AUG2020)	N/N
		Injection site pain/ soreness at injection site	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		Pain/ body aches	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ fever (99.3)	1	29AUG2020	2/1	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ Chills	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Injection site pain/ Arm soreness at injection site	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
		Pain/ Generalized body aches	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1260 12601017	GASTR	Diarrhoea/ diarrhea	1	29AUG2020	2/3	1	Yes		NA	R (31AUG2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	29AUG2020	2/5	1	Yes		NA	R (02SEP2020)	N/N
	GENRL	Injection site pain/ Injection site Soreness	2	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Presyncope/ Vasovagal reaction to blood draw	2	16OCT2020	29/1	1	No	O	NA/TCN	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601018	GENRL	Fatigue/ fatigue	1	28AUG2020	1/2	2	Yes		NA	R (29AUG2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	01JAN2021	2/1	1	Yes		NA/TC	R (01JAN2021)	N/N
	NERV	Headache/ headache#	3	01JAN2021	2/1	1	Yes		NA/TC	R (01JAN2021)	N/N
	BLOOD	Lymphadenopathy/ lymph node swelling in left armpit#	4	22JAN2021	1/2	1	Yes		NA/TC	R (23JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	23JAN2021	2/1	1	Yes		NA/TC	R (23JAN2021)	N/N
		Malaise/ malaise#	4	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N
16-55/ C4591001 1260 12601022	GENRL	Injection site pain/ muscle pain at injection site	2	01OCT2020	16/3	1	No	O	NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	22DEC2020	1/4	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601023	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	08JAN2021	1/33	1	Yes		NA/TC	R (09FEB2021)	N/N
16-55/ C4591001	MUSC	Myalgia/ generalized muscle aches	1	31AUG2020	1/5	1	Yes		NA/TC	R (04SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601024	GENRL	Chills/ chills	1	01SEP2020	2/4	1	Yes		NA/TC	R (04SEP2020)	N/N
		Pyrexia/ fever 101.5 F	1	01SEP2020	2/4	2	Yes		NA/TC	R (04SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	21DEC2020	1/2	1	Yes		NA/TC	R (22DEC2020)	N/N
	NERV	Headache/ headache#	3	21DEC2020	1/3	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601029	GENRL	Fatigue/ fatigue	1	31AUG2020	1/2	1	Yes		NA	R (01SEP2020)	N/N
		Injection site pain/ soreness at the site of injection	1	31AUG2020	1/2	2	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ FATIGUE	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1260 12601034	GENRL	Injection site erythema/ redness at injection site#	3	22DEC2020	2/4	1	Yes		NA	R (25DEC2020)	N/N
		Injection site pain/ arm soreness to touch at injection site#	3	22DEC2020	2/4	1	Yes		NA/TC	R (25DEC2020)	N/N
		Injection site swelling/ swelling at the injection site#	3	22DEC2020	2/4	1	Yes		NA	R (25DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601036	GENRL	Injection site pain/ achy arm at site of injection	1	01SEP2020	2/3	1	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Pain/ generalized body aches	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1260 12601038	GENRL	Chills/ chills#	4	12JAN2021	2/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1260 12601042	GENRL	Injection site pain/ Soreness at injection site	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	2/6	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1260 12601044	GASTR	Diarrhoea/ diarrhea	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	23SEP2020	2/2	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ local arm pain/soreness at the injection site#	3	23JAN2021	2/1	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601045	GENRL	Fatigue/ fatigue#	4	13FEB2021	2/2	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Chills/ chills	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	01SEP2020	1/3	1	Yes		NA/TC	R (03SEP2020)	N/N
	MUSC	Joint range of motion decreased/ unable to rotate right arm	1	01SEP2020	1/3	2	Yes		NA/TC	R (03SEP2020)	N/N
	GENRL	Injection site pain/ SORENESS AT INJECTION SITE	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/Y
16-55/ C4591001 1260 12601047	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	2/3	1	Yes		NA	R (04SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/5	1	Yes		NA	R (28SEP2020)	N/N
		Injection site pain/ Soreness at injection site	2	24SEP2020	2/4	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever (T-max 100.1)	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1260 12601048	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/6	1	Yes		NA	R (01FEB2021)	N/N
16-55/ C4591001 1260 12601050	GENRL	Injection site pain/ soreness at injection site	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601055	GENRL	Fatigue/ Fatigue	1	17SEP2020	16/8	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	24SEP2020	2/1	2	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Chills/ chills#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	GENRL	Pyrexia/ febrile 101.9#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
	MUSC	Myalgia/ myalgias#	4	08JAN2021	1/2	1	Yes		NA/TC	R (09JAN2021)	N/N
16-55/ C4591001 1260 12601058	GASTR	Diarrhoea/ intermittent episodes of diarrhea	1	06SEP2020	3/4	2	Yes		NA	R (09SEP2020)	N/N
	GENRL	Chills/ chills#	3	26DEC2020	5/3	1	Yes		NA	R (28DEC2020)	N/N
	GENRL	Malaise/ malaise#	3	26DEC2020	5/3	1	Yes		NA	R (28DEC2020)	N/N
	GENRL	Chills/ chills#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	13JAN2021	2/2	1	Yes		NA	R (14JAN2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601061	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
	SKIN	Dermatitis contact/ Contact dermatitis	2	16OCT2020	22/3	1	No	O	NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 1260 12601063	GENRL	Injection site pain/ soreness at the injection site	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	NERV	Headache/ headache	1	08SEP2020	5/4	2	Yes		NA/TC	R (11SEP2020)	N/N
16-55/ C4591001 1260 12601065	GENRL	Injection site pain/ soreness at injection site	2	25SEP2020	1/4	2	Yes		NA/TC	R (28SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	27JAN2021	1/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	REPRO	Metrorrhagia/ spotting between periods, on lupron#	3	29JAN2021	3/2	1	Yes		NA	R (30JAN2021)	N/N
16-55/ C4591001 1260 12601067	GENRL	Injection site pain/ soreness at injection site	1	05SEP2020	2/4	1	Yes		NA	R (08SEP2020)	N/N
16-55/ C4591001 1260 12601068	GENRL	Injection site pain/ soreness at injection site	1	04SEP2020	1/7	2	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601074	GENRL	Chills/ chills	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N
		Pyrexia/ fever	1	05SEP2020	2/6	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	23SEP2020	1/3	1	Yes		NA	R (25SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	24SEP2020	2/1	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/4	1	Yes		NA	R (11SEP2020)	N/Y
	MUSC	Myalgia/ Generalized Myalgia	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	NERV	Headache/ Headache	1	08SEP2020	1/1	1	Yes		NA	R (08SEP2020)	N/N
	GENRL	Pain/ Body Aches (Generalized)	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pyrexia/ Fever (101.2 Max)	2	01OCT2020	2/2	2	Yes		NA	R (02OCT2020)	N/N
	NERV	Migraine with aura/ Migraine with aura	2	03OCT2020	4/3	1	Yes		NA	R (05OCT2020)	N/N
16-55/ C4591001 1260 12601075	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Tendon disorder/ worsening of tendopathy (hands)	2	18OCT2020	17/15	2	No	O	NA/TC/TCN	R (01NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601076	INFEC	Appendicitis/ acute appendicitis	2	04DEC2020	64/5	2	No	O	NA/TC	R (08DEC2020)	Y/N
	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
		Injection site pain/ Soreness at injection site	1	08SEP2020	1/2	1	Yes		NA	R (09SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	31DEC2020	1/2	1	Yes		NA	R (01JAN2021)	N/N
	NERV	Headache/ headaches#	3	31DEC2020	1/2	1	Yes		NA	R (01JAN2021)	N/N
16-55/ C4591001 1260 12601077	GENRL	Injection site pain/ soreness at injection site	1	08SEP2020	1/4	2	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1260 12601082	GENRL	Injection site pain/ Soreness at injection site#	3	08JAN2021	22/34	1	Yes		NA	R (10FEB2021)	N/N
		Pyrexia/ Fever#	3	08JAN2021	22/3	1	Yes		NA/TC	R (10JAN2021)	N/N
	GENRL	Chills/ Chills#	4	09JAN2021	2/33	1	Yes		NA/TC	R (10FEB2021)	N/N
		Fatigue/ Fatigue#	4	09JAN2021	2/34	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1260 12601084	GENRL	Chills/ chills	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601085		Pyrexia/ fever	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Myalgia/ generalized myalgia	1	09SEP2020	2/2	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Pain/ Body Aches	2	29SEP2020	2/1	2	Yes		NA	R (29SEP2020)	N/N
	GENRL	Fatigue/ fatigue#	3	23DEC2020	1/3	1	Yes		NA/TC	R (25DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	24DEC2020	2/1	1	Yes		NA/TC	R (24DEC2020)	N/N
	GENRL	Fatigue/ fatigue#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
		Injection site pain/ soreness at the injection site#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
	NERV	Headache/ headache#	4	15JAN2021	1/3	1	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Pain/ body aches#	4	16JAN2021	2/2	1	Yes		NA/TC	R (17JAN2021)	N/N
	GENRL	Fatigue/ Fatigue	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
		Injection site pain/ Injection site pain - Left arm	1	08SEP2020	1/3	2	Yes		NA/TC	R (10SEP2020)	N/Y
	MUSC	Myalgia/ generalized Myalgia	1	08SEP2020	1/3	1	Yes		NA	R (10SEP2020)	N/N
GENRL	Injection site pain/ pain at injection site	2	29SEP2020	1/4	1	Yes		NA	R (02OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pain/ generalized body aches	2	29SEP2020	1/3	2	Yes		NA/TC	R (01OCT2020)	N/N
		Fatigue/ fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pyrexia/ fever	2	30SEP2020	2/2	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601091	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1260 12601092	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Intermittent headaches	1	10SEP2020	2/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	03OCT2020	2/4	1	Yes		NA	R (06OCT2020)	N/N
	NERV	Headache/ mild headaches	2	03OCT2020	2/2	1	Yes		NA	R (04OCT2020)	N/N
16-55/ C4591001 1260 12601094	GENRL	Fatigue/ Fatigue	1	10SEP2020	2/1	2	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
		Pyrexia/ fever 100.8#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N
	NERV	Headache/ headache#	3	30JAN2021	2/2	1	Yes		NA/TC	R (31JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601098	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/38	2	Yes		NA/TC	R (07NOV2020)	N/N
	NERV	Headache/ headache#	4	12FEB2021	2/2	1	Yes		NA/TC	R (13FEB2021)	N/N
16-55/ C4591001 1260 12601099	GASTR	Nausea/ Nausea	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Feeling hot/ feeling of warmth	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Injection site pain/ Soreness at injection site	1	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
		Injection site pain/ Soreness at injection site	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601100	GENRL	Injection site pain/ Soreness at injection site	1	11SEP2020	2/2	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1260 12601104	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
16-55/ C4591001 1260 12601106	NERV	Somnolence/ Drowsiness	1	10SEP2020	1/1	1	Yes		NA	R (10SEP2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GASTR	Nausea/ nausea#	3	12JAN2021	22/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	NERV	Dizziness/ dizziness#	3	12JAN2021	22/2	1	Yes		NA/TC	R (13JAN2021)	N/N
	GENRL	Pyrexia/ fever of 101#	3	14JAN2021	24/2	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1260 12601107	GENRL	Injection site pain/ pain at injection site	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	10SEP2020	1/4	2	Yes		NA/TC	R (13SEP2020)	N/N
	GENRL	Injection site pain/ Soreness at injection site	2	01OCT2020	1/3	2	Yes		NA/TC	R (03OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601108	INFEC	Urinary tract infection/ Urinary Tract Infection#	4	09MAR2021	37/4	2	Yes		NA/TC	R (12MAR2021)	N/N
	INJ&P	Ankle fracture/ Closed trimalleolar fracture of right ankle#	4	09MAR2021	37/C	3	No	O	NA/TC	N	Y/N
		Fall/ fall#	4	09MAR2021	37/C	3	No	O	NA/TC	N	N/N
	NERV	Encephalopathy/ acute encephalopathy#	4	09MAR2021	37/2	2	No	O	NA/TC	R (10MAR2021)	N/N
	PSYCH	Mental status changes/ Altered Mental Status#	4	09MAR2021	37/2	2	No	O	NA/TC	R (10MAR2021)	N/N
	VASC	Hypotension/ hypotension#	4	10MAR2021	38/C	2	No	O	NA/TC	N	N/N
16-55/ C4591001 1260 12601110	GASTR	Diarrhoea/ diarrhea	2	02OCT2020	1/2	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	18DEC2020	1/3	1	Yes		NA	R (20DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
	MUSC	Myalgia/ generalized myalgias#	4	09JAN2021	2/1	1	Yes		NA	R (09JAN2021)	N/N
16-55/ C4591001 1260 12601111	NERV	Headache/ headache	1	01OCT2020	22/1	1	No	O	NA	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	02OCT2020	2/1	1	No	O	NA/TC	R (02OCT2020)	N/N
	NERV	Presyncope/ vasovagal pre syncopal lightheadness	2	02NOV2020	33/1	1	No	O	NA/TCN	R (02NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	MUSC	Myalgia/ General Muscle aches#	3	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
	GENRL	Chills/ chills#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Injection site pain/ injection site pain#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
		Pain/ achy body#	4	10FEB2021	1/2	1	Yes		NA	R (11FEB2021)	N/N
16-55/ C4591001 1260 12601112	GENRL	Injection site pain/ Injection Site Pain - Left arm	1	15SEP2020	6/1	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ generalized Myalgia	1	17SEP2020	8/3	2	Yes		NA/TC	R (19SEP2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Fatigue/ Fatigue	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
		Pain/ Generalized body aches	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601114	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/2	2	Yes		NA/TC	R (11SEP2020)	N/N
	NERV	Headache/ headache	2	01OCT2020	1/3	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Chills/ chills	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
		Fatigue/ fatigue	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
	NERV	Pain/ generalized body aches	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N
NERV	Dizziness/ dizziness	2	02OCT2020	2/3	1	Yes		NA	R (04OCT2020)	N/N	
16-55/ C4591001 1260 12601115	GENRL	Injection site pain/ soreness at injection site	1	10SEP2020	1/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	12SEP2020	3/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ headache	1	12SEP2020	3/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	MUSC	Myalgia/ Generalized Muscle Aches	2	01OCT2020	1/5	1	Yes		NA/TC	R (05OCT2020)	N/N
	NERV	Headache/ Headache (No aura)	2	01OCT2020	1/5	2	Yes		NA/TC	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601117	GENRL	Injection site pain/ Soreness at injection site	2	02OCT2020	2/4	2	Yes		NA/TC	R (05OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	03OCT2020	3/3	1	Yes		NA	R (05OCT2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	3	29DEC2020	1/3	1	Yes		NA	R (31DEC2020)	N/N
	GENRL	Injection site pain/ soreness at the injection site#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N
16-55/ C4591001 1260 12601118		Pain/ body aches#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N
		Pyrexia/ fever 100.7#	4	20JAN2021	2/2	1	Yes		NA/TC	R (21JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	11SEP2020	1/2	1	Yes		NA	R (12SEP2020)	N/N
	NERV	Dizziness/ Dizziness	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601119	GENRL	Injection site pain/ soreness at injection site	1	11SEP2020	1/5	1	Yes		NA	R (15SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Injection site erythema/ redness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
	METAB	Decreased appetite/ lack of appetite	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601120	GENRL	Fatigue/ fatigue	2	04OCT2020	3/1	1	Yes		NA	R (04OCT2020)	N/N
		Injection site pain/ soreness at injection site	2	04OCT2020	3/3	1	Yes		NA	R (06OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
		Injection site pain/ Soreness at injection site	1	12SEP2020	2/4	1	Yes		NA	R (15SEP2020)	N/N
	MUSC	Myalgia/ Generalized muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ Headache	1	12SEP2020	2/2	2	Yes		NA/TC	R (13SEP2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	1	18SEP2020	8/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1260 12601123	GENRL	Injection site pain/ pain at injection site	2	01OCT2020	2/6	2	Yes		NA/TC	R (06OCT2020)	N/N
		Pain/ generalized body aches	2	01OCT2020	2/1	2	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1260 12601125	NERV	Headache/ headache (no aura)	1	02OCT2020	18/2	1	No	O	NA	R (03OCT2020)	N/N
16-55/ C4591001 1260 12601125	GENRL	Injection site pain/ soreness at the injection site#	3	21JAN2021	1/3	1	Yes		NA	R (23JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601126	METAB	Hyperglycaemia/ hyperglycemia (blood sugars 30 points higher than normal)#	3	21JAN2021	1/6	1	Yes		NA	R (26JAN2021)	N/N
	GENRL	Fatigue/ fatigue#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
		Injection site pain/ soreness at the injection site#	4	12FEB2021	2/3	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Chills/ Chills	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
		Fatigue/ Fatigue	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
		Pain/ Aches all over	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	MUSC	Pain in extremity/ Left Arm Pain	1	17SEP2020	1/10	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ fatigue reactogenicity from the vaccine because it was within 24 hours of vaccination	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
		Injection site pain/ soreness at injection site	2	16NOV2020	1/8	1	Yes		NA/TC	R (23NOV2020)	N/N
	Pain/ body aches - reactogenicity from the vaccine, not a covid illness happened within 24 hrs	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N	



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601127	NERV	Headache/ headache was part of the reactogenicity of the medication because it happened in 24 hrs	2	16NOV2020	1/3	1	Yes		NA/TC	R (18NOV2020)	N/N
	GENRL	Feeling hot/ feeling of warmth all over body	1	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	1	17SEP2020	1/3	1	Yes		NA	R (19SEP2020)	N/N
	NERV	Lethargy/ lethargy	1	18SEP2020	2/3	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ pain at injection site	2	06OCT2020	1/5	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Fatigue/ fatigue	2	07OCT2020	2/6	1	Yes		NA	R (12OCT2020)	N/N
		Pyrexia/ fever	2	07OCT2020	2/1	2	Yes		NA	R (07OCT2020)	N/N
	NERV	Headache/ headache	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
		Taste disorder/ change in taste	2	07OCT2020	2/2	1	Yes		NA	R (08OCT2020)	N/N
	16-55/ C4591001 1260 12601128	GENRL	Pain/ achiness - generalized	1	18SEP2020	2/1	1	Yes		NA	R (18SEP2020)
	GENRL	Fatigue/ fatigue#	3	21DEC2020	1/4	1	Yes		NA	R (24DEC2020)	N/N
		Injection site erythema/ redness at injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1260 12601129	BLOOD	Injection site pain/ pain at the injection site#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Malaise/ malaise#	3	21DEC2020	1/2	1	Yes		NA	R (22DEC2020)	N/N
		Lymphadenopathy/ bilateral enlarged lymph nodes in neck#	3	22DEC2020	2/2	1	Yes		NA	R (23DEC2020)	N/N
	GENRL	Pain/ body aches generalized#	4	12JAN2021	1/3	1	Yes		NA/TC/TCN	R (14JAN2021)	N/N
	NERV	Headache/ headache#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site pain/ soreness at injection site	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	CARD	Palpitations/ Intermittent Palpitations	1	24SEP2020	7/9	1	No	O	NA	R (02OCT2020)	N/N
	SKIN	Rash/ small rash on bilateral wrists and bilateral top of the feet	2	23OCT2020	15/12	1	No	O	NA/TC	R (03NOV2020)	N/N
	GENRL	Injection site pain/ soreness at injection site#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
	16-55/ C4591001	GENRL	Pain/ generalized body aches#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)
Pyrexia/ fever 102 degrees#			4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
Injection site pain/ Arm soreness at injection site			1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1260 12601132	GENRL	Fatigue/ Fatigue	1	19SEP2020	2/2	1	Yes		NA	R (20SEP2020)	N/N
	GASTR	Nausea/ Nausea	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
	NERV	Headache/ Headache	1	20SEP2020	3/1	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Injection site pain/ soreness at injection site	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Injection site swelling/ swelling at injection site	2	28OCT2020	20/7	1	No	O	NA	R (03NOV2020)	N/N
	GENRL	Injection site erythema/ redness at injection site#	3	21DEC2020	1/6	1	Yes		NA	R (26DEC2020)	N/N
		Injection site pain/ soreness at injection site#	3	21DEC2020	1/3	1	Yes		NA	R (23DEC2020)	N/N
		Injection site swelling/ swelling at injection site#	3	21DEC2020	1/8	1	Yes		NA	R (28DEC2020)	N/N
16-55/ C4591001 1261 12611001	GENRL	Injection site pain/ Injection site pain	2	16SEP2020	1/8	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	17SEP2020	2/7	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1261 12611002	GENRL	Chills/ Chills#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611005	MUSC	Injection site pain/ Injection Site pain#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
		Pyrexia/ Fever#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
		Myalgia/ Diffuse myalgia#	3	15JAN2021	1/2	1	Yes		NA/TC	R (16JAN2021)	N/N	
		GENRL	Chills/ Chills#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
			Injection site pain/ Injection site arm pain#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Pyrexia/ Fever#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
		Myalgia/ Diffuse myalgia#	4	05FEB2021	1/2	1	Yes		NA/TC	R (06FEB2021)	N/N	
	SKIN	Urticaria/ Urticarial abdominal rash	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N	
	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N	
NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	28AUG2020	2/3	1	Yes		NA/TC	R (30AUG2020)	N/N		
INFEC	Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611007	IMMUN	Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N	
		Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N	
	GENRL	Chills/ Chills#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N	
	16-55/ C4591001 1261 12611009	GENRL	Fatigue/ Fatigue#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N
			Injection site pain/ Injection site pain#	3	30DEC2020	1/2	1	Yes		NA/TC	R (31DEC2020)	N/N
Injection site bruising/ Local bruising at injection site			1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N	
16-55/ C4591001 1261 12611010	GENRL	Injection site pain/ Local myalgia/tenderness at injection site	1	29AUG2020	2/5	2	Yes		NA/TC/TCN	R (02SEP2020)	N/N	
		Chills/ Chills#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	MUSC	Arthralgia/ Diffuse Arthralgia#	4	28JAN2021	1/2	1	Yes		NA/TC	R (29JAN2021)	N/N	
	NERV	Headache/ Headache#	4	28JAN2021	1/3	1	Yes		NA/TC	R (30JAN2021)	N/N	
GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N		

