

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
12-15	C4591001 1006 10061272	1	22	06JAN2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/ANXIETY
		1	22	06JAN2021	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/DEPRESSION
	C4591001 1007 10071409	1	10	31OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion #5 meet
	C4591001 1007 10071593	1	24	20JAN2021	VACCINATION	PROTOCOL DEVIATION	receipt of non-study COVID vaccine prior to study end
		1	47	12FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1007 10071622	1	22	20JAN2021	VACCINATION	OTHER	Participant had COVID-19 prior to second vaccine
	C4591001 1007 10071642	1	22	25JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	clinical or microbiological diagnosis of COVID-19
	C4591001 1008 10081871	1	49	16FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1008 10081884	1	50	18FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested positive for COVID 19
	C4591001 1008 10081901	2	18	12FEB2021	VACCINATION	OTHER	the participant is willing/eligible to receive Vaccination 3
	C4591001 1009 10091229	1	21	09NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Covid positive between visit one and visit 2, exclusion #5

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	C4591001 1009 10091338	1	19	01JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	exclusion #5
	C4591001 1009 10091363	1	11	27DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	has tested positive for COVID-19
	C4591001 1016 10161316	1	17	01NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with positive covid-19
	C4591001 1016 10161379	1	30	05FEB2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject with positive covid test
	C4591001 1044 10441344	2	11	08FEB2021	VACCINATION	OTHER	transitioning to open label
	C4591001 1057 10571413			21DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	DELAY CRITERIA MET
				21DEC2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	DELAY CRITERIA MET
	C4591001 1057 10571420	2	45	24FEB2021	VACCINATION	WITHDRAWAL BY PARENT/GUARDIAN	mother stated she didn't want him to do it anymore
		2	45	24FEB2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	mother stated she didn't want him to do it anymore
	C4591001 1066 10661428	2	17	11FEB2021	VACCINATION	OTHER	subject unblinded for vax 3 per protocol
	C4591001 1077 10771293			18DEC2020	SCREENING	OTHER	SUBJECT WAS RANDOMIZED THE SUBSEQUENTLY UNABLE TO TOLERATE BLOOD DRAW.

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				18DEC2020	VACCINATION	REFUSED FURTHER STUDY PROCEDURES	REFUSED FURTHER STUDY PROCEDURES
	C4591001 1091 10911414	1	14	22DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Tested positive for Covid (exclusion 5)
	C4591001 1091 10911451			04JAN2021	FOLLOW-UP	OTHER	Subject was rescreened under #1462. Subject randomized in error.
	C4591001 1126 11261287	1	15	30DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject did not receive 2nd vaccine due to Covid 19 disease.
	C4591001 1139 11391235	2	19	15FEB2021	VACCINATION	OTHER	Crossed over to Visit 101
	C4591001 1139 11391263	2	19	19FEB2021	VACCINATION	OTHER	Crossed-over
	C4591001 1140 11401346			22DEC2020	SCREENING	OTHER	DISCONTINUED
	C4591001 1147 11471327	1	4	08JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA ADVERSE EVENT	SUBJECT TO BE DISCONTINUED DUE TO UNABLE TO OBTAIN SPECIMEN ADVERSE EVENT/PYREXIA
	C4591001 1156 11561316	2	73	10MAR2021	VACCINATION	PROTOCOL DEVIATION	SUBJECT CAN NOT BE REACHED VIA PHONE. CERTIFIED LETTER SENT. SUBJECT CONTINUES TO COMPLETE eDIARY.
	C4591001 1156 11561320	2	34	25JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT AND FATHER STATED THAT THEY NO LONGER WISHED TO PARTICIPATE IN THE TRIAL.

