

16.2.7.4.1 Listing of Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</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 10131239	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	
	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	

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16-55/ C4591001 1083 10831148	EAR	Vertigo/ Vertigo	2	13JAN2021	122/8	1	No	O	NA/TC	R (20JAN2021)	N/N	
	NERV	Headache/ Headache#	3	06MAR2021	1/C	1	Yes		NA	RG	N/Y	
16-55/ C4591001 1083 10831152	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	
16-55/ 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	

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	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	

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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 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	

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16-55/ C4591001 1150 11501084	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	
		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	
16-55/ C4591001 1150 11501085	GENRL	Chills/ chills	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Fatigue/ fatigue	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
		Injection site pain/ arm soreness (left) injection site	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
	NERV	Headache/ headache	1	03SEP2020	2/2	1	Yes		NA	R (04SEP2020)	N/N	
	GENRL	Fatigue/ Fatigue	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	
	NERV	Headache/ Headache	2	23SEP2020	1/2	1	Yes		NA	R (24SEP2020)	N/N	

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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
16-55/ 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	REPRO	Dysfunctional uterine bleeding/ DYSFUNCTIONAL UTERINE BLEEDING	1	10SEP2020	18/22	2	No	O	NA/TC	R (01OCT2020)	N/N

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1177 11771186 16-55/ C4591001 1177 11771197	GENRL	Pain/ Generalized Body Aches	2	19SEP2020	2/2	2	Yes		NA/TC	R (20SEP2020)	N/N
1177 11771197 16-55/ C4591001 1177 11771198	GENRL	Pyrexia/ Fever Pain/ Generalized Body Aches#	2 3	19SEP2020 26FEB2021	2/1 1/2	2 1	Yes Yes		NA/TC NA	R (19SEP2020) R (27FEB2021)	N/N N/N
1177 11771219 16-55/ C4591001 1177 11771219	GASTR	Abdominal pain upper/ Stomach Pain	1	08SEP2020	9/1	2	No	O	NA/TC	R (08SEP2020)	N/N
1177 11771222 16-55/ C4591001 1177 11771222	GASTR	Nausea/ NAUSEA	2	21SEP2020	1/1	1	Yes		NA	R (21SEP2020)	N/N
1177 11771222 16-55/ C4591001 1177 11771224	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 1177 11771224	GENRL	Pain/ Generalized Body Aches	1	02SEP2020	2/2	1	Yes		NA	R (03SEP2020)	N/N

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	PREG	Abortion spontaneous/ Complete miscarriage	2	27FEB2021	174/12	3	No	O	NA/TC	R (10MAR2021)	Y/N
16-55/ C4591001 1231 12311816	GASTR	Gastroesophageal 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



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1231 12312191 16-55/ C4591001	EYE	Chalazion/ chalazion	2	11OCT2020	31/4	2	No	O	NA	R (14OCT2020)	N/N
1231 12312204 16-55/ C4591001	INJ&P	Exposure during pregnancy/ exposure during pregnancy	2	29SEP2020	23/62		No	O	NA	R (29NOV2020)	N/N
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 12312211	GENRL	Injection site pain/ Injection site pain in right deltoid	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N
1231 12312211	MUSC	Myalgia/ Generalized myalgia	2	12SEP2020	4/4	2	Yes		NA	R (15SEP2020)	N/N
16-55/ C4591001 1231 12312212	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

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	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
16-55/ 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	BLOOD	Iron deficiency anaemia/ Iron deficiency anemia#	3	01FEB2021	4/C	1	No	O	NA/TC	RG	N/N

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16-55/ C4591001 1231 12314132	GENRL	Injection site pain/ pain at the injection site.	1	11SEP2020	17/53	1	Yes		NA/TC	R (02NOV2020)	N/N
	NERV	Paraesthesia/ tingling in left arm	1	11SEP2020	17/C	1	Yes		NA/TC	N	N/N
16-55/ C4591001 1231 12314134	INJ&P	Exposure during pregnancy/ Drug Exposed Pregnancy	1	07DEC2020	104/69		No	O	NA	R (13FEB2021)	N/N
	PREG	Abortion incomplete/ incomplete abortion	1	11FEB2021	170/3	3	No	O	NA/TC/TCN	R (13FEB2021)	Y/N
16-55/ C4591001 1231 12314135	NERV	Headache/ Headache	2	12OCT2020	29/2	2	No	O	NA/TC	R (13OCT2020)	N/N
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	ENDO	Hypothyroidism/ Hypothyroidism	1	01SEP2020	7/46	1	No	O	NA/TC	R (16OCT2020)	N/N