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611011	MUSC	Arthralgia/ Arthralgia- generalized (not injection site arthralgia)	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	28JAN2021	2/3	1	Yes		NA/TC	R (30JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	28JAN2021	2/4	1	Yes		NA/TC	R (31JAN2021)	N/N
	GENRL	Chills/ Chills#	4	29JAN2021	3/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	MUSC	Myalgia/ Diffuse myalgia#	4	29JAN2021	3/2	1	Yes		NA/TC	R (30JAN2021)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
		Malaise/ Malaise	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	12JAN2021	2/4	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1261 12611016	GENRL	Fatigue/ Fatigue#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611017	MUSC	Injection site pain/ Injection site pain#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N
		Pyrexia/ Fever#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N
		Myalgia/ Diffuse myalgia#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N
	NERV	Headache/ Headache#	4	27JAN2021	2/3	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1261 12611020	GENRL	Injection site pain/ Localized myalgia at injection site	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Arthralgia/ Left shoulder pain	1	01SEP2020	1/2	1	Yes		NA	R (02SEP2020)	N/N
		Arthralgia/ Left shoulder pain	2	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1261 12611022	GENRL	Chills/ Chills	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	INFEC	Fatigue/ Fatigue	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Pyrexia/ Fever	2	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
		Conjunctivitis/ Conjunctivitis	2	21SEP2020	1/8	2	No	O	NA	R (28SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611023	GENRL	Injection site pain/ Injection site pain#	4	19JAN2021	1/2	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
	GASTR	Tongue disorder/ Tongue lesion#	4	27JAN2021	9/C	1	No	O	NA	N	N/N
16-55/ C4591001 1261 12611024	GENRL	Chills/ Chills#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
		Pyrexia/ Fever#	4	20JAN2021	2/1	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Diffuse Myalgia#	4	20JAN2021	2/2	1	Yes		NA	R (21JAN2021)	N/N
16-55/ C4591001 1261 12611025	GENRL	Adverse drug reaction/ Systemic injection reaction	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Chills/ Chills	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
		Fatigue/ Fatigue	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1261 12611027	GENRL	Injection site pain/ injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Fatigue/ Fatigue#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	12JAN2021	1/2	1	Yes		NA	R (13JAN2021)	N/N
16-55/ C4591001 1261 12611029	GENRL	Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	NERV	Headache/ Headache	2	25SEP2020	2/2	2	Yes		NA/TC	R (26SEP2020)	N/N
16-55/ C4591001 1261 12611030	NERV	Syncope/ Vasovagal syncope	1	03SEP2020	2/1	2	Yes		NA	R (03SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	28SEP2020	6/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1261 12611031	GENRL	Injection site pain/ Injection site pain	2	24SEP2020	2/5	1	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1261 12611032	GENRL	Chills/ Chills#	4	28JAN2021	4/2	1	Yes		NA/TC	R (29JAN2021)	N/N
		Pyrexia/ Fever#	4	28JAN2021	4/2	1	Yes		NA/TC	R (29JAN2021)	N/N
16-55/ C4591001 1261 12611033	GENRL	Pyrexia/ Fever#	4	19JAN2021	1/2	1	Yes		NA/TC	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611034	INFEC	Urinary tract infection/ Urinary Tract Infection	2	21NOV2020	59/10	2	No	O	NA/TC	R (30NOV2020)	N/N
16-55/ C4591001 1261 12611036	GENRL	Injection site pain/ Injection site arm pain#	2	22DEC2020	90/4	1	Yes		NA	R (25DEC2020)	N/N
	GENRL	Fatigue/ Fatigue#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
		Pyrexia/ Fever#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
	MUSC	Myalgia/ Diffuse myalgia#	4	14JAN2021	1/2	1	Yes		NA/TC	R (15JAN2021)	N/N
16-55/ C4591001 1261 12611038	GENRL	Adverse drug reaction/ Systemic injection reaction	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Chills/ Chills	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	25SEP2020	2/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1261 12611039	NERV	Headache/ Headache	2	25SEP2020	2/3	1	Yes		NA	R (27SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611042	GENRL	Injection site erythema/ Injection site redness	2	27SEP2020	4/3	1	Yes		NA	R (29SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	INJ&P	Vaccination complication/ Vaccine Reaction	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	NERV	Headache/ Headache	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1261 12611043	NERV	Headache/ Headache	2	27SEP2020	3/2	1	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1261 12611046	GENRL	Injection site pain/ Injection site arm pain#	3	18DEC2020	2/2	1	Yes		NA/TC	R (19DEC2020)	N/N
	GENRL	Injection site erythema/ Injection site redness#	4	07JAN2021	1/8	1	Yes		NA/TC	R (14JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	07JAN2021	1/8	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N
		Injection site pain/ Injection site arm pain#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia#	3	23DEC2020	1/5	1	Yes		NA	R (27DEC2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611047	GENRL	Malaise/ Malaise	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
		Pyrexia/ Fever	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	1	05SEP2020	2/2	1	Yes		NA	R (06SEP2020)	N/N
	GENRL	Chills/ Chills	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
		Fatigue/ Fatigue	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	INJ&P	Vaccination complication/ Systemic vaccine reaction	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
	MUSC	Myalgia/ Diffuse Myalgia	2	26SEP2020	2/3	2	Yes		NA	R (28SEP2020)	N/N
16-55/ C4591001 1261 12611050	GENRL	Injection site pain/ Injection site arm pain#	3	22DEC2020	1/2	1	Yes		NA/TC	R (23DEC2020)	N/N
	GENRL	Chills/ Chills#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Fatigue/ Fatigue#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
		Pyrexia/ Fever#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611051	NERV	Headache/ Headache#	4	12JAN2021	1/3	1	Yes		NA/TC	R (14JAN2021)	N/N
	GENRL	Injection site bruising/ Injection site bruising	2	30SEP2020	2/10	1	Yes		NA	R (09OCT2020)	N/N
		Injection site erythema/ Injection site redness (7cm in diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1261 12611052	GENRL	Injection site swelling/ Injection site swelling (7 cm diameter using caliper)	2	30SEP2020	2/10	2	Yes		NA	R (09OCT2020)	N/N
		Chills/ Chills#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Fatigue/ Fatigue#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
16-55/ C4591001 1261 12611053	GENRL	Injection site pain/ Injection site arm pain#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
		Myalgia/ Diffused myalgia#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	NERV	Headache/ Headache#	4	14JAN2021	2/2	1	Yes		NA	R (15JAN2021)	N/N
	RESP	Asthma/ Increased asthma symptoms#	4	14JAN2021	2/2	1	No	O	NA/TC	R (15JAN2021)	N/N
	GENRL	Fatigue/ Fatigue#	4	05FEB2021	1/2	1	Yes		NA	R (06FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Chills/ Chills#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
		Pyrexia/ Fever#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	MUSC	Myalgia/ Diffuse myalgias#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
	NERV	Headache/ Headache#	4	06FEB2021	2/1	1	Yes		NA/TC	R (06FEB2021)	N/N
16-55/ C4591001 1261 12611054	GENRL	Pyrexia/ Fever	1	09SEP2020	2/1	1	Yes		NA	R (09SEP2020)	N/N
	INJ&P	Muscle strain/ Left lower back strain secondary to exercise	1	13SEP2020	6/19	2	No	O	NA/TC	R (01OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Injection site pain/ Pain at injection site	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
		Pyrexia/ Fever	2	05NOV2020	2/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1261 12611056	GENRL	Injection site erythema/ Injection site redness#	4	13JAN2021	1/7	1	Yes		NA/TC	R (19JAN2021)	N/N
		Injection site pain/ Injection site pain#	4	13JAN2021	1/7	1	Yes		NA/TC	R (19JAN2021)	N/N
		Pyrexia/ Fever#	4	13JAN2021	1/3	1	Yes		NA/TC	R (15JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611057	MUSC	Myalgia/ Diffuse myalgia#	4	13JAN2021	1/3	2	Yes		NA/TC	R (15JAN2021)	N/N
	GENRL	Chills/ Chills#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
		Fatigue/ Fatigue#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	4	27JAN2021	1/3	1	Yes		NA	R (29JAN2021)	N/N
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Injection site erythema/ Erythema at Injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		Injection site pain/ Injection site pain	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
		Injection site warmth/ Warmth over injection site	2	30SEP2020	1/4	1	Yes		NA	R (03OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/5	1	Yes		NA	R (05OCT2020)	N/N
	16-55/ C4591001 1261 12611060	GASTR	Diarrhoea/ Diarrhea	1	14SEP2020	6/1	1	No	O	NA	R (14SEP2020)
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611062	GENRL	Injection site pain/ Injection site pain	2	01OCT2020	2/2	1	Yes		NA/TC	R (02OCT2020)	N/N
		Chills/ Chills#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N
		Fatigue/ Fatigue#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
		Myalgia/ Diffuse myalgia#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
		Headache/ Headache#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N
16-55/ C4591001 1261 12611063	GENRL	Adverse drug reaction/ Systemic injection reaction	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Chills/ Chills	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
		Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 2	2	01OCT2020	1/2	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001 1261 12611064	GENRL	Fatigue/ Fatigue#	4	19FEB2021	1/6	2	Yes		NA	R (24FEB2021)	N/N
		Injection site pain/ Injection site pain#	4	19FEB2021	1/6	1	Yes		NA	R (24FEB2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611065	BLOOD	Lymph node pain/ Tender bilateral, neck lymph nodes#	4	20FEB2021	2/5	1	Yes		NA	R (24FEB2021)	N/N
	GENRL	Pyrexia/ Fever#	4	20FEB2021	2/2	1	Yes		NA	R (21FEB2021)	N/N
	MUSC	Arthralgia/ Generalized Arthralgia#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N
		Myalgia/ Myalgia#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N
	NERV	Headache/ Headache#	4	20FEB2021	2/5	2	Yes		NA	R (24FEB2021)	N/N
	GENRL	Injection site pain/ Injection site arm soreness	2	30SEP2020	1/3	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	MUSC	Myalgia/ Diffuse myalgia	2	01OCT2020	2/2	1	Yes		NA	R (02OCT2020)	N/N
	GENRL	Chills/ Chills#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
		Injection site pain/ Injection site arm pain#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N
	Pyrexia/ Fever#	3	30DEC2020	1/2	1	Yes		NA	R (31DEC2020)	N/N	
	GENRL	Chills/ Chills#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611070	GASTR	Fatigue/ Fatigue#	4	21JAN2021	1/2	1	Yes		NA	R (22JAN2021)	N/N
		Aphthous ulcer/ Worsening frequency of canker sores	1	16SEP2020	7/25	1	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 1261 12611071	SKIN	Dermatitis/ Facial dermatitis	2	25OCT2020	25/7	1	No	O	NA	R (31OCT2020)	N/N
	GENRL	Malaise/ Malaise	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
16-55/ C4591001 1261 12611074	MUSC	Myalgia/ Diffuse myalgias	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/1	1	Yes		NA	R (12SEP2020)	N/N
		Pyrexia/ FEVER SECONDARY TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	INJ&P	Vaccination complication/ Systemic Vaccine Reaction	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	MUSC	Myalgia/ DIFFUSE MYALGIA - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N
	NERV	Headache/ HEADACHE - ADVERSE REACTION TO VACCINATION 1	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1261 12611077	INJ&P	Corneal abrasion/ Corneal Abrasion	1	18SEP2020	8/27	2	No	O	NA/TC	R (14OCT2020)	N/N	
	GENRL	Chills/ CHILLS - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
		Pyrexia/ FEVER SECONDARY TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
	MUSC	Arthralgia/ DIFFUSE GENERALIZED ARTHRALGIA AS REACTION RELATED TO 2ND VACCINATION	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
		Myalgia/ MYALGIA - ADVERSE REACTION TO VACCINATION 2	2	02OCT2020	1/2	3	Yes		NA/TC	R (03OCT2020)	N/N	
	SKIN	Urticaria/ Hives around neck	1	30SEP2020	20/2	1	No	O	NA/TC	R (01OCT2020)	N/N	
	INJ&P	Vaccination complication/ Systemic vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
	MUSC	Arthralgia/ Arthralgias secondary to vaccine reaction - diffuse generalized	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
		Myalgia/ Diffuse Myalgia secondary to vaccine reaction	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N	
NERV	Headache/ Headache secondary to vaccine	2	03OCT2020	2/2	2	Yes		NA	R (04OCT2020)	N/N		

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1261 12611078	GENRL	Fatigue/ Fatigue#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
		Injection site bruising/ Injection site bruising#	4	05JAN2021	2/4	1	Yes		NA	R (08JAN2021)	N/N
		Injection site pain/ Injection site arm pain#	4	05JAN2021	2/4	1	Yes		NA/TC	R (08JAN2021)	N/N
		Pyrexia/ Fever#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
	MUSC	Myalgia/ Diffuse Myalgia#	4	05JAN2021	2/2	1	Yes		NA	R (06JAN2021)	N/N
	NERV	Headache/ Headache#	4	05JAN2021	2/2	1	Yes		NA/TC	R (06JAN2021)	N/N
16-55/ C4591001 1264 12641013	GASTR	Dyspepsia/ Heartburn	2	30SEP2020	19/1	1	No	O	NA/TC	R (30SEP2020)	N/N
16-55/ C4591001 1264 12641014	MUSC	Myalgia/ myalgia	1	21AUG2020	1/2	1	Yes		NA	R (22AUG2020)	N/N
	GASTR	Diarrhoea/ diarrhea	1	22AUG2020	2/1	1	Yes		NA	R (22AUG2020)	N/N
16-55/ C4591001 1264 12641017	SKIN	Pain of skin/ Scalp pain	1	07SEP2020	17/10	2	No	O	NA/TC/TCN	R (16SEP2020)	N/N
	MUSC	Back pain/ Back pain	2	01OCT2020	20/C	2	No	O	NA/TC	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1264 12641021	CARD	Sinus tachycardia/ Sinus tachycardia	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	GASTR	Nausea/ Nausea	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	GENRL		Chills/ Chills	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N
			Fatigue/ Fatigue	2	13SEP2020	2/3	1	Yes		NA	R (15SEP2020)	N/N
			Injection site pain/ Injection site pain	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N
			Pyrexia/ Fever	2	13SEP2020	2/2	2	Yes		NA/TC	R (14SEP2020)	N/N
	NERV	Disturbance in attention/ Concentration impairment	2	13SEP2020	2/2	1	Yes		NA	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Myalgia	2	14SEP2020	3/2	1	Yes		NA	R (15SEP2020)	N/N	
	RESP	Rhinorrhoea/ Rhinorrhea	2	15SEP2020	4/1	1	Yes		NA	R (15SEP2020)	N/N	
16-55/ C4591001 1264 12641025	GENRL	Chills/ Chills	2	12SEP2020	1/2	2	Yes		NA/TC	R (13SEP2020)	N/N	
		Fatigue/ Fatigue	2	12SEP2020	1/2	2	No	O	NA/TC	R (13SEP2020)	N/N	
	REPRO	Menorrhagia/ Heavy menstruation	2	10OCT2020	29/7	2	Yes		NA	R (16OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641028	GENRL	Menstruation irregular/ Irregular menstruation	2	10OCT2020	29/7	2	Yes		NA	R (16OCT2020)	N/N
		Chills/ Chills	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	2	13SEP2020	1/2	1	Yes		NA	R (14SEP2020)	N/N
16-55/ C4591001 1264 12641032	METAB	Decreased appetite/ loss of appetite	1	24AUG2020	2/3	1	Yes		NA	R (26AUG2020)	N/N
	NERV	Presyncope/ presyncope	1	27AUG2020	5/1	1	Yes		NA	R (27AUG2020)	N/N
16-55/ C4591001 1264 12641034	REPRO	Scrotal pain/ Scrotal pain	1	25AUG2020	2/2	2	Yes		NA	R (26AUG2020)	N/N
16-55/ C4591001 1264 12641037	INFEC	Tinea infection/ ring worm	1	31AUG2020	8/34	1	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 1264 12641049	EAR	Vertigo/ Vertigo	1	07SEP2020	14/3	1	Yes		NA	R (09SEP2020)	N/N
	EAR	Vertigo/ Vertigo	2	15SEP2020	2/11	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001	MUSC	Arthralgia/ Arthralgia (left hand)	2	30SEP2020	14/6	2	No	O	NA	R (05OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641060 16-55/ C4591001 1264 12641065	GENRL	Chills/ Chills	2	17SEP2020	1/3	2	Yes		NA	R (19SEP2020)	N/N
		Fatigue/ Fatigue	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	17SEP2020	1/3	2	Yes		NA/TC	R (19SEP2020)	N/N
16-55/ C4591001 1264 12641069	GENRL	Influenza like illness/ Flu-like symptoms	2	19SEP2020	2/7	1	Yes		NA	R (25SEP2020)	N/N
16-55/ C4591001 1264 12641070	GENRL	Fatigue/ Fatigue	2	17SEP2020	1/2	1	Yes		NA	R (18SEP2020)	N/N
16-55/ C4591001 1264 12641072	MUSC	Myalgia/ Myalgia (persistent soreness in left deltoid)	2	19SEP2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 1264 12641073	GENRL	Swelling face/ Swelling in lower jaw	2	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1264 12641082	CARD	Tachycardia/ Tachycardia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641083	GENRL	Pyrexia/ Fever	2	21SEP2020	1/4	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
		Myalgia/ Myalgia	2	21SEP2020	1/4	2	Yes		NA	R (24SEP2020)	N/N
	NERV	Headache/ Headache	2	21SEP2020	1/4	2	Yes		NA/TC	R (24SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	02SEP2020	3/7	2	No	O	NA/TC	R (08SEP2020)	N/N
	GENRL	Chills/ Chills	2	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	21SEP2020	1/2	1	Yes		NA/TC	R (22SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	21SEP2020	1/3	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1264 12641090			1	21SEP2020	21/3	1	No	O	NA	R (23SEP2020)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue	2	23SEP2020	3/3	1	Yes		NA	R (25SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641091		Pyrexia/ Fever	2	23SEP2020	3/3	1	Yes		NA/TC	R (25SEP2020)	N/N
16-55/ C4591001 1264 12641092	GENRL	Influenza like illness/ Flu-like symptoms	2	21SEP2020	1/2	2	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 1264 12641093	INFEC	Wound infection/ Wound infection	2	14OCT2020	24/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1264 12641101	MUSC	Muscle spasms/ Muscle cramps in backs of thighs	1	16SEP2020	15/1	1	No	O	NA	R (16SEP2020)	N/N
16-55/ C4591001 1264 12641105	NERV	Peripheral sensory neuropathy/ Peripheral sensory neuropathy	1	03SEP2020	1/2	1	Yes		NA	R (04SEP2020)	N/N
16-55/ C4591001 1264 12641113	GENRL	Fatigue/ Fatigue	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1264 12641116	GENRL	Chills/ Chills	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641120	MUSC	Injection site pain/ Pain at injection site	2	25SEP2020	1/3	1	Yes		NA	R (27SEP2020)	N/N
		Pyrexia/ Fever	2	25SEP2020	1/2	1	Yes		NA/TC	R (26SEP2020)	N/N
		Myalgia/ Myalgia	2	25SEP2020	1/2	2	Yes		NA	R (26SEP2020)	N/N
	GASTR	Constipation/ Constipation	1	08SEP2020	1/C	1	No	O	NA/TCN	RG	N/N
16-55/ C4591001 1264 12641123	EAR	Ear pain/ Ear pain	1	22SEP2020	15/2	1	No	O	NA	R (23SEP2020)	N/N
	GENRL	Injection site pain/ Pain at injection site	2	28SEP2020	1/2	1	Yes		NA	R (29SEP2020)	N/N
16-55/ C4591001 1264 12641135	MUSC	Myalgia/ Myalgia	2	28SEP2020	1/1	2	Yes		NA/TC	R (28SEP2020)	N/N
	MUSC	Back pain/ Back pain	1	23SEP2020	15/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1264 12641141	INFEC	Herpes zoster/ Shingles flare	1	26SEP2020	18/33	2	No	O	NA/TC	R (28OCT2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	29SEP2020	1/2	1	Yes		NA	R (30SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641145	GASTR	Vomiting/ Vomiting	2	13OCT2020	15/6	1	No	O	NA	R (18OCT2020)	N/N
	GASTR	Umbilical hernia/ Umbilical hernia	1	13SEP2020	4/C	2	No	O	NA/TC/TCN	RG	N/N
	METAB	Decreased appetite/ Loss of appetite	2	29SEP2020	1/3	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1264 12641157	GENRL	Fatigue/ Fatigue	2	30SEP2020	2/3	2	Yes		NA	R (02OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1264 12641158	GENRL	Influenza like illness/ Flu-like symptoms	2	07OCT2020	1/2	1	Yes		NA	R (08OCT2020)	N/N
16-55/ C4591001 1264 12641162	GENRL	Injection site pain/ Pain at injection site	2	06OCT2020	1/8	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1264 12641168	VASC	Flushing/ Facial flushing	2	02NOV2020	28/C	1	No	O	NA	N	N/N
	GENRL	Injection site pain/ Injection site pain	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641171	GENRL	Fatigue/ Fatigue	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
		Influenza like illness/ Flu-like symptoms	2	06OCT2020	1/3	1	Yes		NA/TC	R (08OCT2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	06OCT2020	1/3	1	Yes		NA	R (08OCT2020)	N/N
	NERV	Headache/ Headache	2	06OCT2020	1/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 1264 12641172	NERV	Headache/ Headache	1	03OCT2020	17/3	2	No	O	NA/TC	R (05OCT2020)	N/N
16-55/ C4591001 1264 12641173	GASTR	Nausea/ Nausea	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	GENRL	Malaise/ Malaise	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
	NERV	Headache/ Headache	2	08OCT2020	1/2	1	Yes		NA	R (09OCT2020)	N/N
16-55/ C4591001 1264 12641176	RESP	Nasal congestion/ Nasal congestion	1	19SEP2020	3/7	1	No	O	NA	R (25SEP2020)	N/N
16-55/ C4591001 1264 12641177	MUSC	Pain in extremity/ Arm Soreness	2	10OCT2020	2/2	1	Yes		NA/TC	R (11OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	RESP	Oropharyngeal pain/ Sore throat	2	10OCT2020	2/2	1	No	O	NA	R (11OCT2020)	N/N
16-55/ C4591001 1264 12641181	BLOOD	Lymph node pain/ Lymph node pain	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 1264 12641185	GENRL	Chills/ Chills	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1264 12641187	GENRL	Influenza like illness/ Flu-like symptoms	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
		Injection site pain/ Injection site pain	2	12OCT2020	1/4	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Headache/ Headache	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 1264 12641190	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1264 12641197	GENRL	Chills/ Chills	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N
		Fatigue/ Fatigue	2	12OCT2020	1/1	1	Yes		NA	R (12OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1264 12641200	GASTR	Abdominal pain upper/ Stomach pain	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia (generalized)	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	1	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 1264 12641206	GENRL	Injection site pain/ Injection site pain	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	GASTR	Nausea/ Nausea	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Arthralgia/ Arthralgia (generalized)	2	12OCT2020	1/C	2	Yes		NA/TC	RG	N/N
	NERV	Hyperaesthesia/ Increased skin sensitivity	2	12OCT2020	1/C	1	Yes		NA	RG	N/N
	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1264 12641208	GENRL	Fatigue/ Fatigue	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Chills	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1264 12641209	MUSC	Fatigue/ Fatigue	2	15OCT2020	1/2	2	Yes		NA	R (16OCT2020)	N/N	
		Myalgia/ Myalgia (generalized)	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N	
			NERV	Headache/ Headache	2	15OCT2020	1/2	2	Yes	NA/TC	R (16OCT2020)	N/N
	NERV	Dizziness/ Dizziness	1	21OCT2020	1/1	1	Yes		NA	R (21OCT2020)	N/N	
	16-55/ C4591001 1264 12641210	GENRL	Injection site pain/ Injection site pain	1	21OCT2020	1/3	1	Yes		NA	R (23OCT2020)	N/N
		GENRL	Injection site pain/ Injection site pain	2	09NOV2020	1/3	1	Yes		NA	R (11NOV2020)	N/N
	16-55/ C4591001 1264 12641212	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/4	1	Yes		NA	R (16NOV2020)	N/N
	16-55/ C4591001 1264 12641213	GENRL	Injection site reaction/ Injection site reaction	2	09NOV2020	1/1	1	Yes		NA	R (09NOV2020)	N/N
	16-55/ C4591001 1264 12641215	GENRL	Injection site pain/ Pain at injection site	1	22OCT2020	2/4	1	Yes		NA	R (25OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1264 12641221	MUSC	Neck pain/ Neck pain	1	23OCT2020	1/4	1	Yes		NA	R (26OCT2020)	N/N
	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	MUSC	Myalgia/ Myalgia (left side)	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/5	1	Yes		NA	R (17NOV2020)	N/N
16-55/ C4591001 1264 12641225	GENRL	Injection site pain/ Injection site pain	2	13NOV2020	1/1	1	Yes		NA/TC	R (13NOV2020)	N/N
		Pyrexia/ Fever	2	13NOV2020	1/1	1	Yes		NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 1264 12641226	GENRL	Fatigue/ Fatigue	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
		Injection site pain/ Injection site pain	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
	NERV	Headache/ Headache	2	13NOV2020	1/2	1	Yes		NA	R (14NOV2020)	N/N
16-55/ C4591001 1264 12641227	GENRL	Injection site pain/ Injection site pain	1	26OCT2020	1/3	1	Yes		NA	R (28OCT2020)	N/N
	GENRL	Chills/ Chills	2	16NOV2020	1/2	1	Yes		NA	R (17NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1264 12641228	GENRL	Pyrexia/ Fever	2	17NOV2020	2/2	1	Yes		NA	R (18NOV2020)	N/N	
	NERV	Headache/ Headache	2	17NOV2020	2/2	2	Yes		NA	R (18NOV2020)	N/N	
	GENRL	Chills/ Chills	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N	
			Fatigue/ Fatigue	2	16NOV2020	1/3	2	Yes		NA	R (18NOV2020)	N/N
			Pyrexia/ Fever	2	16NOV2020	1/2	2	Yes		NA/TC	R (17NOV2020)	N/N
	MUSC	Myalgia/ Myalgia (generalized)	2	16NOV2020	1/3	2	Yes		NA/TC	R (18NOV2020)	N/N	
16-55/ C4591001 1265 12651004	GENRL	Injection site pain/ Pain at injection site (left deltoid)	2	31OCT2020	48/4	1	No	O	NA	R (03NOV2020)	N/N	
16-55/ C4591001 1265 12651007	GENRL	Chills/ Chills#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
	MUSC	Arthralgia/ Sore shoulders#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N	
16-55/ C4591001 1265 12651010	GENRL	Fatigue/ Fatigue	1	28AUG2020	2/1	2	No	O	NA	R (28AUG2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	29AUG2020	3/1	2	No	O	NA	R (29AUG2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1265 12651013	GENRL	Chills/ Chills#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
		Pyrexia/ Fever#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
	MUSC	Myalgia/ Myalgias#	4	11JAN2021	1/3	1	Yes		NA/TC	R (13JAN2021)	N/N	
	GENRL	Injection site pain/ Pain at injection site (Left deltoid)#	4	12JAN2021	2/2	1	Yes		NA/TC	R (13JAN2021)	N/N	
	GENRL	Fatigue/ Mild fatigue	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
		Injection site pain/ Soreness at injection site	2	02OCT2020	2/2	1	No	O	NA	R (03OCT2020)	N/N	
	MUSC	Myalgia/ New or increased muscle pain	2	02OCT2020	2/2	1	Yes		NA	R (03OCT2020)	N/N	
	MUSC	Myalgia/ New or increased muscle pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N	
	16-55/ C4591001 1265 12651016	MUSC	Myalgia/ New or increased muscle pain	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	16-55/ C4591001 1265 12651024	GENRL	Chills/ Chill#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N
	Fatigue/ Fatigue#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N		
	Pain/ Body aches#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N		
	Pyrexia/ Fever#	4	13JAN2021	2/3	1	Yes		NA	R (15JAN2021)	N/N		