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16-25	C4591001 1270 12701237	1	20	26JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	EC#55: Participant had a positive local COVID-19 test before Vx2, symptomatic with test
	C4591001 1001 10011125	1	37	09SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Withdrew consent and decided not to continue in study.
		1	37	09SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient withdrew consent
	C4591001 1005 10051238	2	65	06JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WAS UNBLINDED AND FOUND OUT HE RECEIVED PLACEBO. HE DECIDED TO WITHDRAW
	C4591001 1005 10051341	1	2	22OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject tested COVID positive between visits 1 and 2
	C4591001 1006 10061174	2	113	22FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Inclusion 2
	C4591001 1007 10071556	2	29	26JAN2021	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion #12; received COVID vaccine outside of study
		2	29	26JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	Receipt of non-study COVID vaccine prior to study end
	C4591001 1008 10081480	2	115	04FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to make contact with subject despite numerous attempts
	C4591001 1009 10091235	2	107	25FEB2021	REPEAT SCREENING 1	OTHER	Visit 101 delayed due to recent vaccination
C4591001 1009 10091257	1	10	05NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	positive for COVID-19	

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	C4591001 1009 10091286	2	13	04JAN2021	VACCINATION	OTHER	subject transitioned to open prior to visit 3
	C4591001 1013 10131395	2	45	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	ATTEMPTED TO CONTACT.
		2	45	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	UNABLE TO CONTACT SUBJECT AFTER MULTIPLE ATTEMPTS.
	C4591001 1013 10131592	2	31	11NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject withdrew consent from study.
		2	31	11NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED OUT OF STATE NO LONGER WANTED TO PARTICIPATE.
	C4591001 1013 10131683	2	129	10MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT DID NOT WISH TO CONTINUE IN STUDY.
	C4591001 1013 10131740			15OCT2020	FOLLOW-UP	OTHER	randomized in error, needed to wait until course of antibiotics was done.
	C4591001 1016 10161348	1	10	14NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject had positive pcr covid test
	C4591001 1018 10181054	1	39	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient returned to home country, did not respond to outreach, certified letter sent
		1	39	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject returned to home country, according to call to emergency contact
	C4591001 1018 10181335	2	104	24FEB2021	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION

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	C4591001 1028 10281294	2 1	104 7	24FEB2021 04NOV2020	FOLLOW-UP VACCINATION	PHYSICIAN DECISION NO LONGER MEETS ELIGIBILITY CRITERIA	PHYSICIAN DECISION patient had positive covid test prior to V2
	C4591001 1036 10361011	1	1	20AUG2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1036 10361032	1 2	1 48	20AUG2020 03NOV2020	FOLLOW-UP VACCINATION	LOST TO FOLLOW-UP LOST TO FOLLOW-UP	Lost to follow up unreachable
	C4591001 1036 10361061	2	48	03NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	unreachable
	C4591001 1036 10361062	2	155	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1036 10361073	2	136	03FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject didn't return for Convalescent visit & multiple attempts to contact have been unsuccessful
	C4591001 1036 10361078	2	151	22FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1037 10371078	1	44	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	SITE ATTEMPTED CONTACT ON 22 SEP 30 SEP AND CERTIFIED LETTER SENT 8 OCT NO RESPONSE
	C4591001 1039 10391093	1	44	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 8 OCT. PT DID NOT RESPOND
	C4591001 1039 10391093	2	137	08FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Contacted multiple times via phone and email, and was sent certified letter, all with no response

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	C4591001 1039 10391244	1	13	23NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for COVID-19.
	C4591001 1042 10421112	2	111	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent
	C4591001 1044 10441287	1	19	29DEC2020	VACCINATION	OTHER	subject proceeded to open label prior to Vax2 in the blinded treatment phase.
	C4591001 1048 10481088	2	49	12NOV2020	VACCINATION	OTHER	out of state at time of visit 3
	C4591001 1052 10521054	1	25	21SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	21SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up
	C4591001 1052 10521064	1	25	24SEP2020	VACCINATION	LOST TO FOLLOW-UP	n/a
		1	25	24SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001 1052 10521080	1	28	29SEP2020	VACCINATION	LOST TO FOLLOW-UP	lost of follow up
		1	28	29SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost of follow up
	C4591001 1054 10541007	2	130	15JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	unblinding of subject occurred due to future non-study covid-19 vaccination
	C4591001 1054 10541022	1	64	23OCT2020	VACCINATION	LOST TO FOLLOW-UP	Pt deemed LTFU by site.