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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	
16-55/ 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	PREG	Abortion spontaneous/ MISCARRIAGE	2	OCT2020	22/	3	No	O	NA	R	Y/N	

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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 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	CARD	Acute myocardial infarction/ ST-segment elevated MYOCARDIAL INFARCTION	1	26OCT2020	13/1	2	No	O	NA/TC	R (26OCT2020)	Y/N	

16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age												
Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</sup>	Toxicity Grade	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 11421202	INFEC	Appendicitis/ Acute Appendicitis	2	05DEC2020	68/2	3	No	O	NA/TCN	R (06DEC2020)	Y/N	
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	INFEC	COVID-19/ COVID-19	2	14JAN2021	66/7	2	No	O	NA	R (20JAN2021)	Y/N	

## 16.2.7.5 Listing of Serious Adverse Events – All Subjects ≥16 Years of Age

Age Group (Years)/ Subject	System Organ Class	Preferred Term/ AE Investigator Text	Dose No.	Onset Date	Rel Day <sup>a</sup> / Dur (Days) <sup>b</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 11461302 16-55/ C4591001 1150 11501001	GASTR	Pancreatitis/ Worsening Pancreatitis	1	21AUG2020	5/34	3	No	O	NA	R (23SEP2020)	Y/N
16-55/ C4591001 1150 11501022	RENAL	Nephrolithiasis/ Kidney Stones	2	02DEC2020	86/7	3	No	O	NA/TC	R (08DEC2020)	Y/N
16-55/ C4591001 1150 11501084	PREG	Abortion spontaneous/ Spontaneous Miscarriage	2	19FEB2021	142/1	2	No	O	NA	R (19FEB2021)	Y/N
16-55/ C4591001 1150 11501153	PSYCH	Depression/ Worsening Depression- no prior hospitalizations for depression#	3	02MAR2021	7/C	4	No	O	NA	RG	Y/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 1156 11561006	VASC	Deep vein thrombosis/ DEEP VEIN THROMBOSIS	1	31AUG2020	12/10	3	No	O	NA/TC	R (09SEP2020)	Y/N
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

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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 1167 11671009	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	NEOPL	Breast cancer/ left breast carcinoma	2	13JAN2021	90/C	3	No	O	NA	N	Y/N	



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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	

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16-55/ C4591001 1231 12313879	INFEC	Urinary tract infection/ Supected 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	

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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)
1007 10071347 >55/ C4591001 1008 10081056	RESP	Dyspnoea/ Shortness of breath#	4	MAR2021	20/C	3	No	O	NA/TC	N	Y/N
>55/ C4591001 1008 10081184	NEOPL	Prostate cancer/ Prostate cancer	2	30SEP2020	7/C	2	No	O	NA/TCN	N	Y/N
>55/ C4591001 1008 10081603	INFEC	Cellulitis/ CELLULITIS UPPER BACK	1	26OCT2020	13/8	3	No	O	NA/TC	R (02NOV2020)	Y/N
		Subcutaneous abscess/ SCALP ABCESS	1	26OCT2020	13/2	3	No	O	NA/TC/TCN	R (27OCT2020)	Y/N
>55/ C4591001 1008 10081667	NEOPL	Hepatic cancer/ liver cancer#	4	25FEB2021	23/C	3	No	O	NA/W	N	Y/N
>55/ C4591001 1009 10091123	NEOPL	Colon adenoma/ TUBULAR ADENOMA OF ASCENDING COLON	2	15DEC2020	92/3	2	No	O	NA/TC/TCN	R (17DEC2020)	Y/N
>55/ C4591001 1009 10091135	NEOPL	Intraductal proliferative breast lesion/ Right Breast Ductal Carcinoma In Situ	1	02SEP2020	3/C	1	No	O	NA/TCN	N	Y/N
>55/ C4591001	INFEC	Diverticulitis/ worsening of diverticulitis	2	31DEC2020	101/3	2	No	O	NA/TC/TCN	R (02JAN2021)	Y/N