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651025	GENRL	Influenza like illness/ Mild flu-like sensation	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
		Injection site discomfort/ Discomfort at injection site	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
	SKIN	Hyperhidrosis/ Mild sweats	1	31AUG2020	1/3	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1265 12651029	GENRL	Chills/ Chills	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
		Malaise/ General malaise	1	01SEP2020	2/2	1	Yes		NA	R (02SEP2020)	N/N
16-55/ C4591001 1265 12651035	MUSC	Myalgia/ Increased muscle pain#	3	11FEB2021	1/3	1	Yes		NA	R (13FEB2021)	N/N
	PSYCH	Insomnia/ insomnia#	3	11FEB2021	1/4	1	Yes		NA	R (14FEB2021)	N/N
	GENRL	Chills/ Chills#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
		Pyrexia/ Fever#	3	12FEB2021	2/2	1	Yes		NA	R (13FEB2021)	N/N
16-55/ C4591001 1265 12651037	GENRL	Chills/ Chills#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N
	MUSC	Myalgia/ New or increased muscle pain#	4	23FEB2021	2/1	1	Yes		NA	R (23FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651040	INFEC	Herpes simplex/ Herpes simplex outbreak	2	10OCT2020	17/11	1	No	O	NA	R (20OCT2020)	N/N
16-55/ C4591001 1265 12651041	GENRL	Pyrexia/ Fever	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1265 12651043	RESP	Rhinitis allergic/ Allergic rhinitis	2	28OCT2020	36/2	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1265 12651044	GENRL	Pain/ Diffuse body ache	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
		Pyrexia/ Fever	1	21SEP2020	20/3	3	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001 1265 12651047	GENRL	Pyrexia/ Fever#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
	NERV	Headache/ Headache#	4	12JAN2021	1/3	2	Yes		NA	R (14JAN2021)	N/N
16-55/ C4591001	GENRL	Injection site pain/ Injection site soreness (left deltoid)#	3	01FEB2021	1/3	1	Yes		NA	R (03FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1265 12651058	GENRL	Fatigue/ Fatigue#	3	02FEB2021	2/2	1	Yes		NA	R (03FEB2021)	N/N
	MUSC	Arthralgia/ Left shoulder pain#	4	24FEB2021	3/8	1	No	O	NA	R (03MAR2021)	N/N
		Pain in extremity/ Left hand pain#	4	24FEB2021	3/8	1	No	O	NA	R (03MAR2021)	N/N
16-55/ C4591001 1265 12651059	EAR	Vertigo positional/ Benign positional vertigo	1	12SEP2020	9/1	1	No	O	NA/TCN	R (12SEP2020)	N/N
16-55/ C4591001 1265 12651061	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/1	2	Yes		NA	R (26SEP2020)	N/N
		Injection site pain/ Pain at the injection site	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
	METAB	Decreased appetite/ Anorexia	2	26SEP2020	2/3	1	Yes		NA	R (28SEP2020)	N/N
	MUSC	Myalgia/ New or increased muscle ache, bilateral lower legs	2	26SEP2020	2/2	1	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 1265 12651062	GENRL	Fatigue/ Fatigue	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
	MUSC	Arthralgia/ Arthralgias	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Myalgia/ Myalgias	2	26SEP2020	2/2	2	Yes		NA/TC	R (27SEP2020)	N/N
16-55/ C4591001 1265 12651065	MUSC	Pain in extremity/ Sore arm	2	30SEP2020	2/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1265 12651072	GENRL	Chills/ Chills#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
		Pyrexia/ Fever#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
	MUSC	Myalgia/ New or increased muscle pain#	4	03MAR2021	2/1	1	Yes		NA	R (03MAR2021)	N/N
16-55/ C4591001 1265 12651079	GENRL	Pyrexia/ Fever	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
	NERV	Headache/ Headache	2	01OCT2020	2/1	1	Yes		NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 1265 12651081	RESP	Upper-airway cough syndrome/ Post nasal drip	2	30SEP2020	2/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1265 12651082	BLOOD	Lymph node pain/ Irritation of lymph nodes under armpit#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	GENRL	Chills/ Chills#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651090	GASTR	Injection site pain/ Muscle ache at injection site#	3	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
		Constipation/ Constipation with left lower quadrant pain	1	14SEP2020	5/1	2	No	O	NA/TC	R (14SEP2020)	N/N
16-55/ C4591001 1265 12651097	MUSC	Tenosynovitis stenosaurs/ De Quervain's tenosynovitis	2	09OCT2020	9/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1265 12651098	GASTR	Vomiting/ Vomiting	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	GENRL	Chills/ Chills	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	30SEP2020	1/2	1	Yes		NA	R (01OCT2020)	N/N
16-55/ C4591001 1265 12651099	GASTR	Dyspepsia/ Dyspepsia	1	25SEP2020	15/C	1	No	CD	NA/TC	RG	N/N
16-55/ C4591001 1265 12651101	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N
	GASTR	Abdominal pain/ Abdominal pain	1	25SEP2020	15/14	2	No	O	NA/TC	R (08OCT2020)	N/N
	PSYCH	Confusional state/ Confusion/altered mental status	1	28SEP2020	18/2	2	No	CD	NA	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651108	IMMUN	Hypersensitivity/ Allergic reaction	2	30OCT2020	31/3	1	No	O	NA/TC	R (01NOV2020)	N/N
	GENRL	Chills/ chills#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
		Injection site pain/ pain at injection site, left deltoid#	4	15FEB2021	1/4	1	Yes		NA	R (18FEB2021)	N/N
16-55/ C4591001 1265 12651110		Pyrexia/ fever#	4	15FEB2021	1/2	1	Yes		NA	R (16FEB2021)	N/N
	MUSC	Myalgia/ Muscle pain	1	15SEP2020	2/6	1	Yes		NA	R (20SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	1	17SEP2020	4/3	1	Yes		NA	R (19SEP2020)	N/N
16-55/ C4591001 1265 12651124	SKIN	Night sweats/ Night sweats	1	17SEP2020	4/3	1	Yes		NA	R (19SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	2	08OCT2020	2/4	1	Yes		NA	R (11OCT2020)	N/N
	SKIN	Night sweats/ Night sweats	2	08OCT2020	2/4	1	Yes		NA	R (11OCT2020)	N/N
	GENRL	Chills/ Chills#	4	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
		Pain/ Body aches#	4	18JAN2021	1/2	1	Yes		NA/TC	R (19JAN2021)	N/N
16-55/ C4591001	GENRL	Chills/ Chills#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1265 12651126		Pyrexia/ Fever#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	MUSC	Myalgia/ Muscle aches#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
	NERV	Headache/ Headache#	4	18JAN2021	1/3	1	Yes		NA	R (20JAN2021)	N/N
16-55/ C4591001	MUSC	Back pain/ Lower back pain	2	26OCT2020	19/C	1	No	O	NA	N	N/N
1265 12651136											
16-55/ C4591001	GENRL	Fatigue/ Mild fatigue	2	13OCT2020	6/4	1	Yes		NA	R (16OCT2020)	N/N
1265 12651138											
	MUSC	Myalgia/ Muscle pain#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N
	NERV	Headache/ Headache#	4	09MAR2021	2/2	1	Yes		NA	R (10MAR2021)	N/N
16-55/ C4591001	GASTR	Diarrhoea/ Diarrhea	2	20OCT2020	14/3	1	No	O	NA	R (22OCT2020)	N/N
1265 12651143†											
	EYE	Meibomianitis/ Right eye meibomitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N
	INFEC	Conjunctivitis/ Right eye conjunctivitis	2	24OCT2020	18/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GASTR	Toothache/ TOOTH PAIN	1	06OCT2020	19/3	1	No	O	NA/TC	R (08OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1265 12651145	BLOOD	Lymphadenopathy/ Sore and swollen underarm lymph node (both arms)	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
1265 12651149	GASTR	Rectal haemorrhage/ Rectal bleeding	2	28OCT2020	15/6	1	No	O	NA	R (02NOV2020)	N/N
1265 12651151	RESP	Asthma/ Asthma exacerbation	1	28SEP2020	8/1	1	No	O	NA/TC	R (28SEP2020)	N/N
1265 12651153	EYE	Amaurosis fugax/ Right eye blindness, diagnosed with Right Amaurosis Fugax	2	01NOV2020	20/1	2	No	O	NA	R (01NOV2020)	N/N
1265 12651155	GENRL	Fatigue/ Slight fatigue	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
1265 12651155		Injection site discomfort/ Discomfort at injection site	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
1265 12651159†	GENRL	Chills/ Chills	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651161	INFEC	Gastroenteritis/ Gastroenteritis	1	11OCT2020	20/2	1	No	O	NA	R (12OCT2020)	N/N
16-55/ C4591001 1265 12651168	MUSC	Back pain/ Lower back pain	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N
	RENAL	Pollakiuria/ Frequent Urination	1	25SEP2020	3/3	1	No	O	NA	R (27SEP2020)	N/N
	RENAL	Costovertebral angle tenderness/ Costovertebral angle tenderness	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
		Pollakiuria/ Urinary frequency	1	28SEP2020	6/4	1	No	O	NA	R (01OCT2020)	N/N
	MUSC	Back pain/ Lower back pain	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
	RENAL	Pollakiuria/ Frequent urination	2	17OCT2020	4/3	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C4591001 1265 12651170	GENRL	Chills/ Chills	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
		Fatigue/ Fatigue	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
	MUSC	Myalgia/ Muscle pain	1	24SEP2020	1/3	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1265 12651174	GENRL	Sensation of foreign body/ Globus Sensation	1	14OCT2020	21/7	1	No	O	NA/TC	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1265 12651177	GENRL	Pyrexia/ fever#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
	NERV	Headache/ headache#	4	16FEB2021	2/1	1	Yes		NA	R (16FEB2021)	N/N
16-55/ C4591001 1265 12651180	REPRO	Ovarian cyst/ New diagnosis of left ovarian complex cyst	1	08OCT2020	14/C	1	No	O	NA	N	N/N
16-55/ C4591001 1265 12651186†	NERV	Hypoaesthesia/ Left arm numbness	2	17OCT2020	2/13	1	No	O	NA	R (29OCT2020)	N/N
16-55/ C4591001 1269 12691016	GENRL	Chills/ chills	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ fever	2	10SEP2020	1/2	1	Yes		NA	R (11SEP2020)	N/N
	RESP	Oropharyngeal pain/ sore throat	2	23SEP2020	14/5	1	No	O	NA	R (27SEP2020)	N/N
16-55/ C4591001 1269 12691022	NERV	Headache/ headache	2	11SEP2020	1/2	1	Yes		NA/TC	R (12SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	13SEP2020	3/3	1	Yes		NA	R (15SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691029	GENRL	Chills/ chills	2	13SEP2020	3/1	1	Yes		NA/TC	R (13SEP2020)	N/N
	NERV	Headache/ headache	2	12SEP2020	2/2	1	Yes		NA/TC	R (13SEP2020)	N/N
16-55/ C4591001 1269 12691042	GENRL	Somnolence/ drowsiness	2	12SEP2020	2/1	1	Yes		NA/TC	R (12SEP2020)	N/N
		Chills/ chills	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1269 12691050	MUSC	Fatigue/ fatigue	2	14SEP2020	1/3	1	Yes		NA	R (16SEP2020)	N/N
	RESP	Pain in extremity/ arm soreness	2	14SEP2020	1/2	1	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1269 12691056	RESP	Dyspnoea/ Shortness of breath	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
	RESP	Nasal congestion/ Nasal congestion	1	28AUG2020	4/1	1	No	O	NA/TC	R (28AUG2020)	N/N
16-55/ C4591001 1269 12691056	GENRL	Dyspnoea/ Shortness of breath	2	15SEP2020	1/1	1	No	O	NA	R (15SEP2020)	N/N
		Chills/ chills	2	16SEP2020	2/1	1	Yes		NA	R (16SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	2/1	1	Yes		NA/TC	R (16SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691058	NERV	Headache/ headache	2	16SEP2020	2/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ chills	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
		Pyrexia/ fever	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
16-55/ C4591001 1269 12691063	MUSC	Myalgia/ body muscle aches	2	16SEP2020	1/2	1	Yes		NA/TC	R (17SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1269 12691064	NERV	Headache/ headache	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Fatigue/ fatigue	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
		Injection site pain/ soreness at injection site	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	NERV	Headache/ headache	2	17SEP2020	1/2	1	Yes		NA/TC	R (18SEP2020)	N/N
	GENRL	Chills/ chills	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N
		Pyrexia/ fever	2	18SEP2020	2/1	1	Yes		NA/TC	R (18SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691065	GENRL	Fatigue/ fatigue	1	28AUG2020	2/2	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Chills/ chills	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
		Pyrexia/ Fever	1	29AUG2020	3/1	2	Yes		NA/TC	R (29AUG2020)	N/N
	RESP	Nasal congestion/ nasal congestion	1	29AUG2020	3/1	1	Yes		NA	R (29AUG2020)	N/N
	GENRL	Fatigue/ fatigue	1	03SEP2020	8/1	1	No	O	NA	R (03SEP2020)	N/N
	RESP	Cough/ cough	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
		Dyspnoea/ shortness of breath	1	03SEP2020	8/1	1	No	O	NA/TC	R (03SEP2020)	N/N
16-55/ C4591001 1269 12691076	GASTR	Diarrhoea/ diarrhea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N
		Nausea/ nausea	1	07SEP2020	11/6	1	No	O	NA/TC	R (12SEP2020)	N/N
		Vomiting/ vomiting	1	07SEP2020	11/1	1	No	O	NA/TC	R (07SEP2020)	N/N
16-55/ C4591001 1269 12691078	GENRL	Chills/ chills	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N
		Fatigue/ fatigue	2	19SEP2020	2/1	1	Yes		NA/TC	R (19SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691087	METAB	Decreased appetite/ loss of appetite	2	19SEP2020	2/1	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Mucosal disorder/ increased mucus production	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 1269 12691088	RESP	Throat irritation/ scratchy throat	2	04OCT2020	14/3	1	No	O	NA	R (06OCT2020)	N/N
	GASTR	Abdominal pain lower/ lower abdominal pain	2	22SEP2020	2/7	1	No	O	NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 1269 12691091	GENRL	Injection site pain/ soreness at injection site	2	22SEP2020	1/3	1	Yes		NA/TC	R (24SEP2020)	N/N
16-55/ C4591001 1269 12691094	GENRL	Chills/ chills	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	GENRL	Chills/ chills	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
16-55/ C4591001 1269 12691097		Pyrexia/ fever	2	22SEP2020	1/2	1	Yes		NA/TC	R (23SEP2020)	N/N
	NERV	Headache/ Headache	2	23SEP2020	2/1	1	Yes		NA/TC	R (23SEP2020)	N/N
	CARD	Palpitations/ palpitation	1	09SEP2020	9/1	1	Yes		NA	R (09SEP2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1269 12691105	GENRL	Chills/ chills	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N	
		Pyrexia/ fever	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N	
	MUSC	Myalgia/ muscle aches	1	09SEP2020	9/1	1	Yes		NA/TC	R (09SEP2020)	N/N	
	INJ&P	Facial bones fracture/ fractured nose	1	17SEP2020	17/5	2	No	O	NA/TC	R (21SEP2020)	N/N	
	GENRL	Pyrexia/ fever	1	02SEP2020	1/2	1	Yes		NA/TC	R (03SEP2020)	N/N	
	NERV	Headache/ headache	1	02SEP2020	1/3	1	Yes		NA/TC	R (04SEP2020)	N/N	
	16-55/ C4591001 1269 12691116	GENRL	Pyrexia/ fever	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	2	24SEP2020	1/2	1	Yes		NA/TC	R (25SEP2020)	N/N	
	SKIN	Intertrigo/ intertrigo	2	14NOV2020	52/C	2	No	O	NA/TC	N	N/N	
	SKIN	Transient acantholytic dermatosis/ grover's disease	2	28NOV2020	66/C	2	No	O	NA/TC	N	N/N	
16-55/ C4591001 1269 12691125	GENRL	Chills/ chills	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N	
		Injection site pain/ soreness at injection site	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691126	MUSC	Pyrexia/ fever	2	30SEP2020	2/1	1	Yes		NA/TC	R (30SEP2020)	N/N
		Myalgia/ myalgias	2	30SEP2020	2/2	1	Yes		NA/TC	R (01OCT2020)	N/N
	GASTR	Paraesthesia oral/ tingling in mouth,lips and tongue	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
	GENRL	Chest discomfort/ chest pressure	1	10SEP2020	2/1	1	Yes		NA	R (10SEP2020)	N/N
	MUSC	Arthralgia/ achy joints	1	10SEP2020	2/3	1	Yes		NA/TC	R (12SEP2020)	N/N
	NERV	Hypogeusia/ diminished sense of taste	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Hyposmia/ Diminished sense of smell	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	RESP	Dyspnoea/ shortness of breath	1	10SEP2020	2/1	1	No	O	NA	R (10SEP2020)	N/N
	GENRL	Oropharyngeal discomfort/ throat discomfort	1	10SEP2020	2/3	1	Yes		NA	R (12SEP2020)	N/N
		Chills/ chills	1	12SEP2020	4/2	1	Yes		NA/TC	R (13SEP2020)	N/N
	RESP	Cough/ dry cough	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
	GENRL	Dyspnoea/ shortness of breath	1	16SEP2020	8/2	1	No	O	NA	R (17SEP2020)	N/N
Oropharyngeal pain/ sore throat		1	16SEP2020	8/2	1	No	O	NA/TC	R (17SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1269 12691127	GENRL	Injection site pain/ tenderness at injection site	1	09SEP2020	1/3	1	Yes		NA	R (11SEP2020)	N/N
	GENRL	Fatigue/ fatigue	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
		Pyrexia/ fever	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
	MUSC	Myalgia/ muscle aches	1	10SEP2020	2/2	1	Yes		NA	R (11SEP2020)	N/N
16-55/ C4591001 1269 12691129	GENRL	Fatigue/ fatigue	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N
		Injection site pain/ muscle pain at the injection site	2	03OCT2020	4/2	1	Yes		NA	R (04OCT2020)	N/N
	PSYCH	Insomnia/ insomnia	2	03OCT2020	4/2	1	No	O	NA	R (04OCT2020)	N/N
16-55/ C4591001 1269 12691136	GENRL	Chills/ chills	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Malaise/ malaise	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
		Pyrexia/ fever	2	02OCT2020	2/1	1	Yes		NA/TC	R (02OCT2020)	N/N
	MUSC	Myalgia/ muscle soreness	2	02OCT2020	2/1	1	Yes		NA	R (02OCT2020)	N/N
16-55/ C4591001	GASTR	Nausea/ Nausea	1	25AUG2020	1/1	1	Yes		NA/TC	R (25AUG2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701003 16-55/ C4591001 1270 12701004	INJ&P	Craniocerebral injury/ Closed Head Injury	2	28OCT2020	43/9	2	No	O	NA/TC	R (05NOV2020)	N/N
		Road traffic accident/ Driver in Motor Vehicle Accident	2	28OCT2020	43/1	2	No	O	NA	R (28OCT2020)	N/N
	MUSC	Arthralgia/ Right Hip Joint Pain	2	28OCT2020	43/C	2	No	O	NA/TC/TCN	RG	N/N
		Back pain/ Low Back Pain	2	28OCT2020	43/C	2	No	O	NA/TC/TCN	RG	N/N
		Neck pain/ Neck Pain	2	28OCT2020	43/72	2	No	O	NA/TC/TCN	R (07JAN2021)	N/N
		Temporomandibular joint syndrome/ Left Temporomandibular Pain	2	28OCT2020	43/C	2	No	O	NA/TC	RG	N/N
16-55/ C4591001 1270 12701011	GENRL	Injection site pain/ Pain at injection site	1	26AUG2020	1/4	1	Yes		NA	R (29AUG2020)	N/N
	NERV	Headache/ Headache	1	26AUG2020	1/3	1	Yes		NA/TC	R (28AUG2020)	N/N
	PSYCH	Attention deficit hyperactivity disorder/ Attention Defecit Hyperactivity Disorder	2	14OCT2020	30/C	1	No	O	NA	N	N/N
16-55/ C4591001 1270 12701015	SKIN	Skin irritation/ Worsening skin irritation in arm pits	2	21OCT2020	35/142	1	No	O	NA/TC	R (11MAR2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701018	GENRL	Pyrexia/ Fever	2	15SEP2020	1/2	1	Yes		NA	R (16SEP2020)	N/N
16-55/ C4591001 1270 12701020	GENRL	Fatigue/ Fatigue	1	30AUG2020	4/3	1	Yes		NA	R (01SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
		Pain/ Body Aches	2	19SEP2020	3/3	2	Yes		NA	R (21SEP2020)	N/N
	INJ&P	Corneal abrasion/ Right corneal abrasion	2	08NOV2020	53/9	1	No	O	NA/TC	R (16NOV2020)	N/N
	NERV	Lumbar radiculopathy/ Lumbar Radiculopathy#	2	20DEC2020	95/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1270 12701022	MUSC	Flank pain/ Flank Pain	2	01OCT2020	14/23	1	No	O	NA	R (23OCT2020)	N/N
		Muscle spasms/ Muscle Spasm of Back	2	01OCT2020	14/23	1	No	O	NA	R (23OCT2020)	N/N
		Spinal osteoarthritis/ Osteoarthritis of Spine	2	01OCT2020	14/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701025	MUSC	Arthralgia/ Left wrist joint pain	1	15SEP2020	19/8	1	No	O	NA/TC/TCN	R (22SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	16SEP2020	1/2	1	Yes		NA	R (17SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701030	GENRL	Chills/ Chills	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NERV	Headache/ Headache	2	22SEP2020	2/1	1	Yes		NA/TC	R (22SEP2020)	N/N
16-55/ C4591001 1270 12701033	GENRL	Injection site pain/ Injetion Site Pain#	4	18FEB2021	1/2	1	Yes		NA	R (19FEB2021)	N/N
16-55/ C4591001 1270 12701034	GENRL	Chills/ Chills	1	04SEP2020	5/2	1	Yes		NA	R (05SEP2020)	N/N
	RESP	Upper-airway cough syndrome/ Postnasal drip	1	04SEP2020	5/2	1	No	O	NA	R (05SEP2020)	N/N
16-55/ C4591001 1270 12701037	GENRL	Injection site pain/ Injection Site Pain	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N
	INV	Alanine aminotransferase increased/ Increased ALT	2	15OCT2020	24/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1270 12701045	INFEC	Diverticulitis/ Diverticulitis	2	19NOV2020	59/11	1	No	O	NA/TC	R (29NOV2020)	N/N
	MUSC	Arthralgia/ Left shoulder joint pain	2	19NOV2020	59/C	1	No	O	NA/TC/TCN	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701051	GENRL	Chills/ Chills	1	23SEP2020	22/2	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 1270 12701056	INFEC	Acute sinusitis/ Acute Sinusitis	1	19OCT2020	47/10	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1270 12701065	REPRO	Postmenopausal haemorrhage/ Post menopausal bleeding	1	11SEP2020	8/12	1	No	O	NA	R (22SEP2020)	N/N
	INV	Blood thyroid stimulating hormone increased/ Elevated Thyroid Stimulating Hormone Lab Test	2	19OCT2020	25/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701068	GENRL	Injection site pain/ Pain at injection site	1	04SEP2020	1/2	1	Yes		NA	R (05SEP2020)	N/N
16-55/ C4591001 1270 12701069	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N
	INV	Blood cholesterol increased/ Elevated Cholesterol	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N
		Low density lipoprotein increased/ Elevated Low-Density Lipoprotein	2	08OCT2020	9/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001	MUSC	Rotator cuff syndrome/ Impingement Syndrome of Bilateral Shoulders	1	18SEP2020	11/C	1	No	O	NA/TC	RG	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701071	EYE	Astigmatism/ Bilateral astigmatism	2	31DEC2020	94/C	1	No	O	NA/TCN	N	N/N
		Hypermetropia/ Bilateral Hyperopia	2	31DEC2020	94/C	1	No	O	NA/TCN	N	N/N
	GENRL	Chills/ Chills#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
		Injection site pain/ Injection site pain#	3	27JAN2021	2/1	1	Yes		NA	R (27JAN2021)	N/N
16-55/ C4591001 1270 12701074	SKIN	Rash/ Rash to Chest	1	12SEP2020	5/15	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 1270 12701076	GASTR	Nausea/ Nausea*		08SEP2020	1/1	1	No	O	NA	R (08SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	30SEP2020	1/2	2	No	O	NA	R (01OCT2020)	N/N
	GENRL	Injection site pain/ Injection site pain	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
		Pyrexia/ Fever	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	METAB	Decreased appetite/ Decreased Appetite	2	30SEP2020	1/2	2	Yes		NA	R (01OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701082	NERV	Headache/ Headache	2	30SEP2020	1/2	2	Yes		NA/TC	R (01OCT2020)	N/N
	MUSC	Arthralgia/ New joint pains	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
		Myalgia/ New muscle aches	1	10SEP2020	2/4	2	Yes		NA	R (13SEP2020)	N/N
	VASC	Hot flush/ Hot Flashes	1	10SEP2020	2/4	1	Yes		NA	R (13SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
	SKIN	Hyperhidrosis/ Sweating	2	01OCT2020	1/5	1	Yes		NA	R (05OCT2020)	N/N
	INFEC	Diverticulitis/ Diverticulitis	2	01OCT2020	3/12	1	No	O	NA/TC	R (12OCT2020)	N/N
	INFEC	Acute sinusitis/ Acute Sinusitis	1	14SEP2020	5/14	2	No	O	NA/TCN	R (27SEP2020)	N/N
	REPRO	Uterine haemorrhage/ Worsening abnormal uterine bleeding	2	27OCT2020	29/29	1	No	O	NA/TC	R (24NOV2020)	N/N
	INV	Serum ferritin decreased/ Decreased ferritin	2	05NOV2020	38/C	1	No	O	NA/TC	N	N/N
MUSC	Plantar fasciitis/ Left Plantar fasciitis	2	08JAN2021	102/C	1	No	O	NA/TCN	N	N/N	