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		1	64	23OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt deemed LTFU by site.
	C4591001 1054 10541165	2	47	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.
		2	47	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subj. did not show up for V3, despite sending certified letter and contacting pt via phone 3 times.
	C4591001 1056 10561392	2	73	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		2	73	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561511	2	103	12FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject informed us he no longer wanted to continue in the study.
	C4591001 1056 10561554	1	86	13JAN2021	VACCINATION	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
		1	86	13JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was discontinued from study after several unsuccessful TC and a Certified Letter.
	C4591001 1056 10561592	2	81	18FEB2021	VACCINATION	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
		2	81	18FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After many attempts to contact subject, Investigator decided to discontinue Pt. as a LTFU
	C4591001 1057 10571211			18SEP2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was randomized but failed to meet entry criteria, no vaccine was given
	C4591001 1057 10571216	2	30	10NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO



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		2	30	10NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	MOVED TO SAN FRANCISCO
	C4591001 1057 10571230	2	56	23DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
		2	56	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	PERSONAL REASONS
	C4591001 1057 10571248	1	36	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject refused to return for Visit 2, withdrew consent, No adverse events reported
		1	36	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent from further study participation
	C4591001 1057 10571319	2	47	28DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
		2	47	28DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	withdrew consent due to transportation issues
	C4591001 1066 10661396	1	22	22DEC2020	VACCINATION	OTHER	unblinded to assess eligibility for vaccination
	C4591001 1073 10731038	1	37	10SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was Discontinue
		1	37	10SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinue
	C4591001 1073 10731067	2	157	05FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1079 10791253	1	67	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	patient unresponsive

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		1	67	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient unresponsive
	C4591001 1080 10801019	2	155	01FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Patient received vaccine outside of the study.
	C4591001 1080 10801055	2	105	21DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Patient was vaccinated for COVID by her employer prior to being unblinded
	C4591001 1084 10841512	2	119	09MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject will not be available for follow-up appointments.
	C4591001 1085 10851081	2	87	30NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject no longer interested in the study.
		2	87	30NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Site received call call from patient stating she was no longer interested in the study.
	C4591001 1085 10851244	2	97	30DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	Received vaccine elsewhere
	C4591001 1087 10871089	1	19	04SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria #5
	C4591001 1087 10871279	2	156	23FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject is unwilling to return for vaccine if in the placebo group.
	C4591001 1087 10871354	1	10	17SEP2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/MYALGIA
		1	10	17SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/MYALGIA

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	C4591001 1087 10871356	1	54	31OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up.
		1	54	31OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1087 10871363	2	56	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	lost to follow up
		2	56	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up.
	C4591001 1089 10891179	2	157	18FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved, withdrew consent
	C4591001 1090 10901328	2	63	25NOV2020	VACCINATION	LOST TO FOLLOW-UP	pt did not come for V3 and was unresponsive to calls and certified letter
		2	63	25NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Pt did not come for V3 and not responsive to calls or certified letter
	C4591001 1090 10901517	2	49	29DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject requested to be unblinded before eligibility
	C4591001 1091 10911122	2	169	16FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	Subject received moderna vaccine
	C4591001 1092 10921055	2	138	29JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is lost to follow-up
	C4591001 1092 10921128			01SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Pt withdrew consent due to anxiety of having blood drawn

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	C4591001 1093 10931055			31AUG2020	FOLLOW-UP	NO LONGER MEETS ELIGIBILITY CRITERIA	UNABLE TO OBTAIN BLOOD FROM SUBJECT.
	C4591001 1093 10931058	1	25	18SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
		1	77	09NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was lost to follow up./EXPOSURE DURING PREGNANCY
	C4591001 1093 10931072	1	81	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
		1	81	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT WAS SENT A CERTIFIED LETTER AND WAS UNABLE TO BE CONTACTED MULTIPLE TIMES.
	C4591001 1094 10941169	2	120	23FEB2021	FOLLOW-UP	PROTOCOL DEVIATION	subject received the non study covid 19 vaccine before being discontinued or withdrawing from study
	C4591001 1095 10951056	1	35	08SEP2020	VACCINATION	OTHER	not able to meet study requirements due to work schedule
		1	35	08SEP2020	FOLLOW-UP	OTHER	Participant not able to continue in study at this time. Participant did not withdraw consent
	C4591001 1095 10951271	2	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	certified letter sent
		2	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	certified letter sent
	C4591001 1096 10961031	1	22	04SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY