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
	SKIN	Skin lesion/ Skin lesion of scalp	2	08JAN2021	102/C	1	No	O	NA	N	N/N	
	GENRL	Chills/ Intermittent Chills#	4	21FEB2021	3/C	1	Yes		NA	RG	N/N	
16-55/ C4591001 1270 12701086	GENRL	Injection site pain/ Left arm injection site pain	1	10SEP2020	1/2	2	Yes		NA	R (11SEP2020)	N/N	
	GENRL	Injection site pain/ Injection Site Pain	2	02OCT2020	1/3	1	Yes		NA/TC	R (04OCT2020)	N/N	
16-55/ C4591001 1270 12701089	IMMUN	Seasonal allergy/ Worsening seasonal allergies	2	15OCT2020	14/14	2	No	O	NA/TC	R (28OCT2020)	N/N	
16-55/ C4591001 1270 12701090	GENRL	Chills/ Chills	1	11SEP2020	2/1	2	Yes		NA	R (11SEP2020)	N/N	
16-55/ C4591001 1270 12701097	NERV	Headache/ Headache	1	11SEP2020	1/4	1	Yes		NA/TC	R (14SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	1	12SEP2020	2/11	2	Yes		NA	R (22SEP2020)	N/N	
		Injection site pain/ Left arm pain at injection site	1	12SEP2020	2/3	1	Yes		NA/TC	R (14SEP2020)	N/N	
	MUSC	Myalgia/ Muscle aches	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	
	NERV	Dizziness/ Dizziness	1	12SEP2020	2/2	1	Yes		NA	R (13SEP2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Tendon disorder/ Cystic lesion in medial patellofemoral retinaculum	1	24SEP2020	14/C	1	No	O	NA	N	N/N
	INFEC	Otitis externa/ Right otitis externa	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N
		Otitis media/ Right otitis media	2	12OCT2020	11/11	1	No	O	NA/TC	R (22OCT2020)	N/N
16-55/ C4591001 1270 12701107	INFEC	Ophthalmic herpes zoster/ Right eye herpes zoster keratitis (worsening)	2	23OCT2020	19/13	1	No	O	NA/TC/TCN	R (04NOV2020)	N/N
	GENRL	Injection site pain/ Injection site pain#	3	22DEC2020	1/2	1	Yes		NA	R (23DEC2020)	N/Y
	GENRL	Fatigue/ Fatigue#	3	23DEC2020	2/2	1	Yes		NA	R (24DEC2020)	N/N
16-55/ C4591001 1270 12701119	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
		Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	MUSC	Myalgia/ Muscle Aches	2	09OCT2020	1/2	1	Yes		NA	R (10OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	10OCT2020	2/1	1	Yes		NA	R (10OCT2020)	N/N
16-55/ C4591001 1270 12701121	EAR	Vertigo/ Vertigo	2	04NOV2020	21/9	1	No	O	NA	R (12NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701122	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/2	2	Yes		NA/TC	R (18SEP2020)	N/N
16-55/ C4591001 1270 12701123	GENRL	Fatigue/ Fatigue#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
		Injection site pain/ Injection Site Pain#	3	27JAN2021	1/2	2	Yes		NA/TC	R (28JAN2021)	N/N
	NERV	Headache/ Headache#	3	27JAN2021	1/2	1	Yes		NA	R (28JAN2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	19FEB2021	1/4	1	Yes		NA/TC	R (22FEB2021)	N/N
	MUSC	Arthralgia/ Joint Pain#	4	19FEB2021	1/4	2	Yes		NA/TC	R (22FEB2021)	N/N
16-55/ C4591001 1270 12701124	GENRL	Injection site pain/ Injection site pain	1	17SEP2020	1/4	1	Yes		NA	R (20SEP2020)	N/Y
16-55/ C4591001 1270 12701128	GENRL	Fatigue/ Fatigue	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	METAB	Decreased appetite/ Loss of appetite	1	18SEP2020	1/2	1	Yes		NA	R (19SEP2020)	N/N
	GENRL	Fatigue/ Fatigue	2	10OCT2020	2/2	1	Yes		NA	R (11OCT2020)	N/N
16-55/ C4591001	GENRL	Chills/ Chills	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1270 12701129		Pain/ Body Aches	2	09OCT2020	1/2	1	Yes		NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 1270 12701132	MUSC	Back pain/ Burning-like back pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
		Neck pain/ Increased neck pain (worsening)	1	23SEP2020	6/22	2	No	O	NA	R (14OCT2020)	N/N
	PSYCH	Sleep disorder/ Sleep disturbance	1	23SEP2020	6/22	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 1270 12701133	INJ&P	Ligament sprain/ Right ankle sprain	2	08NOV2020	31/7	1	No	O	NA/TCN	R (14NOV2020)	N/N
16-55/ C4591001 1270 12701135	EAR	Eustachian tube dysfunction/ Left eustachian tube dysfunction	1	02OCT2020	15/27	1	No	O	NA/TC	R (28OCT2020)	N/N
16-55/ C4591001 1270 12701136	GENRL	Fatigue/ Fatigue#	3	21DEC2020	1/3	2	Yes		NA	R (23DEC2020)	N/N
		Injection site pain/ Pain at injection site#	3	21DEC2020	1/3	2	Yes		NA	R (23DEC2020)	N/N
16-55/ C4591001 1270 12701137	INV	Low density lipoprotein increased/ Elevated low-density lipoprotein	1	23SEP2020	3/C	1	No	O	NA	N	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	INV	Herpes simplex test positive/ Positive Herpes Simplex Virus Test Results	1	24SEP2020	4/1	1	No	O	NA	R (24SEP2020)	N/N
	GASTR	Nausea/ Nausea	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
	GENRL	Chills/ Chills	2	12OCT2020	1/2	2	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ Fever	2	12OCT2020	1/3	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 1270 12701141	INJ&P	Joint dislocation/ Left Temporomandibular Joint Subluxation	2	17DEC2020	66/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701142	BLOOD	Lymphadenopathy/ Swollen left superficial cervical lymph node	1	22SEP2020	2/2	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 1270 12701147	GENRL	Fatigue/ Fatigue#	3	04FEB2021	1/2	1	Yes		NA	R (05FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	04FEB2021	1/4	1	Yes		NA	R (07FEB2021)	N/N
16-55/ C4591001 1270 12701148	GENRL	Chills/ CHLLS	1	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Pain/ BODY ACHES	1	05NOV2020	1/2	1	Yes		NA	R (06NOV2020)	N/N
16-55/ C4591001 1270 12701150	REPRO	Uterine haemorrhage/ Abnormal Uterine Bleeding#	3	03FEB2021	2/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701152	GENRL	Chills/ Chills#	3	03FEB2021	1/1	1	Yes		NA	R (03FEB2021)	N/N
		Fatigue/ Fatigue#	3	03FEB2021	1/7	1	Yes		NA	R (09FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	03FEB2021	1/3	1	Yes		NA	R (05FEB2021)	N/N
	GASTR	Nausea/ Nausea#	3	06FEB2021	4/1	1	Yes		NA	R (06FEB2021)	N/N
	GENRL	Injection site pain/ Injection Site Pain#	4	24FEB2021	1/2	1	Yes		NA	R (25FEB2021)	N/N
16-55/ C4591001 1270 12701154	PSYCH	Generalised anxiety disorder/ Generalized Anxiety Disorder	2	14JAN2021	39/C	1	No	O	NA/TCN	N	N/N
	MUSC	Back pain/ Chronic Low back pain	2	19JAN2021	44/C	1	No	O	NA/TCN	N	N/N
16-55/ C4591001 1270 12701155	GENRL	Chills/ Chills#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
		Injection site pain/ Injection Site Pain#	3	06FEB2021	2/2	2	Yes		NA	R (07FEB2021)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1270 12701164	MUSC	Myalgia/ Muscle pain, generalized#	3	06FEB2021	2/2	1	Yes		NA	R (07FEB2021)	N/N
	MUSC	Pain in extremity/ Right antecubital pain#	2	02FEB2021	51/1	1	No	O	NA/TCN	R (02FEB2021)	N/N
16-55/ C4591001 1270 12701175	NERV	Headache/ Headache#	3	03FEB2021	2/2	1	Yes		NA	R (04FEB2021)	N/N
	GENRL	Injection site pain/ Left Arm Injection Site Pain	1	01DEC2020	1/7	2	Yes		NA	R (07DEC2020)	N/N
16-55/ C4591001 1270 12701178	SKIN	Seborrheic dermatitis/ Seborrheic Dermatitis of Scalp	2	10JAN2021	20/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 1270 12701186	GENRL	Injection site pain/ Injection Site Pain#	3	03FEB2021	1/2	1	Yes		NA/TC	R (04FEB2021)	N/N
	SKIN	Rash/ Rash to trunk	2	21JAN2021	31/C	1	No	O	NA	RG	N/N
16-55/ C4591001 1270 12701190	GENRL	Injection site pain/ Injection site pain#	3	08FEB2021	1/3	1	Yes		NA	R (10FEB2021)	N/N
16-55/ C4591001	GENRL	Fatigue/ Fatigue#	3	09FEB2021	2/2	1	Yes		NA	R (10FEB2021)	N/N
	GENRL	Pyrexia/ fever	2	13OCT2020	2/2	2	Yes		NA/TC	R (14OCT2020)	N/N



16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441003	NERV	Headache/ headache	2	13OCT2020	2/C	2	Yes		NA/TC	N	N/N
16-55/ C4591001 4444 44441007	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N
	REPRO	Haemorrhagic ovarian cyst/ Hemorrhagic cyst of the right ovary	1	21OCT2020	31/30	1	No	O	NA/TC	R (19NOV2020)	N/N
16-55/ C4591001 4444 44441012	INFEC	Oral herpes/ cold sore	2	02NOV2020	21/8	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 4444 44441015	MUSC	Myalgia/ left arm muscle pain	1	21SEP2020	1/2	1	Yes		NA	R (22SEP2020)	N/N
16-55/ C4591001 4444 44441016	NERV	Syncope/ Vasovagal syncope	2	13NOV2020	32/1	1	No	O	NA	R (13NOV2020)	N/N
16-55/ C4591001 4444 44441017	MUSC	Back pain/ Low back pain	2	29OCT2020	17/40	2	No	O	NA/TC	R (07DEC2020)	N/N
16-55/ C4591001 4444 44441026	GENRL	Injection site swelling/ Swelling at injection site	2	12OCT2020	1/9	1	Yes		NA	R (20OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441028	GENRL	Asthenia/ asthenia	2	13OCT2020	2/33	2	Yes		NA	R (14NOV2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	2/1	2	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441045	GENRL	Injection site pain/ injection site pain#	4	11MAR2021	1/1	1	Yes		NA	R (11MAR2021)	N/N
16-55/ C4591001 4444 44441056	GENRL	Pyrexia/ Fever#	4	12MAR2021	2/1	1	Yes		NA/TC	R (12MAR2021)	N/N
	INFEC	Oral candidiasis/ Oral thrush	2	14NOV2020	33/7	1	No	O	NA/TC/TCN	R (20NOV2020)	N/N
	INJ&P	Skin laceration/ Cutting wound on the little finger of the right hand#	3	06MAR2021	15/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44441060	GENRL	Pyrexia/ Fever#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441071	MUSC	Arthralgia/ joint pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
		Myalgia/ muscle pain#	4	19FEB2021	2/2	1	Yes		NA/TC	R (20FEB2021)	N/N
	GENRL	Axillary pain/ Bilateral axillary pain#	4	11MAR2021	22/C	1	No	O	NA/TC	N	N/N
	GASTR	Diarrhoea/ Diarrhea	1	28SEP2020	8/3	1	No	O	NA/TCN	R (30SEP2020)	N/N
	GASTR	Abdominal pain upper/ Left upper quadrant abdominal pain	1	01OCT2020	11/20	2	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 4444 44441095	GENRL	Injection site pain/ Injection site pain	2	23OCT2020	1/105	1	Yes		NA/TC	R (04FEB2021)	N/Y
	MUSC	Neck pain/ Neck pain	1	29SEP2020	9/3	1	No	O	NA/TC	R (01OCT2020)	N/N
16-55/ C4591001 4444 44441100	RENAL	Dysuria/ dysuria	2	27OCT2020	15/14	1	No	O	NA/TC	R (09NOV2020)	N/N
16-55/ C4591001 4444 44441113	GASTR	Toothache/ toothache	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N
	INFEC	Gingivitis/ Gingivitis	1	30SEP2020	10/7	1	No	O	NA/TC	R (06OCT2020)	N/N
	MUSC	Arthralgia/ Right omalgia	2	14NOV2020	32/6	1	No	O	NA/TC	R (19NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441121	MUSC	Arthralgia/ Arthralgia of elbows and knees	2	14OCT2020	2/4	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Costochondritis/ mild acute chostochodritis	2	07NOV2020	26/11	1	No	O	NA	R (17NOV2020)	N/N
16-55/ C4591001 4444 44441125	NERV	Headache/ headache	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441134	MUSC	Back pain/ Worsening low back pain	1	03OCT2020	13/2	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 4444 44441139	MUSC	Plantar fasciitis/ Plantar fasciitis	2	15DEC2020	64/C	1	No	O	NA/TCN	RG	N/N
16-55/ C4591001 4444 44441144	GASTR	Diarrhoea/ diarrhea	1	09OCT2020	19/2	2	No	O	NA	R (10OCT2020)	N/N
16-55/ C4591001 4444 44441147	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	2	08FEB2021	119/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441149	MUSC	Arthralgia/ Left omalgia	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache	1	22SEP2020	2/1	1	No	O	NA	R (22SEP2020)	N/N
	GASTR	Odynophagia/ Odynophagia	1	23SEP2020	3/1	1	Yes		NA	R (23SEP2020)	N/N
	GENRL	Chills/ Shaking chills	1	24SEP2020	4/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 4444 44441150	SKIN	Rash/ Generalized skin rash.	2	26NOV2020	46/12	1	No	O	NA/TC	R (07DEC2020)	N/N
16-55/ C4591001 4444 44441154	GENRL	Pyrexia/ 38.0 C fever	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441157	METAB	Dyslipidaemia/ Dyslipidemia	1	07OCT2020	17/36	1	No	O	NA/TC	R (11NOV2020)	N/N
	VASC	Arteriosclerosis/ Atherosclerosis of vessels of the neck	1	07OCT2020	17/14	1	No	O	NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 4444 44441160	GENRL	Pyrexia/ fever	1	22SEP2020	2/1	1	Yes		NA	R (22SEP2020)	N/N
	NEOPL	Lipoma/ worsening of soft tissue tumor resembling lipoma	1	01OCT2020	11/42	1	No	O	NA	R (11NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441166	GENRL	Injection site pain/ Injection site pain	2	13OCT2020	1/5	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441169	GENRL	Injection site pain/ injection site pain	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	14OCT2020	2/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441175	GASTR	Abdominal pain lower/ hypogastric pain#	2	20FEB2021	131/20	2	No	O	NA/TC	R (11MAR2021)	N/N
16-55/ C4591001 4444 44441176	GENRL	Pyrexia/ Fever	2	14OCT2020	1/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441192	GENRL	Asthenia/ Asthenia	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
		Injection site pain/ Injection site pain	2	13OCT2020	2/3	3	Yes		NA/TC	R (15OCT2020)	N/N
		Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
	MUSC	Muscular weakness/ arm weakness	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pruritus/ Itching at injection site	2	14OCT2020	3/4	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441203 16-55/ C4591001 4444 44441205	VASC	Hypertension/ Exacerbation of arterial hypertension	2	16FEB2021	128/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441209	NERV	Headache/ Headache	1	25SEP2020	5/2	1	Yes		NA	R (26SEP2020)	N/N
16-55/ C4591001 4444 44441232	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441243	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
	NERV	Headache/ headache	2	14OCT2020	2/1	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441249	GASTR	Incarcerated inguinal hernia/ Incarcerated right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N
16-55/ C4591001 4444 44441268	NERV	Presyncope/ Vasovagal pre-syncope	2	26NOV2020	35/1	1	No	O	NA/TCN	R (26NOV2020)	N/N
16-55/ C4591001	INFEC	Periodontitis/ periodontal infection	2	22OCT2020	10/15	1	No	O	NA/TC	R (05NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441275 16-55/ C4591001 4444 44441297	INFEC	Postoperative wound infection/ Surgical site infection	2	16NOV2020	36/12	2	No	O	NA/TC	R (27NOV2020)	Y/N
16-55/ C4591001 4444 44441300	GENRL	Injection site pain/ Injection site pain	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
		Pyrexia/ low-grade fever	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	NERV	Headache/ headache	1	23SEP2020	2/2	1	Yes		NA/TC	R (24SEP2020)	N/N
	GENRL	Pyrexia/ low-grade fever (37.5 C) with chills	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	1/2	1	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441310	MUSC	Muscle spasms/ Cramps in upper limbs	1	25SEP2020	4/14	1	No	O	NA	R (08OCT2020)	N/N
16-55/ C4591001 4444 44441311	METAB	Dyslipidaemia/ dyslipidemia	2	14OCT2020	3/C	1	No	O	NA	N	N/N
16-55/ C4591001 4444 44441321	VASC	Varicose vein/ Worsening varicose veins in lower limbs	1	01OCT2020	10/30	1	No	O	NA	R (30OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441325 16-55/ C4591001 4444 44441326 16-55/ C4591001 4444 44441330 16-55/ C4591001 4444 44441360 16-55/ C4591001 4444 44441361 16-55/ C4591001	GENRL	Pyrexia/ fever	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	SKIN	Rash/ facial skin rash	2	22OCT2020	11/3	1	No	O	NA/TC	R (24OCT2020)	N/N
	GASTR	Gastritis/ Gastritis	2	21OCT2020	8/C	1	No	O	NA/TC	N	N/N
	GENRL	Injection site pain/ Injection site pain	2	14OCT2020	2/2	1	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ Generalized myalgia	2	13OCT2020	1/2	2	Yes		NA	R (14OCT2020)	N/N
	REPRO	Testicular pain/ Pain in left testicle	1	24SEP2020	3/4	2	No	O	NA	R (27SEP2020)	N/N
	GASTR	Rectal haemorrhage/ Proctorrhagia	1	06OCT2020	15/2	2	No	O	NA/TC	R (07OCT2020)	N/N
	GENRL	Fatigue/ Tiredness	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
	MUSC	Myalgia/ mild muscle pain.	1	22SEP2020	1/2	1	Yes		NA	R (23SEP2020)	N/N
MUSC	Rotator cuff syndrome/ Rotator cuff syndrome	1	05OCT2020	14/C	2	No	O	NA/TC	RG	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441384 16-55/ C4591001 4444 44441388	INFEC	Periodontitis/ Periodontal infection	2	06NOV2020	25/7	1	No	O	NA/TCN	R (12NOV2020)	N/N
16-55/ C4591001 4444 44441390	GENRL	Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441400	GENRL	Pyrexia/ fever Injection site pain/ injection site pain	2	12OCT2020	1/2	1	Yes		NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441402	INJ&P	Ligament sprain/ Type 1 sprain on right ankle mild intensity	1	25SEP2020	4/20	1	No	O	NA	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441408	GENRL	Pyrexia/ Fever	2	13OCT2020	1/2	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441413	GENRL	Chills/ Shaking chills	1	23SEP2020	2/1	1	Yes		NA	R (23SEP2020)	N/N
16-55/ C4591001	INFEC	Sinusitis/ Sinusitis	1	23SEP2020	2/7	2	No	O	NA	R (29SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441432 16-55/ C4591001 4444 44441433	MUSC	Arthralgia/ arthralgia	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N
4444 44441433 16-55/ C4591001 4444 44441435	REPRO	Myalgia/ myalgia Pelvic pain/ Pelvic pain	2	14OCT2020	2/2	2	No	O	NA/TC	R (15OCT2020)	N/N
4444 44441435 16-55/ C4591001 4444 44441436	REPRO	Pelvic pain/ Pelvic pain	2	06NOV2020	24/10	1	No	O	NA	R (15NOV2020)	N/N
4444 44441436 16-55/ C4591001 4444 44441438	GENRL	Pyrexia/ Fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
4444 44441438 16-55/ C4591001 4444 44441442	INJ&P	Contusion/ Cutaneous bruises	1	06OCT2020	15/C	1	No	O	NA	N	N/N
4444 44441442 16-55/ C4591001 4444 44441452	REPRO	Haemorrhagic ovarian cyst/ hemorrhagic ovarian cyst	2	17NOV2020	27/44	1	No	O	NA	R (30DEC2020)	N/N
4444 44441452 16-55/ C4591001 4444 44441452	INFEC	Urinary tract infection/ Urinary infection	2	26OCT2020	14/8	1	No	O	NA/TC	R (02NOV2020)	N/N
4444 44441452 16-55/ C4591001 4444 44441452	INJ&P	Animal bite/ Cat bite on right hand with a puncture wound.	2	22OCT2020	10/30	1	No	O	NA/TC	R (20NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441457	INFEC	Tooth infection/ Dental infection	2	07NOV2020	24/6	2	No	O	NA/TC/TCN	R (12NOV2020)	N/N
16-55/ C4591001 4444 44441483	GENRL	Pyrexia/ fever	2	13OCT2020	1/3	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441487	NERV	Headache/ headache	1	24SEP2020	3/6	1	No	O	NA/TC	R (29SEP2020)	N/N
	MUSC	Myalgia/ Myalgia	2	13OCT2020	2/2	1	Yes		NA/TC	R (14OCT2020)	N/N
	EYE	Ulcerative keratitis/ RIGHT EYE CORNEAL ULCER	2	15NOV2020	35/9	2	No	O	NA/TC	R (23NOV2020)	N/N
16-55/ C4591001 4444 44441494	GASTR	Gastritis/ Gastritis	1	24SEP2020	3/65	1	No	O	NA/TC	R (27NOV2020)	N/N
	NEOPL	Colon adenoma/ Colonic Polyp (Histologic analysis: tubular adenoma. Low-grade dysplasia)	1	24SEP2020	3/1	1	No	O	NA/TCN	R (24SEP2020)	N/N
	PSYCH	Depression/ Worsening Depression	2	11NOV2020	30/17	2	No	O	NA/TC	R (27NOV2020)	N/N
16-55/ C4591001 4444 44441499	MUSC	Myalgia/ GENERALIZED MYALGIA	1	23SEP2020	2/2	1	Yes		NA	R (24SEP2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441503	MUSC	Myalgia/ myalgia	2	15OCT2020	2/1	1	Yes		NA	R (15OCT2020)	N/N
	NERV	Migraine/ Worsening of migraine.	1	06OCT2020	15/4	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 4444 44441505	GENRL	Injection site pain/ right arm pain at injection site	1	24SEP2020	3/1	1	Yes		NA	R (24SEP2020)	N/N
16-55/ C4591001 4444 44441506	GENRL	Injection site pain/ Pain at the injection site	2	13OCT2020	1/3	1	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Asthenia/ Asthenia	1	03OCT2020	12/16	1	No	O	NA/TCN	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441514	GENRL	Injection site pain/ Injection site pain	2	12OCT2020	1/5	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441518	GENRL	Asthenia/ Asthenia	2	13OCT2020	2/1	1	Yes		NA	R (13OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/1	2	Yes		NA/TC	R (13OCT2020)	N/N
	GENRL	Asthenia/ asthenia	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
		Pyrexia/ fever	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	13OCT2020	2/4	1	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441528	GENRL	Injection site pain/ Pain at injection site#	3	09MAR2021	2/1	1	Yes		NA	R (09MAR2021)	N/N
16-55/ C4591001 4444 44441536	GENRL	Pyrexia/ Fever	2	14OCT2020	2/1	2	Yes		NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441539	GENRL	Asthenia/ asthenia	2	17OCT2020	4/6	1	Yes		NA	R (22OCT2020)	N/N
		Pyrexia/ Low grade fever	2	17OCT2020	4/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441542	INFEC	Tooth infection/ Dental infection	1	30SEP2020	8/11	1	No	O	NA/TC	R (10OCT2020)	N/N
16-55/ C4591001 4444 44441544	NERV	Headache/ Headache	1	01OCT2020	9/3	2	No	O	NA/TC	R (03OCT2020)	N/N
16-55/ C4591001 4444 44441546	INJ&P	Skin laceration/ Cutting skin lesion on left index finger	1	10OCT2020	18/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001	GASTR	Intestinal perforation/ Intestinal perforation	2	23DEC2020	70/22	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441550	INFEC	Pneumonia/ Hospital-acquired pneumonia	2	30DEC2020	77/15	3	No	O	NA/TC	R (13JAN2021)	Y/N
16-55/ C4591001 4444 44441553	METAB	Insulin resistance/ Insulin resistance	1	30SEP2020	8/45	2	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 4444 44441556	GENRL	Pyrexia/ 38C Fever	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/2	2	Yes		NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441561	GENRL	Injection site pain/ injection site Pain	2	15OCT2020	2/3	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441566	GENRL	Injection site pain/ Pain at the injection site	2	12OCT2020	1/2	1	Yes		NA	R (13OCT2020)	N/N
16-55/ C4591001 4444 44441572	MUSC	Back pain/ low back pain	1	19OCT2020	27/3	1	No	O	NA	R (21OCT2020)	N/N
16-55/ C4591001 4444 44441573	GENRL	Asthenia/ Asthenia	1	23SEP2020	1/9	1	Yes		NA	R (01OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
		Chills/ chills	1	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N
	GENRL	Asthenia/ Asthenia	2	14OCT2020	1/6	1	Yes		NA	R (19OCT2020)	N/N
		Injection site pain/ Pain at the injection site (left arm)	2	14OCT2020	1/5	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441577	SURG	Endodontic procedure/ Root canal treatment	1	14OCT2020	22/1	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441583	GASTR	Toothache/ Right lower molar pain	2	30OCT2020	19/4	2	No	O	NA/TC	R (02NOV2020)	N/N
16-55/ C4591001 4444 44441586	INFEC	Tooth infection/ Odontogenic infection	1	02OCT2020	10/5	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 4444 44441594	GENRL	Injection site pain/ Injection site pain	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/2	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001	GASTR	Dental caries/ Dental cavity	2	30OCT2020	17/11	1	No	O	NA/TC/TCN	R (09NOV2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441603 16-55/ C4591001 4444 44441612	GENRL	Pyrexia/ Fever	1	15OCT2020	23/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441614	MUSC	Myalgia/ right back myalgia	1	29SEP2020	7/4	1	No	O	NA/TC	R (02OCT2020)	N/N
16-55/ C4591001 4444 44441616	GASTR	Vomiting/ Vomiting	2	13OCT2020	2/2	1	Yes		NA	R (14OCT2020)	N/N
	NERV	Headache/ Headache	2	13OCT2020	2/3	2	Yes		NA/TC	R (15OCT2020)	N/N
	GENRL	Pyrexia/ Fever	2	14OCT2020	3/1	2	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441618	MUSC	Intervertebral disc protrusion/ herniated disc	2	02NOV2020	20/29	2	No	O	NA/TC	R (30NOV2020)	N/N
16-55/ C4591001 4444 44441624	INFEC	Acarodermatitis/ Scabies	1	07OCT2020	15/17	1	No	O	NA/TC	R (23OCT2020)	N/N
16-55/ C4591001 4444 44441634	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	28DEC2020	76/8	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441643	MUSC	Osteoporosis/ Osteoporosis	2	26OCT2020	11/117	1	No	O	NA/TC	RS (19FEB2021)	N/N
16-55/ C4591001 4444 44441658	GENRL	Pyrexia/ fever	2	14OCT2020	2/1	1	Yes		NA	R (14OCT2020)	N/N
16-55/ C4591001 4444 44441673	GENRL	Pyrexia/ Fever	2	15OCT2020	2/1	1	Yes		NA/TC	R (15OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	15OCT2020	2/4	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441679	GENRL	Application site pain/ pain at the application site	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	MUSC	Myalgia/ Generalized Myalgia	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441680	GENRL	Pyrexia/ fever	2	14OCT2020	1/2	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441682	INJ&P	Joint injury/ Mild trauma to the left knee while doing regular physical activity	2	07NOV2020	25/1	1	No	O	NA	R (07NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441700	MUSC	Arthralgia/ Left knee pain	2	07NOV2020	25/4	1	No	O	NA/TC	R (10NOV2020)	N/N
	GASTR	Diarrhoea/ Diarrhea	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	GENRL	Illness/ Sickness	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441716	MUSC	Myalgia/ Myalgia	2	14OCT2020	1/2	2	Yes		NA	R (15OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	14OCT2020	1/2	2	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441719	MUSC	Myalgia/ generalized myalgias	1	26SEP2020	4/3	2	Yes		NA/TC	R (28SEP2020)	N/N
16-55/ C4591001 4444 44441725	MUSC	Muscular weakness/ Generalized muscle weakness	1	09OCT2020	17/1	1	No	O	NA	R (09OCT2020)	N/N
16-55/ C4591001 4444 44441733		Myalgia/ Dorsal muscle pain	1	09OCT2020	17/1	1	No	O	NA/TC	R (09OCT2020)	N/N
	INJ&P	Head injury/ Head injury without loss of consciousness.	2	25OCT2020	12/8	1	No	O	NA/TC/TCN	R (01NOV2020)	N/N
16-55/ C4591001	SKIN	Skin lesion/ indurated lesion on left arm	1	30SEP2020	8/18	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441735 16-55/ C4591001 4444 44441744	NERV	Headache/ intermittent headache	1	24SEP2020	2/22	1	Yes		NA	R (15OCT2020)	N/N
4444 44441746 16-55/ C4591001 4444 44441748	GENRL	Injection site oedema/ Edema at the injection site.	2	15OCT2020	2/2	1	Yes		NA/TC	R (16OCT2020)	N/N
4444 44441748 16-55/ C4591001 4444 44441756	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N
4444 44441756 16-55/ C4591001 4444 44441756	GASTR	Nausea/ Nausea	1	24SEP2020	2/4	2	Yes		NA	R (27SEP2020)	N/N
4444 44441756 16-55/ C4591001 4444 44441756	GENRL	Pyrexia/ Fever	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
4444 44441756 16-55/ C4591001 4444 44441756	MUSC	Myalgia/ Generalized myalgia	1	24SEP2020	2/4	2	Yes		NA/TC	R (27SEP2020)	N/N
4444 44441756 16-55/ C4591001 4444 44441756	GASTR	Abdominal pain upper/ epigastralgia	1	11OCT2020	19/2	1	No	O	NA/TC	R (12OCT2020)	N/N
4444 44441756 16-55/ C4591001 4444 44441756	MUSC	Neck pain/ cervicalgia	1	11OCT2020	19/3	2	No	O	NA	R (13OCT2020)	N/N
4444 44441756 16-55/ C4591001 4444 44441756	MUSC	Arthralgia/ Right knee pain	2	04NOV2020	21/8	2	No	O	NA/TC	R (11NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441761	GENRL	Application site rash/ Rash in the arm contralateral to the application of the research product	1	23SEP2020	1/1	1	Yes		NA	R (23SEP2020)	N/N
	BLOOD	Lymphadenopathy/ Right axillary adenopathy#	3	10MAR2021	2/C	1	No	O	NA	RG	N/N
16-55/ C4591001 4444 44441767	GENRL	Pyrexia/ fever	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441771	MUSC	Back pain/ Exacerbation of low back pain	2	02NOV2020	19/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 4444 44441783	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia	1	29SEP2020	7/C	1	No	O	NA/TC	RG	N/N
	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	29OCT2020	15/C	1	No	O	NA/TC	N	N/N
	MUSC	Back pain/ Low back pain	2	07NOV2020	24/4	1	No	O	NA/TC	R (10NOV2020)	N/N
16-55/ C4591001 4444 44441784	METAB	Vitamin D deficiency/ Hypovitaminosis D	2	26OCT2020	13/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441785	GASTR	Vomiting/ Vomiting, 2 episodes	2	15OCT2020	2/2	1	Yes		NA	R (16OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	GENRL	Pyrexia/ FEVER	2	15OCT2020	2/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441786	INFEC	Urinary tract infection/ Urinary infection#	3	11MAR2021	17/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44441788	MUSC	Muscle contracture/ cervical contracture	2	01NOV2020	20/34	1	No	O	NA/TCN	R (04DEC2020)	N/N
16-55/ C4591001 4444 44441796	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44441797	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441801	GENRL	Chest pain/ chest pain	2	28OCT2020	15/3	2	No	O	NA/TC	R (30OCT2020)	N/N
	VASC	Diastolic hypertension/ Diastolic arterial hypertension	2	29OCT2020	16/C	1	No	O	NA	N	N/N
	GASTR	Gastroesophageal reflux disease/ Gastroesophageal reflux	2	03NOV2020	21/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441808	INFEC	Tooth infection/ odontogenic infection	2	07NOV2020	24/7	1	No	O	NA/TC	R (13NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441810	GENRL	Pyrexia/ FEVER	1	28SEP2020	4/2	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 4444 44441815	GASTR	Diarrhoea/ diarrhea	2	17OCT2020	3/2	1	Yes		NA	R (18OCT2020)	N/N
		Vomiting/ Vomits.	2	17OCT2020	3/2	2	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ Headache	2	17OCT2020	3/4	1	Yes		NA	R (20OCT2020)	N/N
16-55/ C4591001 4444 44441824	MUSC	Arthralgia/ Left shoulder pain	1	26SEP2020	2/24	1	No	O	NA	R (19OCT2020)	N/N
16-55/ C4591001 4444 44441825	MUSC	Back pain/ Back pain	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
		Neck pain/ CERVICALGIA	1	11OCT2020	17/29	1	No	O	NA/TC	R (08NOV2020)	N/N
	MUSC	Back pain/ LUMBALGIA	1	26OCT2020	32/14	1	No	O	NA	R (08NOV2020)	N/N
16-55/ C4591001 4444 44441840	GENRL	Pyrexia/ Fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001	NERV	Sciatica/ Lumbociatalgia#	3	24FEB2021	2/4	2	No	O	NA/TC	R (27FEB2021)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441841 16-55/ C4591001 4444 44441851	INJ&P	Craniocerebral injury/ Polychontusion plus cranial brain trauma without loss of consciousness	2	06NOV2020	23/1	2	No	O	NA/TC/TCN	R (06NOV2020)	N/N
16-55/ C4591001 4444 44441854	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
		Injection site pain/ injection site pain	2	16OCT2020	2/5	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Myalgia/ Myalgia generalized	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441859	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/5	1	Yes		NA	R (20OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/5	1	Yes		NA/TC	R (20OCT2020)	N/N
16-55/ C4591001 4444 44441861	GENRL	Fatigue/ FATIGUE	2	16OCT2020	2/3	2	Yes		NA	R (18OCT2020)	N/N
		Injection site pain/ Injection site pain.	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	MUSC	Myalgia/ MYALGIAS	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441872	NERV	Headache/ headache	1	07OCT2020	13/3	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 4444 44441874	NERV	Headache/ headache	1	26SEP2020	2/2	2	Yes		NA	R (27SEP2020)	N/N
16-55/ C4591001 4444 44441881	MUSC	Back pain/ Back pain	2	05NOV2020	23/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441896	GENRL	Pyrexia/ Fever	2	17OCT2020	3/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441900	GENRL	Pyrexia/ Fever	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44441903	MUSC	Myalgia/ Myalgia	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N
	NERV	Headache/ Headache	2	15OCT2020	1/2	1	Yes		NA/TC	R (16OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441909	INFEC  SKIN	Infected dermal cyst/ Left preauricular epidermal cyst infection*		25SEP2020	1/40	2	No	O	NA/TC	R (03NOV2020)	N/N
		Dermal cyst/ Epidermal cyst on right and left preauricular region*		25SEP2020	1/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44441910	GENRL	Pyrexia/ Fever	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44441916	MUSC	Muscle contracture/ Cervical contracture	1	02OCT2020	8/3	1	No	O	NA/TC	R (04OCT2020)	N/N
16-55/ C4591001 4444 44441918	MUSC	Back pain/ Low back pain#	3	10FEB2021	17/19	1	No	O	NA/TC	R (28FEB2021)	N/N
16-55/ C4591001 4444 44441933	GENRL	Axillary pain/ pain in right armpit	1	13OCT2020	19/3	1	No	O	NA	R (15OCT2020)	N/N
16-55/ C4591001 4444 44441934	INFEC	Urinary tract infection/ Lower urinary tract infection	2	11NOV2020	28/6	1	No	CND	NA/TC	R (16NOV2020)	N/N
16-55/ C4591001 4444 44441937	MUSC	Back pain/ Low back pain	2	08NOV2020	26/13	2	No	O	NA/TC/TCN	R (20NOV2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 4444 44441949	NERV	Paraesthesia/ Paresthesia in the anterior aspect of the left thigh	2	11NOV2020	29/5	1	No	O	NA	R (15NOV2020)	N/N	
	INJ&P	Limb injury/ Right index finger injury#	4	13MAR2021	24/C	1	No	O	NA/TC	N	N/N	
16-55/ C4591001 4444 44441953	PSYCH	Anxiety disorder/ Anxiety disorder	1	10OCT2020	16/2	1	No	O	NA/TC	R (11OCT2020)	N/N	
16-55/ C4591001 4444 44441955	GASTR	Gastritis/ Gastritis	1	04OCT2020	10/14	1	No	O	NA/TC	R (17OCT2020)	N/N	
16-55/ C4591001 4444 44441963	GENRL	Asthenia/ asthenia	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
		Pyrexia/ fever	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
	NERV	Headache/ headache	2	17OCT2020	2/4	1	Yes		NA/TC	R (20OCT2020)	N/N	
	NERV	Tremor/ BOTH HANDS FINE TREMOR	2	19OCT2020	4/2	1	Yes		NA	R (20OCT2020)	N/N	
16-55/ C4591001 4444 44441965	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N	
		Pyrexia/ Fever	2	17OCT2020	2/2	2	Yes		NA/TC	R (18OCT2020)	N/N	

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44441967	SURG	Wisdom teeth removal/ Retained wisdom tooth extraction	1	09OCT2020	15/1	1	No	CND	NA	R (09OCT2020)	N/N
16-55/ C4591001 4444 44441973	GENRL	Asthenia/ Asthenia	2	29OCT2020	1/2	2	Yes		NA/TCN	R (30OCT2020)	N/N
		Injection site pain/ Injection site pain	2	29OCT2020	1/2	1	Yes		NA/TC	R (30OCT2020)	N/N
16-55/ C4591001 4444 44441979	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	25SEP2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 4444 44441988	INFEC	Diverticulitis/ Diverticulitis	1	30SEP2020	6/22	2	No	O	NA/TC/TCN	R (21OCT2020)	N/N
16-55/ C4591001 4444 44442007	GENRL	Injection site rash/ Erythematous rash at injection site#	4	01MAR2021	4/3	1	Yes		NA/TC	R (03MAR2021)	N/N
16-55/ C4591001 4444 44442009	BLOOD	Lymphadenopathy/ left axillary adenopathy	2	15OCT2020	2/4	1	Yes		NA	R (18OCT2020)	N/N
16-55/ C4591001 4444 44442015	GASTR	Toothache/ Tooth pain	2	04NOV2020	20/3	1	No	O	NA/TC/TCN	R (06NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44442021	SURG	Tooth extraction/ Tooth extraction	2	06NOV2020	22/1	1	No	O	NA	R (06NOV2020)	N/N
	INJ&P	Ankle fracture/ Right ankle fracture	2	15NOV2020	32/68	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N
16-55/ C4591001 4444 44442032	MUSC	Fall/ fall from a bicycle	2	15NOV2020	32/1	2	No	O	NA/TCN	RS (15NOV2020)	N/N
		Arthralgia/ Worsening of Hands arthralgia episode	1	04OCT2020	10/27	1	No	O	NA	R (30OCT2020)	N/N
16-55/ C4591001 4444 44442033	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442035	MUSC	Myalgia/ myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
	GENRL	Injection site erythema/ injection site erythema	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	MUSC	Pyrexia/ Fever	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
		Myalgia/ generalized Muscle pain	2	17OCT2020	2/19	1	Yes		NA	R (04NOV2020)	N/N
16-55/ C4591001	NERV	Headache/ Headache	2	17OCT2020	2/3	1	Yes		NA/TC	R (19OCT2020)	N/N
	NERV	Headache/ Headache	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442037 16-55/ C4591001 4444 44442041	INJ&P	Fall/ Fall down stairs	2	05DEC2020	51/1	1	No	O	NA	R (05DEC2020)	N/N
		Humerus fracture/ Right displaced proximal humeral fracture	2	05DEC2020	51/41	2	No	O	NA/TC/TCN	R (14JAN2021)	Y/N
	PSYCH	Adjustment disorder with depressed mood/ Reactive depression	2	25JAN2021	102/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44442047	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Headache/ headache	2	18OCT2020	3/2	1	Yes		NA/TC	R (19OCT2020)	N/N
16-55/ C4591001 4444 44442050	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/3	1	Yes		NA	R (18OCT2020)	N/N
		Pyrexia/ Fever	2	16OCT2020	1/3	2	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44442053	INFEC	Tonsillitis bacterial/ Bacterial tonsillitis	1	02OCT2020	8/8	1	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442062	REPRO	Metrorrhagia/ mild metrorrhagia	2	16OCT2020	2/C	1	No	O	NA	N	N/N
16-55/ C4591001 4444 44442065	VASC	Hypertension/ Arterial hypertension	2	17NOV2020	34/6	2	No	O	NA/TC	R (22NOV2020)	N/N
16-55/ C4591001 4444 44442069	ENDO	Hypothyroidism/ Worsening of hypothyroidism#	3	05MAR2021	9/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44442071	INFEC	Tooth infection/ odontogenic infection	1	10OCT2020	14/3	1	No	O	NA/TC	R (12OCT2020)	N/N
16-55/ C4591001 4444 44442081	GASTR	Constipation/ Constipation	1	28SEP2020	2/19	1	No	O	NA	R (16OCT2020)	N/N
16-55/ C4591001 4444 44442084	NERV	Sciatica/ lumbosciatalgia	1	07OCT2020	11/3	2	No	O	NA/TC	R (09OCT2020)	N/N
16-55/ C4591001 4444 44442101	MUSC	Neck pain/ cervicalgia	2	19NOV2020	36/9	1	No	O	NA/TC/TCN	R (27NOV2020)	N/N
16-55/ C4591001	GENRL	Pyrexia/ fever	2	16OCT2020	1/2	1	Yes		NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442102 16-55/ C4591001 4444 44442105	GENRL	Chills/ shaking chills	1	27SEP2020	1/2	2	Yes		NA/TC	R (28SEP2020)	N/N
4444 44442105	MUSC	Myalgia/ Muscle pain	1	27SEP2020	1/3	2	Yes		NA/TC	R (29SEP2020)	N/N
16-55/ C4591001 4444 44442106	MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/2	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44442113	EYE	Conjunctivitis allergic/ worsening of allergic conjunctivitis	1	01OCT2020	5/6	1	No	O	NA	R (06OCT2020)	N/N
16-55/ C4591001 4444 44442117	NERV	Headache/ headache	2	16OCT2020	2/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44442119	MUSC	Back pain/ Lumbar pain	2	13NOV2020	30/1	1	No	O	NA/TC	R (13NOV2020)	N/N
16-55/ C4591001 4444 44442122	GENRL	Injection site pain/ Pain at injection site	2	16OCT2020	1/2	2	Yes		NA	R (17OCT2020)	N/N
	MUSC	Arthralgia/ generalized arthralgia	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N



## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ headache	2	17OCT2020	2/1	2	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442124	SKIN	Rash maculo-papular/ maculopapular rash on the face, upper limbs and abdomen	2	14NOV2020	30/7	1	No	O	NA/TC	R (20NOV2020)	N/N
16-55/ C4591001 4444 44442135	GENRL	Pyrexia/ fever of 38 degrees Celsius	2	15OCT2020	1/2	1	Yes		NA/TCN	R (16OCT2020)	N/N
	GENRL	Injection site swelling/ injection site swelling	2	16OCT2020	2/6	1	Yes		NA/TC	R (21OCT2020)	N/N
16-55/ C4591001 4444 44442146	GENRL	Pyrexia/ fever	2	17OCT2020	2/3	2	Yes		NA/TC/TCN	R (19OCT2020)	N/N
16-55/ C4591001 4444 44442151	MUSC	Neck pain/ Acute Cervicalgia	2	16NOV2020	33/C	1	No	O	NA/TC/TCN	RG	N/N
16-55/ C4591001 4444 44442154	GENRL	Pyrexia/ low grade fever	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
	MUSC	Myalgia/ myalgia	2	17OCT2020	2/2	1	Yes		NA	R (18OCT2020)	N/N
	NERV	Headache/ headache	2	17OCT2020	2/1	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001	GENRL	Injection site pain/ injection site pain	2	14NOV2020	1/2	1	Yes		NA	R (15NOV2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442157 16-55/ C4591001 4444 44442159	MUSC	Myalgia/ myalgia.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
4444 44442159	NERV	Headache/ headache.	2	15OCT2020	1/2	2	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44442160	INFEC	Vaginal infection/ vaginal infection	2	11NOV2020	28/C	1	No	O	NA/TC	RG	N/N
16-55/ C4591001 4444 44442163	MUSC	Back pain/ back pain	2	16OCT2020	1/C	1	No	O	NA	RG	N/N
4444 44442167	GENRL	Pyrexia/ fever	2	17OCT2020	2/1	2	Yes		NA/TC/TCN	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442167	GENRL	Injection site erythema/ Injection site erythema	2	17OCT2020	2/4	1	Yes		NA/TCN	R (20OCT2020)	N/N
4444 44442171	GENRL	Injection site pain/ Injection site pain (left arm)	2	17OCT2020	2/3	1	Yes		NA	R (19OCT2020)	N/N
16-55/ C4591001 4444 44442171	GENRL	Asthenia/ Asthenia	2	17OCT2020	2/4	2	Yes		NA/TC	R (20OCT2020)	N/N
4444 44442171	GENRL	Pyrexia/ Fever 39,2 c	2	17OCT2020	2/1	3	Yes		NA/TC	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 4444 44442182	GENRL	Pyrexia/ Fever	2	16OCT2020	1/2	1	Yes		NA/TCN	R (17OCT2020)	N/N
	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442193	GENRL	Injection site pain/ Pain at injection site	1	27SEP2020	1/16	1	Yes		NA	R (12OCT2020)	N/Y
	GENRL	Asthenia/ Asthenia	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
		Injection site pain/ Right arm pain at the injection site of the research product	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442203	MUSC	Myalgia/ Myalgia	2	16OCT2020	1/2	2	Yes		NA/TC	R (17OCT2020)	N/N
	NERV	Dizziness/ Dizziness	2	09NOV2020	25/1	1	No	O	NA	R (09NOV2020)	N/N
16-55/ C4591001 4444 44442215	NERV	Headache/ headache	2	16OCT2020	2/6	2	Yes		NA/TC	R (21OCT2020)	N/N
	PSYCH	Insomnia/ Insomnia	2	04DEC2020	51/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001	GENRL	Pyrexia/ Febrile syndrome	2	16OCT2020	1/2	1	Yes		NA	R (17OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442221	INFEC	Paronychia/ Periungual infection of the index finger	2	09NOV2020	26/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44442226	GENRL	Pyrexia/ Isolated feverish record	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
4444 44442230	MUSC	Myalgia/ generalized myalgia	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442232	MUSC	Back pain/ Low back pain	1	12OCT2020	16/2	2	No	O	NA/TC	R (13OCT2020)	N/N
16-55/ C4591001 4444 44442237	GENRL	Injection site pain/ Pain at injection site	2	15OCT2020	1/1	1	Yes		NA/TC	R (15OCT2020)	N/N
16-55/ C4591001 4444 44442241	NERV	Headache/ headache	2	18OCT2020	4/1	1	No	O	NA/TC/TCN	R (18OCT2020)	N/N
16-55/ C4591001 4444 44442268	REPRO	Amenorrhoea/ amenorrhea	2	10NOV2020	27/13	1	No	O	NA	R (22NOV2020)	N/N
16-55/ C4591001	MUSC	Back pain/ back pain	1	13OCT2020	17/2	2	No	O	NA/TC	R (14OCT2020)	N/N

16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442274	GASTR	Diarrhoea/ diarrhea	2	12NOV2020	2/2	1	Yes		NA	R (13NOV2020)	N/N
16-55/ C4591001 4444 44442278	GENRL	Pyrexia/ Fever	2	16OCT2020	2/2	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442281	VASC	Hypertensive urgency/ Hypertensive urgency	2	04MAR2021	141/1	3	No	O	NA/TC	R (04MAR2021)	Y/N
16-55/ C4591001 4444 44442281	GASTR	Toothache/ Odontalgia	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44442299	INFEC	Gingivitis/ gingivitis	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44442304	INFEC	Tooth infection/ odontogenic infection	1	10OCT2020	14/5	1	No	O	NA/TC	R (14OCT2020)	N/N
16-55/ C4591001 4444 44442306	GENRL	Injection site pain/ Post vaccination injection site pain.	2	17OCT2020	2/1	1	Yes		NA/TC	R (17OCT2020)	N/N
16-55/ C4591001 4444 44442304	METAB	Hyperglycaemia/ hyperglycemia	2	29OCT2020	15/C	1	No	O	NA/TC	N	N/N
16-55/ C4591001 4444 44442306	MUSC	Myalgia/ Myalgia	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N