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	C4591001 1096 10961081	1	54	12OCT2020	VACCINATION	LOST TO FOLLOW-UP	LTFU, unresponsive to contact attempts
		1	54	12OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	site unable to contact subject after multiple attempts and certified letter sent
	C4591001 1096 10961141	1	22	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criteria #5
	C4591001 1096 10961321	1	22	03OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject met exclusion #1 on visit 2 (suicidal ideation) so no vaccine was administered
	C4591001 1096 10961388	1	21	29OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	subject was diagnosed with COVID between vaccination one and vaccination two
	C4591001 1098 10981200	1	46	05NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject
		1	46	05NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject called multiple times and certified letter was sent. No response from subject.
	C4591001 1098 10981243	2	139	08MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Discontinued
	C4591001 1098 10981244	2	84	12JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Subject has been discontinued due to lost of followup.
	C4591001 1109 11091030	2	37	23SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TO BUSY.
		2	37	23SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT CALLED TO WITHDRAW FROM TRIAL DUE TO TRANSPORTATION ISSUES AS WELL AS BEING TO BUSY.

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	C4591001 1109 11091059	1	40	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
		1	40	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RETURNED PHONE CALLS OR RESPOND TO CERTIFIED LETTER.
	C4591001 1109 11091335	1	43	07OCT2020	VACCINATION	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
		1	43	07OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	SUBJECT NEVER RESPONDED TO MULTIPLE CALLS AND CERTIFIED LETTER SENT TO HER
	C4591001 1109 11091515	1	30	14OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
		1	30	14OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject never returned for visit, responded to call or certified letter sent.
	C4591001 1110 11101010	2	63	22OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
		2	63	22OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not comply with inclusion criteria #2.
	C4591001 1110 11101038	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject was contact over the phone 3 times and a certified letter was sent. Subject never reply.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow is status, subject has been withdrawn from trial.
	C4591001 1110 11101039	1	35	08SEP2020	VACCINATION	LOST TO FOLLOW-UP	subject failed to contact site after many calls and certified letter.
		1	35	08SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not respond to many phones calls from site and did not respond to certified letter from i

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Subjects 12 Through 25 Years of Age**

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	C4591001 1110 11101085	1	58	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject was tried to contact by phone, text, email and certified letter several times.
		1	58	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	we did 4 phone call attempts, 1 text message, 1 email and a certified letter.
	C4591001 1110 11101110	1	22	08SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent
		1	22	08SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew consent
	C4591001 1110 11101156	1	96	01DEC2020	VACCINATION	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
		1	96	01DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was attempt to contact by 2 text messages, 1 certified letter, 1 email and 8 phone call.
	C4591001 1110 11101380	2	38	29JAN2021	VACCINATION	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinue subject because he states subject is too busy with school.
		2	38	29JAN2021	FOLLOW-UP	WITHDRAWAL BY PARENT/GUARDIAN	Parent discontinued subject because he states subject is too busy with school.
	C4591001 1112 11121058	1	22	25AUG2020	VACCINATION	OTHER	(b) (6)
		1	22	25AUG2020	FOLLOW-UP	OTHER	(b) (6)
	C4591001 1112 11121229			04SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject left clinic after randomization and prior to vaccination
	C4591001 1116 11161292	1	52	14NOV2020	VACCINATION	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		1	52	14NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Contact attempts 16OCT 22OCT 23OCT 3NOV 4NOV 9NOV 10NOV
	C4591001 1116 11161322	2	55	07DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW FROM STUDY
		2	55	07DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1117 11171138	2	31	17DEC2020	VACCINATION	PROTOCOL DEVIATION	COULD NOT GET PARTICIPANT SCHEDULED FOR V3
	C4591001 1120 11201038			29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdraw consent
	C4591001 1120 11201240	2	163	20FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject is moving out of town
	C4591001 1121 11211009	2	40	22OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew due to busy schedule.
		2	40	22OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent due to busy schedule. Does not want to be FU
	C4591001 1121 11211010	2	180	11MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject asked to be withdrawn then hung up. Attempted to reach her again, she answered then hung up.
	C4591001 1121 11211067	2	100	30DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent to receive vaccine at work.
	C4591001 1122 11221026			11SEP2020	FOLLOW-UP	ADVERSE EVENT	ADVERSE EVENT/PRESYNCOPE



**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1123 11231027			11SEP2020 04AUG2020	FOLLOW-UP FOLLOW-UP	ADVERSE EVENT WITHDRAWAL BY SUBJECT	ADVERSE EVENT/VOMITING subject withdrew consent after randomization prior to vaccination.
	C4591001 1123 11231051	2	43	08OCT2020	VACCINATION	OTHER	moved to hawaii
	C4591001 1123 11231069	2	43	08OCT2020	FOLLOW-UP	OTHER	Moved to Hawaii
	C4591001 1123 11231069	2	190	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Certified letter sent. Left voicemail with the patient.
	C4591001 1123 11231154	1	73	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	no response from subject after certified letter
	C4591001 1124 11241038	1	73	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	no response from subject after certified letter
	C4591001 1124 11241038	2	106	16DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew to receive Covid-19 at workplace
	C4591001 1124 11241049	1	26	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
	C4591001 1124 11241141	1	26	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject not responding to any phone calls, certified letter sent
	C4591001 1124 11241141	2	64	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up after multiple calls and certified letter sent
	C4591001 1125 11251059	2	64	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1125 11251059	2	76	24NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject missed appt and diary entries. Multiple contact attempts with subject were not returned.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001	2	76	24NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Patient deemed lost to follow moved from the area no longer able to make visits
	1125 11251142	2	154	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	
	C4591001	1	12	02NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Patient tested positive for Covid-19, EXC #5
	1125 11251238						
	C4591001	1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/HEADACHE
	1125 11251243						
	C4591001	1	2	09DEC2020	VACCINATION	ADVERSE EVENT	ADVERSE EVENT/INJECTION SITE PAIN
	1127 11271078	2	137	11JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to followup
	C4591001	1	22	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Subject tested positive and symptoms for COVID
	1127 11271099						
	C4591001	2	113	19JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	SUBJECT RECEIVED COVID-19 VACCINE OUTSIDE OF STUDY
	1128 11281177						
	C4591001			04AUG2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	screen fail
	1129 11291048						
	C4591001			04AUG2020	FOLLOW-UP	PROTOCOL DEVIATION	violation exclusion criteria 2.f. immunocompromised. randomized but not dosed
	1129 11291260	2	44	27JAN2021	OPEN LABEL TREATMENT	ADVERSE EVENT	ADVERSE EVENT/ANAPHYLACTOID REACTION

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1133 11331037	1	27	26AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject withdrew consent.
		1	27	26AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331047	2	8	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject does not want to continue in the study
		2	8	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
	C4591001 1133 11331135	2	166	16FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent after unblinding. Requested time to think about it. Made decision on 16/FEB
	C4591001 1133 11331207	1	43	30SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	SUBJECT WITHDREW CONSENT
		1	43	30SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject withdrew consent
	C4591001 1133 11331480	2	127	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	CERTIFIED LETTER SENT 08/FEB/2021
	C4591001 1133 11331647	2	31	23DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject leaving and does not want to come in for any future visits.
	C4591001 1135 11351199	1	39	01OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up, certified letter sent to patient.
		1	39	01OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject lost to follow-up, certified letter sent

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1135 11351428	1	27	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
		1	27	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject contact attempted several times and certified letter was sent on 19OCT2020
	C4591001 1141 11411077	2	118	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew to receive EUA vaccine outside of the study.
	C4591001 1146 11461140	2	178	13MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject withdrew
	C4591001 1149 11491332	2	23	03DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved out of State and will not be able to committee to follow-ups
		2	23	03DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject moved out of state and withdrew from study.
	C4591001 1152 11521030	1	22	02SEP2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1152 11521208	2	81	04DEC2020	VACCINATION	PROTOCOL DEVIATION	Non-compliant with attending study visits.
		2	115	07JAN2021	FOLLOW-UP	PHYSICIAN DECISION	PHYSICIAN DECISION
	C4591001 1156 11561015	1	39	28SEP2020	VACCINATION	PREGNANCY	PREGNANCY/EXPOSURE DURING PREGNANCY
	C4591001 1157 11571077	2	30	14OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject W/C due to moving