## 16.2.7.4.1.2 Listing of Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	NERV	Headache/ Headache with mild retro ocular pain	2	16OCT2020	2/3	1	Yes		NA/TC	R (18OCT2020)	N/N
16-55/ C4591001 4444 44442311	GENRL	Pyrexia/ Fever	2	24OCT2020	2/3	1	Yes		NA/TC	R (26OCT2020)	N/N
16-55/ C4591001 4444 44442314	VASC	Hypotension/ Mild arterial hypotension	2	12FEB2021	121/1	1	No	O	NA	R (12FEB2021)	N/N
16-55/ C4591001 4444 44442317	GENRL	Injection site pain/ pain at the injection site	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N
		Pyrexia/ fever	2	16OCT2020	1/1	1	Yes		NA/TC	R (16OCT2020)	N/N
16-55/ C4591001 4444 44442319	PSYCH	Panic attack/ Worsening of panic attacks	1	15OCT2020	19/C	3	No	O	P/W	N	N/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = prevaccination AE, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (18:13)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: .nda2\_unblinded/C4591001\_EUA\_1655/adae\_1002\_1655

**16.2.7.5.1 Listing of Serious Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational		SAE/Imm AE (Yes/No)
										Vaccine Dose/ Subject	Outcome (End Date)	
12-15	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
	C4591001 1007 10071581	INFEC	Appendicitis/ Appendicitis	2	11MAR2021	64/C	3	No	O	NA/TC	RG	Y/N
	C4591001 1007 10071620	NERV	Neuralgia/ generalized Functional neurologic pain	2	21JAN2021	2/C	2	No	O	NA/TC	RG	Y/N
		GASTR	Abdominal pain/ Functional Abdominal Pain	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
			Constipation/ Constipation	2	28FEB2021	40/C	3	No	O	NA/TC	N	Y/N
	C4591001 1039 10391326	PSYCH	Depression/ Depression Exacerbation	1	26JAN2021	16/5	3	No	O	NA/TC/TCN	R (30JAN2021)	Y/N
	C4591001 1123 11231507	PSYCH	Depression/ Worsening of Depression	2	19JAN2021	2/5	2	No	O	NA/TC	R (23JAN2021)	Y/N
	C4591001 1147 11471281	INFEC	Appendicitis/ Acute appendicitis	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
			Focal peritonitis/ localized peritonitis, without perforation or gangrene	2	22JAN2021	19/2	4	No	O	NA/TC/TCN	R (23JAN2021)	Y/N
	C4591001 1270 12701222	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	16FEB2021	40/C	3	No	O	NA/TCN	N	Y/N
	16-25	C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N
C4591001 1005 10051411		GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
C4591001 1129 11291260#		IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N

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**16.2.7.5.1 Listing of Serious Adverse Events – Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> /Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Investigational Vaccine Dose/Subject	Action: Outcome (End Date)	SAE/Imm AE (Yes/No)
	C4591001 1150 11501153#	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
	C4591001 1203 12031026	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
	C4591001 1231 12311281	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
	C4591001 1231 12311387	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
	C4591001 1246 12461070	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
	C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: # = AE occurring on or after subject unblinding date.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_sae\_ped



## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1003 10031111	MUSC	Psoriatic arthropathy/ psoriatic arthritis	2	26SEP2020	38/C	2	Yes		NA/TC	N	Y/N
16-55/ C4591001 1003 10031197	CONG	Congenital ureteropelvic junction obstruction/ Congenital right ureteropelvic junction obstruction	2	01DEC2020	90/58	3	No	O	NA/TC/TCN	R (27JAN2021)	Y/N
16-55/ C4591001 1003 10031207	VASC	Deep vein thrombosis/ bilateral lower extremity DVT	2	27DEC2020	115/48	3	No	O	NA/TC	R (12FEB2021)	Y/N
	RESP	Pulmonary embolism/ pulmonary embolism	2	28DEC2020	116/15	3	No	O	NA/TC	R (11JAN2021)	Y/N
16-55/ C4591001 1005 10051054	GENRL	Non-cardiac chest pain/ INTERMITTENT NON CARDIAC CHEST PAIN	2	09SEP2020	6/9	2	No	O	NA	R (17SEP2020)	Y/N
16-55/ C4591001 1005 10051411	GASTR	Abdominal pain/ ABDOMINAL PAIN	2	29JAN2021	2/4	3	No	O	NA/TC	R (01FEB2021)	Y/N
16-55/ C4591001 1006 10061176	RESP	Asthma/ Acute Asthma Exacerbation#	2	03FEB2021	77/8	3	No	O	NA/TC	R (10FEB2021)	Y/N
16-55/ C4591001 1007 10071276	NEOPL	Chronic myeloid leukaemia/ chronic myelogenous leukemia	2	24SEP2020	8/C	4	No	O	NA/TC	RG	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1008 10081152	NERV	Optic neuritis/ Optic neuritis left eye	2	09DEC2020	80/14	3	No	O	NA/TC	R (22DEC2020)	Y/N	
16-55/ C4591001 1013 10131084	GENRL	Vascular stent occlusion/ OBSTRUCTED RENAL STENT (ARTERY)	2	01SEP2020	7/C	2	No	O	NA	RG	Y/N	
16-55/ C4591001 1013 10131089	VASC	Deep vein thrombosis/ LEFT ARM DEEP VEIN THROMBOSIS	2	20DEC2020	116/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131165	RESP	Pulmonary embolism/ Pulmonary Embolism Bilateral	2	14DEC2020	104/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1013 10131190	RENAL	Nephrolithiasis/ kidney stones	2	04JAN2021	119/2	3	No	O	NA/TCN	R (05JAN2021)	Y/N	
16-55/ C4591001 1013 10131255	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N	
16-55/ C4591001 1013 10131653	VASC	Deep vein thrombosis/ RIGHT LOWER EXTREMITY DEEP VEIN THROMBOSIS	2	15NOV2020	20/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001	METAB	Diabetic ketoacidosis/ DIABETIC KETOACIDOSIS	2	18JAN2021	84/4	3	No	O	NA/TC	R (21JAN2021)	Y/N	

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1013 10131656 16-55/ C4591001	HEPAT	Cholecystitis/ CHOLECYSTITIS#	3	07MAR2021	12/4	2	No	O	NA/TC	R (10MAR2021)	Y/N
1013 10131718 16-55/ C4591001	GENRL	Shoulder injury related to vaccine administration/ SIRVA - shoulder injury related to vaccine administration	2	09SEP2020	1/153	3	Yes		NA	R (08FEB2021)	Y/N
1015 10151047 16-55/ C4591001	NERV	Brachial plexopathy/ left brachial nerve plexopathy#	3	11JAN2021	20/18	3	No	O	NA	R (28JAN2021)	Y/N
1016 10161120 16-55/ C4591001	NEOPL	Intraductal proliferative breast lesion/ ductal carcinoma in situ, right breast	2	26OCT2020	48/45	2	No	O	NA/TCN	R (09DEC2020)	Y/N
1016 10161128 16-55/ C4591001	CARD	Atrial fibrillation/ atrial fibrillation	2	09OCT2020	8/4	2	No	O	NA/TC	R (12OCT2020)	Y/N
1016 10161277 16-55/ C4591001	INJ&P	Facial bones fracture/ facial fractures	2	31OCT2020	25/C	3	No	O	NA/TC	RG	Y/N
1016 10161289 16-55/ C4591001	INFEC	Appendicitis/ Appendicitis	2	06JAN2021	136/3	4	No	O	NA/TC/TCN	R (08JAN2021)	Y/N
1018 10181031											

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1018 10181090	VASC	Deep vein thrombosis/ Deep Vein Thrombosis, left leg	2	27NOV2020	93/C	3	No	O	NA/TC	RG	Y/N	
	RESP	Pulmonary embolism/ Pulmonary Embolism, bilateral, segmental and sub segmental	2	14DEC2020	110/C	4	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1018 10181159	NERV	Paraesthesia/ Right Leg Paresthesia	2	20OCT2020	47/C	2	Yes		NA/TC	RG	Y/N	
16-55/ C4591001 1019 10191145	NEOPL	Breast cancer/ Ductal carcinoma right Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Invasive ductal breast carcinoma/ Ductal Carcinoma Left Breast	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
		Metastases to lymph nodes/ Right Axillary Metastases	2	13NOV2020	52/C	3	No	O	NA/TC	N	Y/N	
	INJ&P	Intentional overdose/ Overdose Intentional#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
	PSYCH	Suicide attempt/ Attempted Suicide#	2	09MAR2021	168/2	3	No	CD	NA	RS (10MAR2021)	Y/N	
16-55/ C4591001 1019 10191226	INFEC	COVID-19/ COVID-19 Illness	2	28DEC2020	76/27	3	No	O	NA	R (23JAN2021)	Y/N	
16-55/ C4591001	INFEC	Urinary tract infection/ Urinary Tract Infection	1	15OCT2020	11/10	3	No	O	NA/TC	R (24OCT2020)	Y/N	

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1019 10191254 16-55/ C4591001 1021 10211127	CARD	Acute left ventricular failure/ NYHA Class IV Acute on Chronic Systolic Heart Failure	2	19OCT2020	27/3	3	No	O	NA/TC	R (21OCT2020)	Y/N
	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N
16-55/ C4591001 1022 10221164	NEOPL	Plasma cell myeloma/ IGA Kappa Multiple Myeloma	2	27NOV2020	51/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1028 10281033	SOCCI	Miscarriage of partner/ miscarriage for pregnant partner	2	22DEC2020	103/1	2	No	O	NA	R (22DEC2020)	Y/N
16-55/ C4591001 1028 10281059	NEOPL	Invasive ductal breast carcinoma/ invasive ductal carcinoma stage 1B, left breast	2	30SEP2020	15/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1028 10281060	INJ&P	Upper limb fracture/ Closed fracture of right elbow	2	28OCT2020	42/2	2	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1030 10301110	INFEC	Pharyngitis streptococcal/ pharyngitis streptococcal#	2	17JAN2021	101/14	2	No	O	NA/TC	R (30JAN2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1037 10371052	RESP	Dyspnoea/ INCREASED SHORTNESS OF BREATH#	2	31JAN2021	140/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1042 10421034	HEPAT	Cholecystitis/ cholecystitis#	2	07FEB2021	167/3	3	No	O	NA/TC/TCN	R (09FEB2021)	Y/N
16-55/ C4591001 1044 10441152†	NEOPL	Breast cancer/ breast cancer initial diagnosis	2	28DEC2020	71/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1046 10461175	INFEC	COVID-19/ CoVid19	2	14JAN2021	115/12	3	No	O	NA/TC	R (25JAN2021)	Y/N
16-55/ C4591001 1048 10481032	GASTR	Gastritis/ Worsening of gastritis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
		Impaired gastric emptying/ Worsening of gastroparesis	2	14FEB2021	153/4	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1052 10521172	NERV	Seizure/ Seizure#	4	05FEB2021	11/1	1	No	O	NA/TC	R (05FEB2021)	Y/N
16-55/ C4591001 1055 10551176	CARD	Arteriospasm coronary/ Coronary vasospasm	2	25SEP2020	3/2	3	No	O	NA	R (26SEP2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1057 10571065	HEPAT	Cholecystitis acute/ ACUTE CHOLECYSTITIS#	2	05FEB2021	150/4	3	No	O	NA/TCN	R (08FEB2021)	Y/N
	INFEC	Postoperative abscess/ POST CHOLECYSTECTOMY ABSCESS#	2	12FEB2021	157/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1057 10571137	NEOPL	Uterine leiomyoma/ WORSENING OF UTERINE FIBROIDS	1	14SEP2020	14/6	2	No	O	NA/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1066 10661242	RESP	Pulmonary embolism/ Pulmonary Embolism with bilateral lower lobe Pulmonary embolisms#	4	15FEB2021	6/2	3	No	O	NA/TC	RS (16FEB2021)	Y/N
16-55/ C4591001 1077 10771137	INJ&P	Tibia fracture/ LEFT TIBIAL PLATEAU FRACTURE	2	28JAN2021	134/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N
16-55/ C4591001 1079 10791199	NERV	Seizure/ Seizure#	2	03MAR2021	169/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001	INFEC	Appendicitis/ Appendicitis	2	09FEB2021	153/1	3	No	O	NA/TCN	R (09FEB2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1080 10801059 16-55/ C4591001 1081 10811036	INFEC	Appendicitis/ Appendicitis	1	21AUG2020	9/3	3	No	O	NA/TC/TCN	R (23AUG2020)	Y/N
16-55/ C4591001 1081 10811046	METAB	Diabetic ketoacidosis/ Diabetic Ketoacidosis	2	17SEP2020	9/2	3	No	O	NA	R (18SEP2020)	Y/N
16-55/ C4591001 1081 10811135	CARD	Myocardial infarction/ Myocardial Infarction	2	21OCT2020	30/8	4	No	O	NA/TC/TCN	RS (28OCT2020)	Y/N
16-55/ C4591001 1081 10811194	METAB	Type 2 diabetes mellitus/ Type II Diabetes Mellitus	2	27OCT2020	36/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N
16-55/ C4591001 1082 10821083	CARD	Myocardial infarction/ myocardial infarction	2	28OCT2020	62/8	4	No	O	NA	R (04NOV2020)	Y/N
16-55/ C4591001 1082 10821149	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N



## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1083 10831029	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N
16-55/ C4591001 1083 10831060	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N
16-55/ C4591001 1083 10831162	PREG	Abortion spontaneous/ Miscarriage	2	04DEC2020	80/2	2	No	O	NA	R (05DEC2020)	Y/N
16-55/ C4591001 1083 10831194	CARD	Atrial fibrillation/ New Onset Atrial Fibrillation with rapid ventricular response	2	26OCT2020	34/C	2	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1084 10841141	INFEC	Appendicitis/ Appendicitis	2	20DEC2020	110/3	3	No	O	NA/TC/TCN	R (22DEC2020)	Y/N
16-55/ C4591001 1084 10841317	INFEC	Cellulitis/ Cellulitis in Left leg	1	08SEP2020	12/9	2	No	O	NA/TC/TCN	R (16SEP2020)	Y/N
16-55/ C4591001 1084 10841480	CARD	Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N
16-55/ C4591001	PSYCH	Bipolar I disorder/ Bipolar I#	2	31JAN2021	63/C	3	No	O	NA/TC/TCN	RG	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1084 10841538 16-55/ C4591001 1085 10851018	REPRO	Endometrial thickening/ Endometrial thickening#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N
		Endometriosis/ Endometriosis#	2	09FEB2021	172/3	3	No	O	NA/TCN	R (11FEB2021)	Y/N
16-55/ C4591001 1088 10881220	NEOPL	Meningioma/ right frontal meningioma	1	23SEP2020	6/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1089 10891065	INFEC	Diabetic foot infection/ Infection right pinky toe (secondary to diabetes)	2	17JAN2021	144/33	3	No	O	NA/TC/TCN	R (18FEB2021)	Y/N
16-55/ C4591001 1089 10891182	INJ&P	Hip fracture/ Left Hip Closed Fracture	1	09SEP2020	16/17	3	No	O	NA/TC	R (25SEP2020)	Y/N
	PSYCH	Psychotic disorder/ Psychosis	1	27SEP2020	34/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1089 10891289	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N
16-55/ C4591001 1090 10901140	INFEC	Appendicitis perforated/ acute appendicitis with perforation#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1090 10901384	REPRO	Focal peritonitis/ localized peritonitis#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
		Pelvic abscess/ pelvic abscess#	3	04FEB2021	9/8	4	No	O	NA/TC/TCN	R (11FEB2021)	Y/N
		Adnexal torsion/ Right ovarian torsion	2	07DEC2020	63/6	4	No	O	NA/TCN	R (12DEC2020)	Y/N
16-55/ C4591001 1090 10901536	INFEC	Pyelonephritis/ pyelonephritis	2	11FEB2021	91/2	2	No	O	NA/TC	R (12FEB2021)	Y/N
16-55/ C4591001 1091 10911197	INJ&P	Toxicity to various agents/ poisoning by cocaine	2	26SEP2020	10/2	4	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
	RESP	Hypoxia/ hypoxia	2	26SEP2020	10/2	3	No	O	NA/TC/TCN	R (27SEP2020)	Y/N
		Pneumonia aspiration/ Aspiration Pneumonia	2	26SEP2020	10/11	3	No	O	NA/TC	R (06OCT2020)	Y/N
16-55/ C4591001 1091 10911300	INFEC	Appendicitis/ Appendicitis	2	21OCT2020	16/2	4	No	O	NA/TCN	R (22OCT2020)	Y/N
16-55/ C4591001 1093 10931067	INFEC	Subcutaneous abscess/ Cutaneous abscess of left upper extremity#	2	20FEB2021	158/17	1	No	O	NA/TC	R (08MAR2021)	Y/N
16-55/ C4591001	INJ&P	Colon injury/ colon injury	1	16OCT2020	22/8	3	No	O	NA/TC/TCN	RS (23OCT2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1094 10941155 16-55/ C4591001 1095 10951009	REPRO	Adnexal torsion/ torsion of right ovary	2	23DEC2020	125/27	3	No	O	NA/TC/TCN	R (18JAN2021)	Y/N
16-55/ C4591001 1095 10951173	CARD	Acute myocardial infarction/ STEMI: ST elevation Myocardial Infarction	1	05SEP2020	8/5	4	No	O	NA/TC/TCN	R (09SEP2020)	Y/N
16-55/ C4591001 1095 10951197	MUSC	Intervertebral disc degeneration/ exacerbation of Degenerative Disc Disease	2	14JAN2021	88/2	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
16-55/ C4591001 1096 10961036	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N
16-55/ C4591001 1096 10961062	METAB	Hypokalaemia/ HYPOKALEMIA	2	SEP2020	1/	3	No	O	NA/TC	R	Y/N
	MUSC	Muscular weakness/ bilateral lower extremity weakness	2	04OCT2020	26/2	3	No	O	NA	R (05OCT2020)	Y/N
16-55/ C4591001 1101 11011115	PREG	Abortion spontaneous/ spontaneous abortion#	2	20FEB2021	101/1	3	No	O	NA	R (20FEB2021)	Y/N
16-55/ C4591001	GASTR	Colitis/ ASCENDING COLITIS	2	25NOV2020	73/19	3	No	O	NA/TC	R (13DEC2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1107 11071031 16-55/ C4591001 1107 11071065	BLOOD	Microcytic anaemia/ MICROCYTIC ANEMIA	2	09NOV2020	75/C	3	No	O	NA/TC/TCN	N	Y/N
	INV	Red blood cell morphology abnormal/ ABNORMAL RBC MORPHOLOGY INCLUDING SICKLE CELLS	2	09NOV2020	75/C	3	No	O	NA	N	Y/N
16-55/ C4591001 1109 11091204	INFEC	Appendicitis/ ACUTE APPENDICITIS	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
		Peritoneal abscess/ Peritoneal Abscess	1	17AUG2020	7/17	4	No	O	NA/TC	R (02SEP2020)	Y/N
16-55/ C4591001 1109 11091448	NERV	Hemiplegic migraine/ Hemiplegic Migraine	2	20OCT2020	23/C	4	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1110 11101187	INFEC	Appendicitis/ Acute Appendicitis	2	07DEC2020	77/4	3	No	O	NA/TC/TCN	R (10DEC2020)	Y/N
16-55/ C4591001 1110 11101236	EYE	Visual impairment/ change in vision	2	06DEC2020	66/2	2	No	O	NA	R (07DEC2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1111 11111130	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	1	26AUG2020	9/9	2	No	O	NA/TC/TCN	R (03SEP2020)	Y/N
16-55/ C4591001 1112 11121122	NEOPL	Uterine leiomyoma/ Worsening INTRAMURAL AND SUBSEROUS LEIOMYOMA OF UTERUS	2	14SEP2020	14/66	3	No	O	NA/TCN	R (18NOV2020)	Y/N
16-55/ C4591001 1116 11161059	GASTR	Obstructive pancreatitis/ Gall Stone Pancreatitis	1	13SEP2020	14/6	3	No	O	NA/TC/TCN	R (18SEP2020)	Y/N
	HEPAT	Bile duct stone/ Cholelithiasis	1	13SEP2020	14/7	3	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1117 11171036	NERV	Syncope/ Syncopal Episode	1	26AUG2020	7/5	4	No	O	NA	R (30AUG2020)	Y/N
	PSYCH	Suicidal ideation/ Suicidal ideation	1	27AUG2020	8/4	4	No	O	NA/TC	R (30AUG2020)	Y/N
	PSYCH	Suicidal ideation/ SUICIDAL IDEATION	2	20NOV2020	72/6	4	No	O	NA/TC/TCN	R (25NOV2020)	Y/N
	PSYCH	Major depression/ MODERATE EPISODE OF MAJOR DEPRESSIVE DISORDER W/ PSYCHOSIS	2	30DEC2020	112/3	3	No	O	NA/TC/TCN	R (01JAN2021)	Y/N
16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1120 11201266	EYE	Blindness unilateral/ LOSS OF VISION LEFT EYE	2	04DEC2020	67/C	4	No	O	NA	N	Y/N	
	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N	
16-55/ C4591001 1121 11211112	INFEC	COVID-19/ COVID-19	2	24OCT2020	26/C	3	No	O	NA/TC	RS	Y/N	
16-55/ C4591001 1124 11241106	CARD	Acute myocardial infarction/ ST elevation myocardial infarction	2	27SEP2020	12/17	4	No	O	NA	R (13OCT2020)	Y/N	
16-55/ C4591001 1125 11251020	INJ&P	Cranocerebral injury/ traumatic brain injury	2	23DEC2020	111/30	3	No	O	NA/TC	R (21JAN2021)	Y/N	
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N	
16-55/ C4591001 1128 11281103	INFEC	Escherichia urinary tract infection/ Escherichia coli urinary tract infection	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
	METAB	Hypokalaemia/ Severe Hypokalemia	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	
	RENAL	Nephrolithiasis/ Kidney Stones	2	03OCT2020	33/20	2	No	O	NA/TC	R (22OCT2020)	Y/N	

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1128 11281123	INFEC	Appendicitis/ APPENDICITIS#	2	15JAN2021	129/2	3	No	O	NA/TC/TCN	R (16JAN2021)	Y/N	
16-55/ C4591001 1128 11281153	HEPAT	Hepatocellular injury/ Hepatocellular injury	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N	
	INFEC	Sepsis/ Sepsis	2	04NOV2020	57/10	3	No	O	NA/TC	R (13NOV2020)	Y/N	
16-55/ C4591001 1128 11281267	REPRO	Vaginal prolapse/ Vaginal Prolapse	2	01DEC2020	70/18	3	No	O	NA/TCN	R (18DEC2020)	Y/N	
	REPRO	Rectocele/ Rectocele	2	17DEC2020	86/2	3	No	O	NA/TCN	R (18DEC2020)	Y/N	
16-55/ C4591001 1129 11291005	GASTR	Intestinal obstruction/ bowel obstruction	2	21JAN2021	157/2	4	No	O	NA/TC/TCN	RS (22JAN2021)	Y/N	
16-55/ C4591001 1129 11291045	INJ&P	Wrist fracture/ compound fracture left wrist	2	31JAN2021	160/C	2	No	O	NA/TCN	N	Y/N	
16-55/ C4591001 1129 11291260	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N	
16-55/ C4591001	PSYCH	Anxiety/ Increased Anxiety#	3	02MAR2021	21/C	3	No	O	NA/TC	N	Y/N	



## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1131 11311094	PSYCH	Major depression/ Major Depressive Disorder, single episode#	3	03MAR2021	22/C	3	No	O	NA/TC	N	Y/N
		Suicide attempt/ Suicidal Attempt#	3	03MAR2021	22/3	3	No	O	NA	R (05MAR2021)	Y/N
16-55/ C4591001 1133 11331317	NEOPL	Brain cancer metastatic/ Metastatic Brain Tumor#	2	08FEB2021	139/17	3	No	O	NA/TC	R (24FEB2021)	Y/N
16-55/ C4591001 1134 11341327	INFEC	Pneumonia/ DOUBLE PNEUMONIA#	2	10MAR2021	160/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1135 11351265	VASC	Accelerated hypertension/ accelerated hypertension	2	23JAN2021	121/5	3	No	O	NA/TC	R (27JAN2021)	Y/N
16-55/ C4591001 1135 11351368	NERV	Guillain-Barre syndrome/ Guillain barre syndrome	2	29DEC2020	84/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1135 11351563	GASTR	Pancreatitis acute/ acute pancreatitis	2	21NOV2020	2/4	2	No	O	NA/TC	R (24NOV2020)	Y/N
16-55/ C4591001	IMMUN	Anaphylactic reaction/ Anaphylaxis Status Post Bee Sting	2	28AUG2020	9/1	4	No	O	NA/TC	R (28AUG2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1140 11401009 16-55/ C4591001	NEOPL	B-cell lymphoma/ B-Cell Lymphoma	2	03DEC2020	101/C	2	No	O	NA/TC	N	Y/N
1140 11401020 16-55/ C4591001	RESP	Pulmonary embolism/ Bilateral Pulmonary Embolisms#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N
1140 11401282	VASC	Deep vein thrombosis/ Deep Vein Thrombosis Left Leg#	4	15FEB2021	12/C	4	No	O	NA	RG	Y/N
16-55/ C4591001 1140 11401306	EYE	Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N
	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N
16-55/ C4591001 1141 11411153	CARD	Junctional ectopic tachycardia/ Junctional ectopic tachycardia	2	02OCT2020	12/97	4	No	O	NA/TC/TCN	RS (06JAN2021)	Y/N
16-55/ C4591001 1142 11421084	PSYCH	Suicidal ideation/ Suicidal Ideation	1	19AUG2020	8/3	4	No	O	NA/TC	R (21AUG2020)	Y/N
16-55/ C4591001 1142 11421202	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1145 11451042	GASTR	Ileus/ Ileus	2	25DEC2020	102/4	3	No	O	NA	R (28DEC2020)	Y/N
16-55/ C4591001 1145 11451059	INFEC	Appendicitis/ appendicitis	2	04JAN2021	109/4	3	No	O	NA/TC/TCN	R (07JAN2021)	Y/N
16-55/ C4591001 1145 11451063	NERV	Paraesthesia/ Paresthesias of Skin	1	21SEP2020	22/8	3	No	CD	NA/TC	R (28SEP2020)	Y/N
16-55/ C4591001 1146 11461133	PREG	Abortion spontaneous/ spontaneous abortion#	2	21JAN2021	126/1	3	No	O	NA	R (21JAN2021)	Y/N
	REPRO	Vaginal haemorrhage/ Vaginal Bleeding#	2	21JAN2021	126/2	2	No	O	NA	R (22JAN2021)	Y/N
16-55/ C4591001 1146 11461200	CARD	Bradycardia/ Acute Bradycardia	2	27SEP2020	3/2	3	No	O	NA/TC	R (28SEP2020)	Y/N
	NERV	Syncope/ syncope	2	27SEP2020	3/3	2	No	O	NA	R (29SEP2020)	Y/N
16-55/ C4591001 1146 11461302	INFEC	COVID-19/ COVID-19	2	14JAN2021	66/7	2	No	O	NA	R (20JAN2021)	Y/N
16-55/ C4591001	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1150 11501001 16-55/ C4591001	RENAL	Nephrolithiasis/ Kidney Stones	2	02DEC2020	86/7	3	No	O	NA/TC	R (08DEC2020)	Y/N
1150 11501022 16-55/ C4591001	PREG	Abortion spontaneous/ Spontaneous Miscarriage	2	19FEB2021	142/1	2	No	O	NA	R (19FEB2021)	Y/N
1150 11501084 16-55/ C4591001	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression#	3	02MAR2021	7/C	4	No	O	NA	RG	Y/N
1150 11501153 16-55/ C4591001	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N
1152 11521085 16-55/ C4591001	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N
1156 11561006 16-55/ C4591001	PREG	Abortion spontaneous incomplete/ INCOMPLETE SPONTANEOUS ABORTION	2	04OCT2020	25/4	3	No	O	NA/TCN	R (07OCT2020)	Y/N
1156 11561007 16-55/ C4591001	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
1156 11561124											

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Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1167 11671009	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N
	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	21AUG2020	5/2	3	No	O	NA/TC/TCN	R (22AUG2020)	Y/N
	HEPAT	Hepatitis acute/ Acute hepatitis#	4	25FEB2021	53/C	2	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1167 11671175	NERV	Cerebrovascular accident/ Cerebrovascular accident	2	21OCT2020	23/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1170 11701121	INJ&P	Lower limb fracture/ Right Lower Extremity Fracture#	4	22JAN2021	3/C	3	No	O	NA/TCN	RG	Y/N
16-55/ C4591001 1177 11771222	PREG	Abortion spontaneous/ Abortion Spontaneous#	2	23DEC2020	94/1		No	O	NA	R (23DEC2020)	Y/N
16-55/ C4591001 1178 11781107	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N
16-55/ C4591001 1178 11781257	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N
16-55/ C4591001	MUSC	Spondylolisthesis/ Spondylolisthesis L4/5#	2	05FEB2021	93/33	2	No	O	NA	R (09MAR2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1195 11951003 16-55/ C4591001	GASTR	Anal prolapse/ anal prolapse#	4	18FEB2021	10/10	3	No	O	NA	R (27FEB2021)	Y/N
1195 11951008 16-55/ C4591001	MUSC	Spondylolisthesis/ worsening of Spondylolisthesis	2	19DEC2020	47/29	3	No	O	NA/TC	R (16JAN2021)	Y/N
1195 11951017 16-55/ C4591001	MUSC	Intervertebral disc protrusion/ herniated disc cervical vertebra	2	16NOV2020	13/5	1	No	O	NA/TC/TCN	R (20NOV2020)	Y/N
1195 11951023 16-55/ C4591001	GASTR	Inguinal hernia/ inguinal hernia left	1	09NOV2020	21/103	2	No	O	NA/TC/TCN	R (19FEB2021)	Y/N
1203 12031026 16-55/ C4591001	INFEC	Anal abscess/ Anal Abscess	2	04JAN2021	35/3	2	No	O	NA/TC/TCN	R (06JAN2021)	Y/N
1205 12051075 16-55/ C4591001	NEOPL	Lipoma/ Encapsulated Lipoma	2	11JAN2021	41/10	2	No	O	NA/TC	R (20JAN2021)	Y/N
1205 12051077	RESP	Nasal septum deviation/ Nasal Septum Deviation	2	11JAN2021	41/10	2	No	O	NA/TC/TCN	R (20JAN2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1210 12101026	INFEC	Upper respiratory tract infection/ Acute upper respiratory tract infections	1	16NOV2020	18/22	3	No	O	NA/TC	R (07DEC2020)	Y/N
16-55/ C4591001 1212 12121024	CARD	Myocardial infarction/ Heart Attack#	2	03FEB2021	71/1	4	Yes		NA/TC/TCN	R (03FEB2021)	Y/N
16-55/ C4591001 1214 12141018	MUSC	Intervertebral disc protrusion/ recurrence vertebral disc herniation	1	18NOV2020	17/15	2	No	O	NA/TC/TCN	R (02DEC2020)	Y/N
	RESP	Pulmonary embolism/ pulmonary embolism	2	05DEC2020	13/1	2	No	O	NA/TC	R (05DEC2020)	Y/N
16-55/ C4591001 1218 12181001	HEPAT	Cholecystitis acute/ Acute cholecystitis#	2	18JAN2021	69/4	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N
16-55/ C4591001 1218 12181012	PSYCH	Alcohol abuse/ Alcohol abuse	2	09JAN2021	47/C	1	No	O	NA/TCN	RG	Y/N
16-55/ C4591001 1218 12181023	PSYCH	Alcohol withdrawal syndrome/ Alcohol withdrawal#	4	03MAR2021	30/2	2	No	O	NA/TC	R (04MAR2021)	Y/N
16-55/ C4591001 1218 12181046	HEPAT	Cholecystitis acute/ Acute Cholecystitis	1	20DEC2020	19/3	2	No	O	NA/TC	R (22DEC2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1218 12181051	RESP	Asthma/ Asthma exacerbation#	2	16JAN2021	25/3	1	No	O	NA/TC	R (18JAN2021)	Y/N
16-55/ C4591001 1218 12181057	GASTR	Oesophageal varices haemorrhage/ Esophageal varices hemorrhage	1	09JAN2021	33/1	4	No	O	NA/TC/TCN	R (09JAN2021)	Y/N
16-55/ C4591001 1221 12211007	INFEC	Meningitis bacterial/ Meningitis Bacterial	1	10NOV2020	26/23	3	No	O	NA/TC	R (02DEC2020)	Y/N
16-55/ C4591001 1223 12231014	INFEC	Appendicitis/ appendicitis	2	11JAN2021	116/4	4	No	O	NA/TC/TCN	R (14JAN2021)	Y/N
16-55/ C4591001 1223 12231075	GASTR	Gastrointestinal necrosis/ Bowel necrosis#	4	04FEB2021	30/C	4	No	O	NA/TC/TCN	N	Y/N
	INJ&P	Postoperative ileus/ Postoperative ileus#	4	11FEB2021	37/5	3	No	O	NA/TC	R (15FEB2021)	Y/N
	GASTR	Small intestinal obstruction/ Small Bowel Obstruction#	4	16FEB2021	42/4	3	No	O	NA/TC	R (19FEB2021)	Y/N
16-55/ C4591001 1223 12231166	VASC	Hypertensive urgency/ hypertensive urgency	2	28OCT2020	22/9	2	No	O	NA/TC	R (05NOV2020)	Y/N
16-55/ C4591001	INFEC	Herpes zoster oticus/ Ramsay Hunt Syndrome#	2	25JAN2021	153/21	4	No	O	NA/TC	RS (14FEB2021)	Y/N



## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1226 12261043 16-55/ C4591001 1226 12261067	RENAL	Nephrolithiasis/ Worsening of nephrolithiasis	2	09NOV2020	70/18	3	No	O	NA/TC	R (26NOV2020)	Y/N
1226 12261094 16-55/ C4591001 1226 12261136	RENAL	Nephrolithiasis/ Worsening of Nephrolithiasis	2	21DEC2020	112/33	3	No	O	NA/TC/TCN	R (22JAN2021)	Y/N
1226 12261137 16-55/ C4591001 1226 12261282	GASTR	Haemorrhoids/ Hemorrhoid Worsening	2	26JAN2021	145/2	4	No	O	NA/TC/TCN	R (27JAN2021)	Y/N
1226 12261300 16-55/ C4591001 1226 12261338	INJ&P	Forearm fracture/ Right forearm fracture	2	20SEP2020	18/10	3	No	O	NA/TC/TCN	R (29SEP2020)	Y/N
	INFEC	Appendicitis/ Appendicitis	2	01OCT2020	22/3	3	No	O	NA/TC/TCN	R (03OCT2020)	Y/N
	RENAL	Renal colic/ Renal colic	1	29AUG2020	10/2	4	No	O	NA/TC/TCN	R (30AUG2020)	Y/N
	INFEC	Gastroenteritis/ Gastroenterocolitis	2	20NOV2020	73/10	2	No	O	NA/TC	R (29NOV2020)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1226 12261571	INJ&P	Cervical vertebral fracture/ Fracture of the fourth cervical vertebra	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
		Road traffic accident/ hit by motorcycle	2	21OCT2020	27/1	3	No	O	NA	R (21OCT2020)	Y/N	
		Spinal cord injury cervical/ Cervical spinal cord contusion	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
	NERV	Subarachnoid haemorrhage/ Subarachnoid hemorrhage	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
	RENAL	Subcapsular renal haematoma/ Peri-renal hematoma	2	21OCT2020	27/10	3	No	O	NA/TC	R (30OCT2020)	Y/N	
16-55/ C4591001 1226 12261583	RENAL	Ureterolithiasis/ Left ureteral stone	2	13NOV2020	46/3	2	No	O	NA/TCN	R (15NOV2020)	Y/N	
16-55/ C4591001 1226 12261745	NEOPL	Leydig cell tumour of the testis/ Leydig cell tumor in left testicle	1	23SEP2020	8/15	2	No	O	NA	R (07OCT2020)	Y/N	
16-55/ C4591001 1226 12261769	NERV	Idiopathic intracranial hypertension/ idiopathic intracranial hypertension	2	22OCT2020	16/9	3	No	O	NA/TC/TCN	R (30OCT2020)	Y/N	
	INFEC	Postoperative wound infection/ surgical site infection (Flank)	2	03NOV2020	28/39	3	No	O	NA/TC	R (11DEC2020)	Y/N	
16-55/ C4591001 1226 12261836	MUSC	Myalgia/ Muscle pain#	3	12FEB2021	21/2	3	No	O	NA/TC	R (13FEB2021)	Y/N	

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1226 12262000	INFEC	COVID-19/ COVID-19	2	20DEC2020	60/26	4	No	O	NA/TC/TCN	RS (14JAN2021)	Y/N
16-55/ C4591001 1226 12262052	VASC	Deep vein thrombosis/ Deep vein thrombosis in right lower limb	2	05JAN2021	72/9	2	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
16-55/ C4591001 1226 12262089	INFEC	Urinary tract infection/ Urinary tract infection	1	18OCT2020	13/5	3	No	O	NA/TC	R (22OCT2020)	Y/N
16-55/ C4591001 1226 12262129	NERV	Transient ischaemic attack/ Transient Ischemic Attack	2	04DEC2020	36/5	4	No	O	NA/TC	R (08DEC2020)	Y/N
16-55/ C4591001 1229 12291083†	METAB	Diabetes mellitus/ Diabetes Mellitus	2	28DEC2020	68/C	4	No	O	NA	N	Y/N
	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N
16-55/ C4591001 1231 12311081	INFEC	Arthritis bacterial/ septic arthritis of the right knee.	2	13DEC2020	104/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311118	RENAL	Nephrolithiasis/ worsening of renal lithiasis	2	21NOV2020	79/7	3	No	O	NA/TC	R (27NOV2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311128	NERV	Peripheral nerve lesion/ Right index finger collateral nerve lesion	2	08OCT2020	37/63	3	No	O	NA/TC/TCN	R (09DEC2020)	Y/N
16-55/ C4591001 1231 12311205	INJ&P	Ulna fracture/ Left arm olecranon fracture	2	17SEP2020	15/149	3	No	O	NA/TC/TCN	R (12FEB2021)	Y/N
16-55/ C4591001 1231 12311281	INFEC	Appendicitis/ acute appendicitis	2	18SEP2020	15/19	3	No	O	NA/TC/TCN	R (06OCT2020)	Y/N
16-55/ C4591001 1231 12311294	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	12DEC2020	97/33	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
16-55/ C4591001 1231 12311315	NEOPL	Malignant melanoma/ Pigmented epithelioid melanoma of the vagina	2	25SEP2020	23/C	2	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001 1231 12311352	GENRL	Influenza like illness/ Flu like syndrome	1	20AUG2020	6/9	3	No	O	NA	R (28AUG2020)	Y/N
16-55/ C4591001 1231 12311387	INFEC	Urinary tract infection/ Complicated Urinary Tract Infection	2	04JAN2021	123/15	3	No	O	NA/TC	R (18JAN2021)	Y/N
16-55/ C4591001	INFEC	Gangrene/ Rightfoot transmetatarsal limited gangrene	2	03DEC2020	88/77	3	No	O	NA/TC/TCN	RS (17FEB2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12311538 16-55/ C4591001 1231 12311556	INJ&P	Ligament rupture/ Rupture of the anterior cruciate ligament of the left knee	2	21NOV2020	76/75	2	No	O	NA/TCN	R (03FEB2021)	Y/N
		Meniscus injury/ Rupture of the external meniscus of the left knee	2	21NOV2020	76/75	2	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
16-55/ C4591001 1231 12311635	NEOPL	Benign hydatidiform mole/ Molar pregnancy in partner	2	JAN2021	120/	3	No	O	NA	R	Y/N
16-55/ C4591001 1231 12311711	INFEC	Urosepsis/ Urosepsis	2	15SEP2020	9/8	3	No	O	NA/TC	R (22SEP2020)	Y/N
16-55/ C4591001 1231 12311730	NEOPL	Invasive ductal breast carcinoma/ Right breast invasive ductal carcinoma	2	15NOV2020	70/C	2	No	O	NA	N	Y/N
16-55/ C4591001 1231 12311766	HEPAT	Biliary colic/ biliary colic	2	30OCT2020	54/5	3	No	O	NA/TC	R (03NOV2020)	Y/N
16-55/ C4591001 1231 12311812	PREG	Abortion spontaneous/ Complete miscarriage	2	27FEB2021	174/12	3	No	O	NA/TC	R (10MAR2021)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1231 12311834	INJ&P	Foot fracture/ Hallux fracture and second toe of the right foot	2	16SEP2020	10/35	3	No	O	NA/TC/TCN	R (20OCT2020)	Y/N	
16-55/ C4591001 1231 12311844	METAB	Hypoglycaemia/ severe hipoglycemia	2	16OCT2020	40/1	3	No	O	NA	R (16OCT2020)	Y/N	
16-55/ C4591001 1231 12311862	VASC	Aortic stenosis/ Severe aortic stenosis	2	13OCT2020	35/C	3	No	O	NA/TC	RG	Y/N	
16-55/ C4591001 1231 12311901	HEPAT	Cholecystitis chronic/ chronic lithiasic cholecystitis	2	27OCT2020	50/134	2	No	O	NA/TC/TCN	R (09MAR2021)	Y/N	
16-55/ C4591001 1231 12312125	INFEC	Appendicitis/ Acute appendicitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
		Peritonitis/ Peritonitis	2	06JAN2021	122/37	3	No	O	NA/TC/TCN	R (11FEB2021)	Y/N	
16-55/ C4591001 1231 12312205	PREG	Abortion spontaneous/ Spontaneous abortion	2	26NOV2020	81/4	2	No	O	NA/TC/TCN	R (29NOV2020)	Y/N	
16-55/ C4591001 1231 12312335	METAB	Hypoglycaemia/ Severe hypoglycemia	2	16DEC2020	100/8	3	No	O	NA/TC	R (23DEC2020)	Y/N	

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312390	MUSC	Osteochondritis/ Osteochondritis	1	05SEP2020	18/2	2	No	O	NA	R (06SEP2020)	Y/N
16-55/ C4591001 1231 12312420	INFEC	Appendicitis/ Acute Appendicitis	2	28DEC2020	110/16	3	No	O	NA/TC/TCN	R (12JAN2021)	Y/N
16-55/ C4591001 1231 12312476	HEPAT	Bile duct stone/ Choledochal lithiasis	2	23JAN2021	136/C	3	No	O	NA	N	Y/N
	HEPAT	Biliary colic/ Biliary colic	2	25FEB2021	169/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1231 12312576	RENAL	Nephrolithiasis/ nephrolithiasis	2	05NOV2020	58/47	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N
16-55/ C4591001 1231 12312593	CARD	Acute coronary syndrome/ Acute coronary syndrome without ST-T segment elevation	2	16SEP2020	6/4	2	No	O	NA/TC	R (19SEP2020)	Y/N
16-55/ C4591001 1231 12312696	CARD	Acute coronary syndrome/ acute coronary syndrome	2	22NOV2020	74/48	3	No	O	NA/TC/TCN	R (08JAN2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12312854	CARD	Arrhythmia supraventricular/ Arrhythmia supraventricular	2	17SEP2020	7/3	4	No	O	NA/TC/TCN	R (19SEP2020)	Y/N
16-55/ C4591001 1231 12312868	NERV	Syncope/ syncope	2	08OCT2020	1/1	3	No	O	NA/TCN	R (08OCT2020)	Y/N
16-55/ C4591001 1231 12312982	INFEC	Suspected COVID-19/ Suspected COVID-19 Illness	2	09SEP2020	1/6	3	No	O	NA/TC	R (14SEP2020)	Y/N
16-55/ C4591001 1231 12312996	RESP	Asthmatic crisis/ SEVERE ASTHMATIC CRISIS	2	21OCT2020	42/9	3	No	O	NA/TC/TCN	R (29OCT2020)	Y/N
16-55/ C4591001 1231 12313028	NERV	Optic neuritis/ Optic Neuritis	2	01DEC2020	82/C	3	No	O	NA/TC	RG	Y/N
16-55/ C4591001 1231 12313140	NEOPL	Papillary thyroid cancer/ Suspected papillary thyroid carcinoma	2	28JAN2021	137/C	3	No	O	NA/TCN	N	Y/N
16-55/ C4591001 1231 12313184	NERV	Carpal tunnel syndrome/ right carpal tunnel syndrome	2	15OCT2020	36/128	2	No	O	NA/TCN	R (19FEB2021)	Y/N
16-55/ C4591001	RENAL	Urinary bladder polyp/ Bladder polyp	2	18SEP2020	9/C	1	No	O	NA/TCN	RG	Y/N



## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12313193 16-55/ C4591001	NEOPL	Clear cell renal cell carcinoma/ Clear cell renal cell carcinoma	2	12OCT2020	32/C	3	No	O	NA/TCN	N	Y/N
1231 12313345 16-55/ C4591001	INFEC	Renal abscess/ Right kidney abscess	2	07DEC2020	86/C	2	No	O	NA/TC/TCN	RG	Y/N
1231 12313437 16-55/ C4591001	HEPAT	Cholelithiasis/ cholelithiasis	2	24DEC2020	103/13	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
1231 12313504 16-55/ C4591001	NERV	Ischaemic stroke/ Ischemic Stroke	2	06NOV2020	55/78	3	No	O	NA/TC	RS (22JAN2021)	Y/N
1231 12313653 16-55/ C4591001	HEPAT	Cholecystitis/ Cholecystitis	2	25DEC2020	104/35	2	No	O	NA/TC/TCN	R (28JAN2021)	Y/N
1231 12313689 16-55/ C4591001	INJ&P	Ankle fracture/ Right Ankle Fracture	2	02JAN2021	112/59	3	No	O	NA/TC/TCN	RS (01MAR2021)	Y/N
1231 12313715 16-55/ C4591001	INFEC	Appendicitis/ Acute appendicitis	2	22OCT2020	39/16	2	No	O	NA/TC/TCN	R (06NOV2020)	Y/N
1231 12313785											

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12313879	INFEC	Urinary tract infection/ Suspected Complicated Urinary Tract Infection	2	31JAN2021	141/18	3	No	O	NA/TC	R (17FEB2021)	Y/N
16-55/ C4591001 1231 12313998	PREG	Abortion spontaneous complete/ Complete spontaneous abortion#	2	24JAN2021	132/16	3	No	O	NA/TC	R (08FEB2021)	Y/N
16-55/ C4591001 1231 12314075	HEPAT	Cholelithiasis obstructive/ Cholestatic syndrome secondary to lithiasis#	2	05MAR2021	170/6	2	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001 1231 12314134	PREG	Abortion incomplete/ incomplete abortion	1	11FEB2021	170/3	3	No	O	NA/TC/TCN	R (13FEB2021)	Y/N
16-55/ C4591001 1231 12314407	INJ&P	Multiple injuries/ Polytrauma	2	20SEP2020	5/93	3	No	O	NA/TC/TCN	R (21DEC2020)	Y/N
16-55/ C4591001 1231 12314494	GASTR	Food poisoning/ Food poisoning	2	03FEB2021	141/5	3	No	O	NA/TC	R (07FEB2021)	Y/N
16-55/ C4591001 1231 12314531	INFEC	Urinary tract infection/ Complicated urinary infection	2	08JAN2021	103/47	3	No	O	NA/TC	R (23FEB2021)	Y/N
16-55/ C4591001	GASTR	Pancreatitis acute/ acute pancreatitis	2	30NOV2020	77/15	2	No	O	NA/TC	R (14DEC2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12314583 16-55/ C4591001	MUSC	Intervertebral disc protrusion/ Worsening of herniated disc	2	21SEP2020	5/107	3	No	O	NA/TC/TCN	R (05JAN2021)	Y/N
1231 12314813 16-55/ C4591001	INFEC	Appendicitis/ Acute Appendicitis	2	16OCT2020	29/9	3	No	O	NA/TC/TCN	R (24OCT2020)	Y/N
1231 12314833	INFEC	Abdominal abscess/ Intra-abdominal Abscess	2	29OCT2020	42/37	3	No	O	NA/TC/TCN	R (04DEC2020)	Y/N
16-55/ C4591001	INJ&P	Burns second degree/ Second degree burn of the right arm and forearm.#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N
1231 12314921		Burns third degree/ Third degree burn on the right hand#	2	27JAN2021	134/C	3	No	O	NA/TC/TCN	RG	Y/N
16-55/ C4591001	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N
1231 12314987											
16-55/ C4591001	NEOPL	Adenocarcinoma pancreas/ pancreatic ductal adenocarcinoma#	2	17FEB2021	154/C	3	No	O	NA/TC/TCN	RG	Y/N
1231 12315186											
16-55/ C4591001	EYE	Choroidal neovascularisation/ Myopic choroidal neovascular membrane of the left eye	1	06SEP2020	9/83	1	No	O	NA/TC	R (27NOV2020)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1231 12315291 16-55/ C4591001	CARD	Angina unstable/ Unstable Angina Pectoris	2	14OCT2020	26/3	3	No	O	NA/TCN	R (16OCT2020)	Y/N
1231 12315473 16-55/ C4591001	RENAL	Nephrolithiasis/ Nephrolithiasis	2	05DEC2020	78/48	3	No	O	NA/TC	R (21JAN2021)	Y/N
1231 12315498 16-55/ C4591001	INFEC	Gastroenteritis/ gastroenterocolitis	2	09JAN2021	113/3	2	No	O	NA/TC/TCN	R (11JAN2021)	Y/N
1231 12315622 16-55/ C4591001	GASTR	Gastroesophageal reflux disease/ Non-erosive reflux esophagitis#	3	31JAN2021	7/C	3	No	O	NA/TC/TCN	RG	Y/N
1241 12411053 16-55/ C4591001	REPRO	Breast hyperplasia/ Atypical intraductal hyperplasia in left breast	2	29SEP2020	21/2	2	No	O	NA/TC	R (30SEP2020)	Y/N
1241 12411206 16-55/ C4591001	INJ&P	Fall/ Fall from own height#	4	06MAR2021	17/1	3	No	O	NA	R (06MAR2021)	Y/N
1241 12411269		Scapula fracture/ Fracture of the anterior border of the right glenoid#	4	06MAR2021	17/C	3	No	O	NA/TCN	N	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1241 12411279	PREG	Retained products of conception/ RETAINED PRODUCTS OF CONCEPTION	1	14OCT2020	57/1	3	No	O	NA/TC	R (14OCT2020)	Y/N
16-55/ C4591001 1241 12411887	NEOPL	Teratoma/ High grade immature teratoma	2	18JAN2021	102/10	3	No	O	NA	R (27JAN2021)	Y/N
16-55/ C4591001 1241 12411978	INFEC	Cellulitis/ Cellulitis on the right foot	2	27DEC2020	76/C	2	No	O	NA/TC	N	Y/N
16-55/ C4591001 1241 12412053	INJ&P	Clavicle fracture/ Fracture of right clavicle#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
		Rib fracture/ Fracture of ribs#	2	31JAN2021	103/4	3	No	O	NA/TC/TCN	R (03FEB2021)	Y/N
		Road traffic accident/ Motor Vehicle Accident#	2	31JAN2021	103/1	3	No	O	NA	R (31JAN2021)	Y/N
16-55/ C4591001 1241 12412218	INFEC	Appendicitis/ APPENDICITIS	2	23NOV2020	18/3	3	No	O	NA/TC/TCN	R (25NOV2020)	Y/N
16-55/ C4591001 1246 12461070	PSYCH	Depression/ Worsening of depression	2	25DEC2020	63/22	3	No	O	NA/TC/TCN	R (15JAN2021)	Y/N
16-55/ C4591001	REPRO	Endometriosis/ Worsening of Endometriosis left ovary	2	06JAN2021	68/15	3	No	O	NA/TC/TCN	R (20JAN2021)	Y/N