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	30	14OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Voluntary withdrawal not due to an AE or SAE
	C4591001 1161 11611006	1	111	18NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study
		1	111	18NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to withdraw from study.
	C4591001 1161 11611007	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	No longer meets an eligibility criteria per exclusion #5. VAX2 is not given but FUP will be complete
		1	146	23DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	unable to contact, certified letter was sent and no response.
	C4591001 1161 11611008	1	103	10NOV2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1161 11611010	1	134	11DEC2020	VACCINATION	PHYSICIAN DECISION	PHYSICIAN DECISION
		1	216	03MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject stated he did not want to continue in study.
	C4591001 1161 11611018	1	115	23NOV2020	VACCINATION	LOST TO FOLLOW-UP	multiple calls and cert. letter sent. No response from subject.
		1	115	23NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple calls and certified letter sent. no response from subject
	C4591001 1161 11611023	1	72	13OCT2020	VACCINATION	LOST TO FOLLOW-UP	subject had several contact attempts by site along with certified letter. Unable to contact subject.
		1	72	13OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	cert. letter sent and signed by subject. unable to contact and subject has not called site.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1161 11611024	1	107	17NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	unable to contact subject. certified letter returned, no response from subject
		1	107	17NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject did not want to continue in study
	C4591001 1161 11611028	2	83	02FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	3 phone call attempts and certified letter sent with no response.
	C4591001 1162 11621005	1	32	31AUG2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject prematurely withdrew from study.
		1	32	31AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject prematurely withdrawn from study.
	C4591001 1162 11621044	2	194	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow-up
	C4591001 1162 11621074	2	73	13NOV2020	VACCINATION	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
		2	73	13NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	subject LTFU after multiple contact attempts.
	C4591001 1162 11621080	2	64	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		2	64	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU
	C4591001 1162 11621310	1	60	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	60	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1162 11621374	1	54	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTFU
		1	54	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTFU after many contact attempts.
	C4591001 1162 11621434	2	1	19OCT2020	VACCINATION	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
		2	1	19OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	LOST TO FOLLOW-UP
	C4591001 1167 11671111	1	38	08OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject is lost to follow up tried multiple calls and certified letter
		1	38	08OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	no answer after multiple calls and sent certified letter
	C4591001 1167 11671132	2	98	28DEC2020	FOLLOW-UP	PROTOCOL DEVIATION	subject received out of study covid vaccine
	C4591001 1168 11681212	2	1	15OCT2020	VACCINATION	OTHER	The visit was missed due to pt working out of state. The subject will continue on in the study.
	C4591001 1168 11681221	2	54	21DEC2020	VACCINATION	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
		2	54	21DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject chose to no longer participate, complete study procedures, or respond to follow up requests.
	C4591001 1168 11681227	1	37	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent
		1	37	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject LTF after several attempts to contact and certified letter sent

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1169 11691014	2	104	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject did not want to wait 28 days to receive study vaccine after receiving HPV vaccine 12/21/20
	C4591001 1169 11691060	2	36	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Lost to Follow Up
		2	36	17NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1170 11701048	2	166	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701076	2	163	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701089	2	161	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701146	2	168	09MAR2021	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow up subject contacted multiple times for scheduling
	C4591001 1170 11701311	1	33	16OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject contacted multiple times, never responded.
		1	33	16OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	lost to follow-up subjects subject didnt come for visit.
	C4591001 1170 11701487	2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1170 11701494	2	99	23FEB2021	VACCINATION	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response



**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	99	23FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts have been made to contact subject with no response
	C4591001 1195 11951029	2	78	20JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the upcoming visits is to stressful for the patient at this time.
	C4591001 1195 11951061	1	21	06NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	patient withdrawal consent. she is afraid about the second vaccination
		1	21	06NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	patient is afraid for the second vaccination
	C4591001 1218 12181011	2	99	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	We made contact with participant 02MAR2021, she was informed of her vaccine status but withdrew.
		2	99	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant requested to withdraw from study as they have moved out of state
	C4591001 1218 12181050	1	21	23DEC2020	VACCINATION	OTHER	Subject proceeded to open label prior to Vax2 in blinded treatment phase
	C4591001 1220 12201036	1	44	17DEC2020	VACCINATION	LOST TO FOLLOW-UP	unable to contact participant due to multiple attempts
		1	44	17DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	Unable to contact participant after multiple attempts
	C4591001 1221 12211036	2	52	27JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Withdrew from study
	C4591001 1224 12241009	1	37	18SEP2020	VACCINATION	LOST TO FOLLOW-UP	PT failed to attend V2; site attempted contact via phone and certified letter
		1	37	18SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	PT failed to return for V2; site attempted contact via phone and certified letter