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1246 12461131 16-55/ C4591001 1247 12471121	INJ&P	Flail chest/ Flail Chest	2	30OCT2020	10/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1247 12471137	MUSC	Intervertebral disc protrusion/ Worsening pain related to L5/S1 and L4/L5 disc protrusion	2	09NOV2020	20/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1247 12471226	PSYCH	Depression/ Severe depressive episode	2	04FEB2021	98/5	2	No	O	NA	R (08FEB2021)	Y/N
16-55/ C4591001 1251 12511031	METAB	Diabetes mellitus inadequate control/ worsening diabetes type 11#	4	25FEB2021	14/C	4	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 1251 12511033	NERV	Idiopathic intracranial hypertension/ Pseudotumor Cerebri	2	JAN2021	114/C	3	No	O	NA/TC	N	Y/N
16-55/ C4591001 1251 12511239	CARD	Myocardial ischaemia/ Myocardial ischemia	2	13NOV2020	12/4	4	No	O	NA/TC	R (16NOV2020)	Y/N
16-55/ C4591001 1260 12601075	INFEC	Appendicitis/ acute appendicitis	2	04DEC2020	64/5	2	No	O	NA/TC	R (08DEC2020)	Y/N

16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1260 12601108	INJ&P	Ankle fracture/ Closed trimalleolar fracture of right ankle#	4	09MAR2021	37/C	3	No	O	NA/TC	N	Y/N	
16-55/ C4591001 1261 12611006	INFEC	Abscess/ Lip Abscess	2	23SEP2020	7/9	3	No	O	NA/TC/TCN	R (01OCT2020)	Y/N	
		Cellulitis/ Lip cellulitis	2	23SEP2020	7/9	3	No	O	NA/TC	R (01OCT2020)	Y/N	
	IMMUN	Drug hypersensitivity/ Hypersensitivity to antibiotics	2	26SEP2020	10/2	3	No	CD	NA/TC	R (27SEP2020)	Y/N	
16-55/ C4591001 1265 12651101	METAB	Hypoglycaemia/ Hypoglycemia	1	12SEP2020	2/2	3	No	CD	NA/TC	R (13SEP2020)	Y/N	
16-55/ C4591001 1270 12701069	INFEC	Appendicitis/ APPENDICITIS	1	20SEP2020	17/3	3	No	O	NA/TC/TCN	R (22SEP2020)	Y/N	
16-55/ C4591001 4444 44441007	INJ&P	Procedural haemorrhage/ Intraoperative hemorrhage during an elective laparoscopic ovarian cystectomy	1	03OCT2020	13/5	3	No	O	NA/TC	R (07OCT2020)	Y/N	
16-55/ C4591001 4444 44441249	GASTR	Incarcerated inguinal hernia/ Incarcerated right inguinal hernia	1	05OCT2020	15/18	3	No	O	NA/TC/TCN	R (22OCT2020)	Y/N	
16-55/ C4591001	INFEC	Postoperative wound infection/ Surgical site infection	2	16NOV2020	36/12	2	No	O	NA/TC	R (27NOV2020)	Y/N	

## 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44441297 16-55/ C4591001 4444 44441550	GASTR	Intestinal perforation/ Intestinal perforation	2	23DEC2020	70/22	3	No	O	NA/TC/TCN	R (13JAN2021)	Y/N
4444 44441550	INFEC	Pneumonia/ Hospital-acquired pneumonia	2	30DEC2020	77/15	3	No	O	NA/TC	R (13JAN2021)	Y/N
16-55/ C4591001 4444 44441634	HEPAT	Cholecystitis acute/ Acute cholecystitis	2	28DEC2020	76/8	3	No	O	NA/TC/TCN	R (04JAN2021)	Y/N
16-55/ C4591001 4444 44441748	GASTR	Oesophageal food impaction/ esophageal impaction with food	1	28SEP2020	6/2	3	No	O	NA/TCN	R (29SEP2020)	Y/N
16-55/ C4591001 4444 44441771	MUSC	Back pain/ Exacerbation of low back pain	2	02NOV2020	19/C	3	No	O	NA/TC/TCN	N	Y/N
16-55/ C4591001 4444 44442021	INJ&P	Ankle fracture/ Right ankle fracture	2	15NOV2020	32/68	3	No	O	NA/TC/TCN	R (21JAN2021)	Y/N
16-55/ C4591001 4444 44442041	INJ&P	Humerus fracture/ Right displaced proximal humeral fracture	2	05DEC2020	51/41	2	No	O	NA/TC/TCN	R (14JAN2021)	Y/N
16-55/ C4591001	VASC	Hypertensive urgency/ Hypertensive urgency	2	04MAR2021	141/1	3	No	O	NA/TC	R (04MAR2021)	Y/N



### 16.2.7.5.2 Listing of Serious Adverse Events – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
4444 44442278											
<p>Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.            Note: MedDRA (v23.1) coding dictionary applied.            Note: * = prevaccination AE, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.            a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.            b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.            c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.            PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (12:07)            (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adae_l002_sae_1655</p>											

**16.2.7.6.1 Listing of Adverse Events Leading to Discontinuation –  
Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a/</sup> Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
12-15	C4591001 1006 10061272	PSYCH	Anxiety/ Worsening of anxiety	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
			Depression/ Worsening of Depression	1	23DEC2020	8/27	3	No	O	P/TC/TCN	R (18JAN2021)	Y/N
	C4591001 1147 11471327	GENRL	Pyrexia/ Fever (104.7)	1	06JAN2021	2/3	4	Yes		P/TC	R (08JAN2021)	N/N
16-25	C4591001 1096 10961031	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N
	C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N
		NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N
	C4591001 1129 11291260#	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N
C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: # = AE occurring on or after subject unblinding date.

a. Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.

b. Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.

c. Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

**16.2.7.6.1 Listing of Adverse Events Leading to Discontinuation –  
Subjects 12 Through 25 Years of Age (Reactogenicity Subset)**

Age Group (Years)	Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
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PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_1002\_disc\_ped

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1012 10121163	GENRL	Injection site dermatitis/ LEFT UPPER ARM DERMATITIS AT INJECTION SITE	1	11SEP2020	3/C	2	Yes		P/W	RG	N/N
16-55/ C4591001 1015 10151134	EAR	Vertigo/ Worsening and continuing episode of Vertigo	1	28AUG2020	2/116	2	Yes		P	R (21DEC2020)	N/N
16-55/ C4591001 1016 10161087	GENRL	Injection site swelling/ injection site swelling	1	10AUG2020	1/10	3	Yes		P/TC	R (19AUG2020)	N/N
16-55/ C4591001 1021 10211127	CARD	Cardiac failure congestive/ Acute on Chronic Combined Systolic and Diastolic Congestive Heart Failure	2	30NOV2020	69/20	4	No	O	NA/TC/W	F (19DEC2020)	Y/N
16-55/ C4591001 1027 10271105	IMMUN	Drug hypersensitivity/ Allergic Reaction to investigational product	1	29AUG2020	2/14	2	Yes		P/TC	R (11SEP2020)	N/N
16-55/ C4591001 1028 10281003	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29NOV2020	87/C		Yes		NA/W	N	N/N
16-55/ C4591001 1044 10441163	GENRL	Injection site pain/ Injection site pain#	3	04MAR2021	1/1	1	Yes		NA/TC/W	R (04MAR2021)	N/N
16-55/ C4591001	GASTR	Dysphagia/ Dysphagia	1	AUG2020	1/C	1	No	O	P	N	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Vax Grade Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)		
1055 10551145 16-55/ C4591001 1079 10791004	NEOPL	Adenocarcinoma gastric/ INFILTRATING, POORLY DIFFERENTIATED ADENOCARCINOMA - STOMACH	1	20AUG2020	23/C	3	No	O	P/W	N	Y/N	
16-55/ C4591001 1081 10811194	CARD	Myocardial infarction/ Myocardial Infarction	2	04NOV2020	37/1	4	No	O	NA/W	F (04NOV2020)	Y/N	
16-55/ C4591001 1082 10821149	NEOPL	Malignant melanoma/ Malignant Melanoma (etiology unknown)	2	24NOV2020	63/C	3	No	O	NA/W	N	Y/N	
16-55/ C4591001 1083 10831029	CARD	Atrial fibrillation/ Paroxysmal Atrial fibrillation with rapid ventricular response	1	23AUG2020	20/17	3	No	O	P/TC/TCN	R (08SEP2020)	Y/N	
16-55/ C4591001 1083 10831060	GASTR	Diverticular perforation/ Ruptured diverticulum	1	14AUG2020	9/11	4	No	O	P/TC/TCN	R (24AUG2020)	Y/N	
16-55/ C4591001 1085 10851129	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	23DEC2020	105/C		No	O	NA/W	N	N/N	
16-55/ C4591001 1087 10871354	MUSC	Myalgia/ Myalgia	1	11SEP2020	4/C	1	Yes		P/W	N	N/N	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1087 10871557	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	24OCT2020	11/C		No	O	P	UNK	N/N
16-55/ C4591001 1089 10891289	HEPAT	Acute hepatic failure/ Acute Liver Failure#	2	19DEC2020	79/C	4	No	O	NA/W	N	Y/N
16-55/ C4591001 1090 10901140	GENRL	Injection site pain/ Injection site pain-right arm#	4	18FEB2021	1/3	2	Yes		NA/TC/W	R (20FEB2021)	N/N
16-55/ C4591001 1090 10901507	SKIN	Urticaria/ Hives, upper chest	1	19OCT2020	4/4	2	Yes		P/TC	R (22OCT2020)	N/N
16-55/ C4591001 1091 10911297	GENRL	Fatigue/ fatigue#	3	22FEB2021	1/5	2	Yes		NA/W	R (26FEB2021)	N/N
16-55/ C4591001 1093 10931058	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		25AUG2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1095 10951141	SKIN	Diabetic foot/ Diabetic Foot Ulcer R Foot	1	14SEP2020	20/C	1	No	O	P/TCN/W	N	N/N
16-55/ C4591001	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	14AUG2020	1/40		No	O	P	R (22SEP2020)	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
1096 10961031 16-55/ C4591001 1096 10961036	PSYCH	Depression suicidal/ worsening of depression with suicidal ideation	2	OCT2020	23/	3	No	O	P/TC	RS (14NOV2020)	Y/N	
16-55/ C4591001 1117 11171186	PSYCH	Suicide attempt/ SUICIDAL IDEATION WITH ATTEMPT	1	19OCT2020	14/8	3	No	O	P/TC/TCN	R (26OCT2020)	Y/N	
16-55/ C4591001 1120 11201266	NEOPL	Lung cancer metastatic/ Metastatic Lung cancer	2	04DEC2020	67/47	4	No	O	NA/TC/W	F (19JAN2021)	Y/N	
16-55/ C4591001 1122 11221026	GASTR	Vomiting/ vomiting*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
	NERV	Presyncope/ pre-syncope*		11SEP2020	/1	1	No	O	NA/W	R (11SEP2020)	N/N	
16-55/ C4591001 1125 11251243	GENRL	Injection site pain/ Grade 3 Pain at Injection site	1	09DEC2020	2/1	3	Yes		P	R (09DEC2020)	N/N	
	NERV	Headache/ Grade 3 Headache	1	09DEC2020	2/1	3	Yes		P/TC	R (09DEC2020)	N/N	
16-55/ C4591001 1126 11261017	IMMUN	Allergy to vaccine/ VACCINE ALLERGIC REACTION#	3	07JAN2021	1/2	2	Yes		P/TC/TCN	R (08JAN2021)	N/Y	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1127 11271112	CARD	Cardio-respiratory arrest/ Cardiopulmonary arrest	2	04DEC2020	86/1	4	No	O	NA/W	F (04DEC2020)	Y/N	
16-55/ C4591001 1128 11281241	NEOPL	Breast cancer/ Breast Cancer	2	NOV2020	42/C	3	No	O	NA/TC/W	RG	N/N	
16-55/ C4591001 1129 11291260	IMMUN	Anaphylactoid reaction/ Anaphylactoid Reaction#	3	27JAN2021	3/1	4	Yes		P/TC	R (27JAN2021)	Y/N	
16-55/ C4591001 1134 11341153	EYE	Eye pain/ right eye pain	1	25AUG2020	2/28	2	Yes		P	R (21SEP2020)	N/N	
16-55/ C4591001 1134 11341174	NERV	Headache/ WORSENING HEADACHE	1	27AUG2020	2/8	2	Yes		P/TC	R (03SEP2020)	N/N	
16-55/ C4591001 1140 11401306	EYE	Visual impairment/ Change in Visual Perception	1	07NOV2020	17/3	3	No	O	P/W	R (09NOV2020)	Y/N	
	NERV	Amnesia/ short term memory loss	1	07NOV2020	17/4	1	No	O	P/TC/TCN	R (10NOV2020)	Y/N	
		Paraparesis/ Worsening of Chronic Spastic Paraparesis	1	07NOV2020	17/C	3	No	O	P/TC/TCN	N	N/N	



16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)	
16-55/ C4591001 1152 11521085	GENRL	Death/ UNDETERMINED CAUSE OF DEATH	1	26AUG2020	8/1	4	No	O	P/W	F (26AUG2020)	Y/N	
16-55/ C4591001 1156 11561015	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY*		21AUG2020	1/C		No	O	P	UNK	N/N	
16-55/ C4591001 1156 11561124	INJ&P	Overdose/ MULTIPLE DRUG OVERDOSE	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
	RESP	Respiratory arrest/ RESPIRATORY ARREST	2	02NOV2020	32/1	4	No	O	NA/W	F (02NOV2020)	Y/N	
16-55/ C4591001 1163 11631059	IMMUN	Drug hypersensitivity/ Allergic Reaction to study investigational product	1	08AUG2020	2/18	2	Yes		P/TC	R (25AUG2020)	N/N	
16-55/ C4591001 1166 11661047	NERV	Dizziness/ Dizziness	1	31AUG2020	1/1	1	Yes		P	R (31AUG2020)	N/N	
16-55/ C4591001 1170 11701013	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	2	NOV2020	55/C		No	O	NA/W		N/N	
16-55/ C4591001 1171 11711023	SKIN	Urticaria/ Urticaria on forehead, posterior neck, bilateral posterior hands and bilateral plantar areas#	3	10FEB2021	2/7	2	Yes		P/TC	R (16FEB2021)	N/N	

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
	SKIN	Angioedema/ Angioedema - Forehead#	3	11FEB2021	3/6	1	Yes		P/TC	R (16FEB2021)	N/N
16-55/ C4591001 1178 11781107	BLOOD	Lymphadenopathy/ right axilla lymphadenopathy	1	16SEP2020	13/66	2	Yes		P/TC	R (20NOV2020)	Y/N
16-55/ C4591001 1205 12051028	INV	Blood pressure increased/ Increasing of systolic and diastolic blood pressure*		30OCT2020	/1	2	No	O	NA/W	R (30OCT2020)	N/N
16-55/ C4591001 1217 12171031	INJ&P	Exposure during pregnancy/ exposure during pregnancy	1	30OCT2020	1/C		No	O	P	UNK	N/N
16-55/ C4591001 1224 12241065	INV	Heart rate irregular/ Irregular Heart Rate	1	24AUG2020	1/18	2	Yes		P	R (10SEP2020)	N/N
16-55/ C4591001 1226 12261072	MUSC	Myalgia/ Muscle pain (shoulders and neck, on the right body side)	1	18AUG2020	8/C	2	Yes		P/TC/W	N	N/N
16-55/ C4591001 1229 12291083†	INFEC	COVID-19 pneumonia/ Covid 19 Pneumonia	2	01JAN2021	72/5	4	No	O	NA/W	F (05JAN2021)	Y/N
16-55/ C4591001 1230 12301045†	INJ&P	Exposure during pregnancy/ Exposure during Pregnancy	1	20OCT2020	22/C		No	O	P	UNK	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1231 12311409	GASTR	Vomiting/ vomits*		15AUG2020	/1	1	No	O	P/TCN/W	R (15AUG2020)	N/N
	NERV	Syncope/ Syncope*		15AUG2020	/1	2	No	O	P/TCN/W	R (15AUG2020)	N/N
16-55/ C4591001 1231 12311926	NERV	Syncope/ Syncope*		18AUG2020	/1	2	No	O	NA/W	R (18AUG2020)	N/N
16-55/ C4591001 1231 12312577	NEOPL	Metastases to central nervous system/ Brain metastasis	1	28AUG2020	9/C	2	No	O	P/TC	N	Y/N
16-55/ C4591001 1231 12314987	CARD	Cardio-respiratory arrest/ Non-traumatic cardiorespiratory arrest	2	05DEC2020	81/2	4	No	O	NA/W	F (06DEC2020)	Y/N
16-55/ C4591001 1231 12315429	GENRL	Injection site pain/ pain at injection site	1	30AUG2020	1/18	2	Yes		P/TC/W	R (16SEP2020)	N/Y
16-55/ C4591001 1231 12315441	PSYCH	Depression/ Depressive syndrome	1	10SEP2020	12/137	3	No	O	P/TC	RS (24JAN2021)	N/N
16-55/ C4591001 1232 12321175	VASC	Hypertension/ high blood pressure	1	25SEP2020	23/29	2	No	O	P	R (23OCT2020)	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
16-55/ C4591001 1232 12321213	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	01OCT2020	23/C		No	O	P	UNK	N/N
16-55/ C4591001 1232 12321293	INJ&P	Exposure during pregnancy/ Exposure During Pregnancy	1	22OCT2020	22/C		No	O	P	RG	N/N
16-55/ C4591001 1232 12321299	VASC	Hypertension/ Hypertension*		06OCT2020	1/C	2	No	O	NA/W	UNK	N/N
16-55/ C4591001 1241 12411208	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	10FEB2021	6/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411279	INJ&P	Exposure during pregnancy/ Exposure during pregnancy	1	10SEP2020	23/35		No	O	P	R (14OCT2020)	N/N
16-55/ C4591001 1241 12411514	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy#	3	05FEB2021	10/C		No	O	P	UNK	N/N
16-55/ C4591001 1241 12411766	INJ&P	Maternal exposure during pregnancy/ Maternal exposure during pregnancy	1	17SEP2020	2/C		No	O	P	UNK	N/N
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	2	21JAN2021	72/C		No	O	P	UNK	N/N

16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age											
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	Vax Rel <sup>c</sup>	Cause of AE	Action: Investigational Vaccine Dose/ Subject	Outcome (End Date)	SAE/Imm AE (Yes/No)
1241 12412369		Maternal exposure during pregnancy									
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	3	12FEB2021	5/C		No	O	P	UNK	N/N
1241 12412411		Maternal exposure during pregnancy#									
16-55/ C4591001	SKIN	Urticaria/ Intermittent urticaria generalised.	1	07OCT2020	10/27	2	Yes		P/TC	R (02NOV2020)	N/N
1246 12461025											
16-55/ C4591001	NERV	Syncope/ vasovagal syncope*		20SEP2020	/1	2	No	O	NA/W	R (20SEP2020)	N/N
1248 12481218											
16-55/ C4591001	INJ&P	Maternal exposure during pregnancy/	1	12SEP2020	1/C		No	O	P	UNK	N/N
1254 12541142		Maternal Exposure During Pregnancy									
16-55/ C4591001	NERV	Headache/ headache#	4	18FEB2021	2/2	2	Yes		NA/TC/W	R (19FEB2021)	N/N
1254 12541189											
16-55/ C4591001	INJ&P	Exposure during pregnancy/ EXPOSURE DURING PREGNANCY	1	25SEP2020	1/C		No	O	P	UNK	N/N
4444 44441979											
16-55/ C4591001	PSYCH	Panic attack/ Worsening of panic attacks	1	15OCT2020	19/C	3	No	O	P/W	N	N/N
4444 44442319											

### 16.2.7.6.2 Listing of Adverse Events Leading to Discontinuation – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel	Toxicity Grade	Vax Rel <sup>c</sup>	Action:		SAE/Imm AE (Yes/No)
					Day <sup>a</sup> / Dur (Days) <sup>b</sup>			Cause of Investigational Vaccine Dose/ Subject	Outcome (End Date)	

Abbreviations: C = continuing; Dur = duration; Imm = immediate. Refer to the AE legend page (Listing 16.2.7.1) for additional definitions.

Note: MedDRA (v23.1) coding dictionary applied.

Note: \* = prevaccination AE, † = human immunodeficiency virus (HIV)-positive subject, # = AE occurring on or after unblinding.

- Relative day (Rel Day) = date of AE - date of last vaccination + 1. For an AE that occurred before the date of the first study vaccination, + 1 was not added to compute relative day.
- Duration (days) was calculated as the difference from the start of the first reported event to resolution of the last reported event, inclusive.
- Vaccine related (Vax Rel): relationship to investigational vaccine as assessed by the investigator.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 30MAR2021 (18:13)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001 EUA 1655/adae 1002 disc 1655

### 16.2.7.7.1 Listing of Deaths – Subjects 12 Through 25 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
No subject meets the reporting criteria.								
Note: MedDRA (v23.1) coding dictionary applied. a. Relative day (Rel Day) = date of death - date of last vaccination + 1. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adsl Table Generation: 27MAR2021 (06:44) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/cdl_dth_ped								

## 16.2.7.7.2 Listing of Deaths – Phase 2/3 Subjects 16-55 Years of Age

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Sex	Date of Death	Age at Death (Years)	Primary Cause of Death	Secondary Cause(s) of Death
16-55	C4591001 1021 10211127 $\infty$	2	88	M	19DEC2020	54	Cardiac failure congestive	
	C4591001 1081 10811194	2	37	F	04NOV2020	51	Myocardial infarction	
	C4591001 1120 11201266 $\infty$	2	113	M	19JAN2021	51	Lung cancer metastatic	
	C4591001 1127 11271112 $\infty$	2	86	M	04DEC2020	53	Cardio-respiratory arrest	
	C4591001 1152 11521085	1	8	F	26AUG2020	42	Death	
	C4591001 1156 11561124	2	32	M	02NOV2020	53	Overdose	
	C4591001 1229 12291083 $\dagger$	2	76	F	05JAN2021	56	COVID-19 pneumonia	
	C4591001 1231 12314987	2	82	M	06DEC2020	47	Cardio-respiratory arrest	

Note: MedDRA (v23.1) coding dictionary applied.

Note:  $\dagger$  = Human immunodeficiency virus (HIV)-positive subject,  $\infty$  = subjects who originally received BNT162b2.

a. Relative day (Rel Day) = date of death - date of last vaccination + 1.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adsl Table Generation: 31MAR2021 (04:13)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_EUA\_1655/cdl\_dth\_1655