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1224 12241167	1	27	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1224 12241169	2	23	06JAN2021	VACCINATION	OTHER	subject proceeded to open label prior to V3 in the blinded Rx phase
	C4591001 1224 12241170			24NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject chose to discontinue from trial
	C4591001 1224 12241175	1	17	16DEC2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion Criteria 5
	C4591001 1226 12262189	1	14	27OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Exclusion criterion 5
	C4591001 1230 12301065	2	97	02MAR2021	VACCINATION	WITHDRAWAL BY SUBJECT	Participant translocated and will no longer be able to attend site visits
		2	97	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Participant confirmed that he has translocated. Attending additional visits will be difficult.
	C4591001 1231 12311031	1	37	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311062	2	165	12FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	After multiple contact attempts, a registered letter is sent. Subject receives it on 3FEB2021
	C4591001 1231 12311088	1	48	28SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Withdrawal Date</b>	<b>Study Phase</b>	<b>Withdrawal Reason</b>	<b>Comment<sup>b</sup></b>
	C4591001 1231 12311191	1	32	14SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311431	1	27	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject is afraid of exposure to COVID-19 in next study visits
		1	27	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	you fear going to a health institution and that this will expose you to be reinfected by SARS-COV2
	C4591001 1231 12311593	2	147	01FEB2021	VACCINATION	LOST TO FOLLOW-UP	After multiple unanswered phone calls, a certified letter was sent and it was never responded.
		2	147	01FEB2021	FOLLOW-UP	LOST TO FOLLOW-UP	Volunteer with loss of follow-up
	C4591001 1231 12311641	1	29	13SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12311656	1	40	24SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312326	1	34	21SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12312365	1	28	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	56	13OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject decided to withdraw consent due to lack of time
	C4591001 1231 12312403	1	24	11SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The patient does not want to take the second dose.

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1231 12312451	1	23	11SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Participants who are willing and able to comply with all scheduled visits, vaccination plan, lab...
	C4591001 1231 12312528	2	123	11JAN2021	FOLLOW-UP	PROTOCOL DEVIATION	On JAN-9-2021, subject received the Gam-COVID-Vac vaccine (trade name Sputnik V).
	C4591001 1231 12312594	1	77	04NOV2020	VACCINATION	WITHDRAWAL BY SUBJECT	Stop participating for personal reasons
		1	77	04NOV2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdraws his consent for personal reasons
	C4591001 1231 12312916	1	20	09SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19.
	C4591001 1231 12313443			23AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	randomized, no vaccinated
	C4591001 1231 12313467	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
	C4591001 1231 12313498	1	25	16SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	the subject did not agree to be vaccinated a second time,but will continue in the study
	C4591001 1231 12313519	1	24	15SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Did not accept to receive second dose but accept continue with the rest of study procedures
	C4591001 1231 12313546	1	26	17SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	Subject did not receive the second vaccination but continued otherwise with study procedures

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Withdrawal Date</b>	<b>Study Phase</b>	<b>Withdrawal Reason</b>	<b>Comment<sup>b</sup></b>
	C4591001 1231 12313622	1	24	16SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Healthy participants eligible for inclusion in the study and Previous diagnosis of COVID-19
	C4591001 1231 12313758	1	44	06OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
	C4591001 1231 12313981	2	45	29OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
		2	45	29OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The decision to stop participating must be a move to the province of Santiago del Estero.
	C4591001 1231 12314492	1	20	15SEP2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	Previous clinical or microbiological diagnosis of COVID-19
		1	142	15JAN2021	FOLLOW-UP	LOST TO FOLLOW-UP	12 telephone contact attempts. 2 email contact attempts. 1 certified letter sent.
	C4591001 1231 12315357	1	13	10SEP2020	VACCINATION	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
		1	13	10SEP2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	The subject does not specify the reasons for withdrawing from the study
	C4591001 1232 12321015	1	21	02SEP2020	VACCINATION	LOST TO FOLLOW-UP	patient is labeled a "no show"
		1	21	02SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	patient labeled as a "no show"
	C4591001 1232 12321142	1	24	23SEP2020	VACCINATION	OTHER	re-joined trial in the revaccination open label portion

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Withdrawal Date</b>	<b>Study Phase</b>	<b>Withdrawal Reason</b>	<b>Comment<sup>b</sup></b>
	C4591001 1232 12321210	2	67	06DEC2020	VACCINATION	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
		2	67	06DEC2020	FOLLOW-UP	LOST TO FOLLOW-UP	multiple attempts to contact patient, phone is no longer in service
	C4591001 1232 12321244	1	1	11SEP2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return the sites calls
		1	1	11SEP2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject is not returning any of the sites phone calls. Will not be rejoining.
	C4591001 1232 12321412	1	1	27OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
		1	1	27OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and would not return calls from the site
	C4591001 1232 12321429	1	1	28OCT2020	VACCINATION	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
		1	1	28OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject did not attend V2 and has not returned calls from the site
	C4591001 1235 12351187	1	9	24OCT2020	VACCINATION	NO LONGER MEETS ELIGIBILITY CRITERIA	meets exclusion #5
	C4591001 1247 12471107	2	29	17NOV2020	VACCINATION	LOST TO FOLLOW-UP	Pt did not arrive for Visit 3. After multiple attempts by site staff, pt still did not arrive for V3
	C4591001 1247 12471121	2	10	30OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
		2	10	30OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Patient withdrew after motorcycle accident (Undisclosed medical condition)
	C4591001 1248 12481025			29AUG2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject Withdrew Consent
	C4591001 1248 12481046	1	66	04NOV2020	VACCINATION	LOST TO FOLLOW-UP	Missed V2 on 20Sep2020; site has been unable to contact subject despite multiple calls.
		1	66	04NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Please see EOT page
	C4591001 1248 12481110	1	59	06NOV2020	VACCINATION	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
		1	59	06NOV2020	FOLLOW-UP	LOST TO FOLLOW-UP	Subject was no show for V2; unable to contact subject.
	C4591001 1248 12481138	2	125	02FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject said she no longer wishes to participate in the study. No reason given.
	C4591001 1248 12481206	2	1	09OCT2020	VACCINATION	LOST TO FOLLOW-UP	Lost to follow up
		2	1	09OCT2020	FOLLOW-UP	LOST TO FOLLOW-UP	Lost to follow up
	C4591001 1254 12541142	1	26	07OCT2020	VACCINATION	PREGNANCY	PREGNANCY/MATERNAL EXPOSURE DURING PREGNANCY
	C4591001 1258 12581069	2	55	04JAN2021	VACCINATION	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent
		2	55	04JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	subject moved and withdrew consent

**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

Age Group (Years)	Subject	Dose No.	Rel Day <sup>a</sup>	Withdrawal Date	Study Phase	Withdrawal Reason	Comment <sup>b</sup>
	C4591001 1269 12691047	2	126	18JAN2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Subject discontinued her participation
	C4591001 1270 12701175	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father request to drop participant as has been non-compliant with study activities
	C4591001 1270 12701176	2	66	24FEB2021	VACCINATION	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant, non-compliant with study activities
		2	66	24FEB2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Per LAR/father, request to drop participant as participant is non-compliant with study activities
	C4591001 4444 44441329	2	81	31DEC2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is due to personal issues.
	C4591001 4444 44442006	2	140	02MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision to stop participating is for personal reasons
	C4591001 4444 44442081	2	145	08MAR2021	FOLLOW-UP	WITHDRAWAL BY SUBJECT	the decision is due to "the little collaboration of Pfizer with the Argentine State."
	C4591001 4444 44442263	1	24	20OCT2020	VACCINATION	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons
		1	24	20OCT2020	FOLLOW-UP	WITHDRAWAL BY SUBJECT	Will not be able to continue in the trial since she has had to travel abroad for personal reasons

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



**16.2.1.1.1 Listing of Subjects Discontinued From Vaccination and/or From the Study –  
Subjects 12 Through 25 Years of Age**

<b>Age Group (Years)</b>	<b>Subject</b>	<b>Dose No.</b>	<b>Rel Day<sup>a</sup></b>	<b>Withdrawal Date</b>	<b>Study Phase</b>	<b>Withdrawal Reason</b>	<b>Comment<sup>b</sup></b>
b. MedDRA (v23.1) coding dictionary applied. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (00:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adds_1001_withdraw_ped							