

16.2.3.1.1 Listing of Subjects Excluded From All-Available and Evaluable Immunogenicity Populations – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Population	Reason for Exclusion	
BNT162b1	65-85	10 µg	C4591001 1002 10021053	Dose 1 evaluable	Had major protocol deviation(s) as determined by the clinician.	
				Dose 2 evaluable	Had major protocol deviation(s) as determined by the clinician.	
BNT162b2	18-55	10 µg	C4591001 1003 10031021	Dose 1 evaluable	Had major protocol deviation(s) as determined by the clinician.	
				Dose 2 evaluable	Had major protocol deviation(s) as determined by the clinician.	
Placebo	18-55	Placebo	C4591001 1007 10071050	Dose 2 evaluable	Did not have blood collection within 6-8 days after Dose 2.	
				C4591001 1003 10031017	Dose 1 evaluable	Had major protocol deviation(s) as determined by the clinician.
					Dose 2 evaluable	Had major protocol deviation(s) as determined by the clinician.
BNT162b2	65-85	20 µg	C4591001 1003 10031055	Dose 1 evaluable	Had major protocol deviation(s) as determined by the clinician.	
				Dose 2 evaluable	Did not have blood collection within 6-8 days after Dose 2.	
		30 µg	C4591001 1003 10031047	Dose 1 evaluable	Had major protocol deviation(s) as determined by the clinician.	
				Dose 2 evaluable	Had major protocol deviation(s) as determined by the clinician.	

PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 17SEP2020 (23:36)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001 IA P1 Serology/adsl 1001 excl eval p1

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16.2.3.1.1.1 Listing of Subjects Excluded From All-Available and Evaluable Immunogenicity Populations – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Population	Reason for Exclusion
No subject meets the reporting criteria.					
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adsl Table Generation: 22SEP2020 (00:02) (Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_100/adsl_l001_excl_eval_100_p1					

16.2.3.1.2 Listing of Subjects Excluded From All-Available and Evaluable Immunogenicity Populations – Phase 2

Age Group (Years)	Subject	Population	Reason for Exclusion
18-55	C4591001 1003 10031101	Dose 2 Evaluable	Had important protocol deviation(s) as determined by the clinician.
	C4591001 1003 10031104	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1007 10071095	Dose 2 Evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1013 10131019	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1013 10131025	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1079 10791004	Dose 2 All-available	Did not receive Dose 2.
		Dose 2 Evaluable	Did not receive 2 doses of the vaccine to which they are randomly assigned.
	C4591001 1082 10821004	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1085 10851003	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1109 11091006	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1109 11091018	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1109 11091024	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1109 11091030	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1120 11201001	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1129 11291005	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.

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16.2.3.1.2 Listing of Subjects Excluded From All-Available and Evaluable Immunogenicity Populations – Phase 2

Age Group (Years)	Subject	Population	Reason for Exclusion
56-85	C4591001 1129 11291014	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1001 10011096	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
	C4591001 1082 10821001	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1084 10841006	Dose 2 Evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1089 10891004	Dose 2 Evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1109 11091032	Dose 2 Evaluable	Did not have blood collection within 28-42 days after Dose 2.
	C4591001 1127 11271002	Dose 2 Evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1127 11271003	Dose 2 Evaluable	Did not receive Dose 2 within 19-42 days after Dose 1.
	C4591001 1140 11401002	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.
	C4591001 1140 11401003	Dose 2 All-available	Did not have at least 1 valid and determinate immunogenicity result after Dose 2.
		Dose 2 Evaluable	Did not have at least 1 valid and determinate immunogenicity result after Dose 2; did not have blood collection within 28-42 days after Dose 2.

PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (02:22)
 (Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adsl_1001_excl_p2_eval

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16.2.3.2.1 Listing of Subjects Excluded From Safety Population – Phase 1, 2 Doses, 21 Days Apart

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Reason for Exclusion
No subject meets the reporting criteria.				
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 31AUG2020 (10:58) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: (CDISC)/C4591001 IA P1/adsl l001 excl saf p1				

16.2.3.2.1.1 Listing of Subjects Excluded From Safety Population – Phase 1 – BNT162b1 (100 µg)

Vaccine Candidate	Age Group (Years)	Vaccine Group (as Randomized)	Subject	Reason for Exclusion
No subject meets the reporting criteria.				
PFIZER CONFIDENTIAL SDTM Creation: 28AUG2020 (16:27) Source Data: adsl Table Generation: 18SEP2020 (13:43) (Cutoff Date: 24AUG2020, Snapshot Date: 28AUG2020) Output File: ./nda3/C4591001 IA P1 100/adsl 1001 excl saf 100 p1				

16.2.3.2.2 Listing of Subjects Excluded From Safety Population – Phase 2**Age Group
(Years)****Subject****Reason for Exclusion**

No subject meets the reporting criteria.

PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (14:18) Source Data: adsl Table Generation: 09SEP2020 (23:18)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adsl_1001_excl_p2_saf

16.2.3.2.4 Listing of Subjects Excluded From Safety Population – All Subjects

Age Group (Years)	Subject	Reason for Exclusion
16-55	C4591001 1003 10031140	Subject did not receive study vaccine.
	C4591001 1003 10031143	Subject did not receive study vaccine.
	C4591001 1005 10051381	Subject did not receive study vaccine.
	C4591001 1013 10131017	Subject did not receive study vaccine.
	C4591001 1013 10131740	Subject did not receive study vaccine.
	C4591001 1036 10361050	Subject did not receive study vaccine.
	C4591001 1057 10571031	Subject did not receive study vaccine.
	C4591001 1057 10571211	Subject did not receive study vaccine.
	C4591001 1057 10571212	Subject did not receive study vaccine.
	C4591001 1057 10571215	Subject did not receive study vaccine.
	C4591001 1057 10571268	Subject did not receive study vaccine.
	C4591001 1066 10661335	Subject did not receive study vaccine.
	C4591001 1071 10711162	Subject did not receive study vaccine.
	C4591001 1081 10811105	Subject did not receive study vaccine.
	C4591001 1082 10821013	Subject did not receive study vaccine.
	C4591001 1089 10891346	Subject did not receive study vaccine.
	C4591001 1089 10891351	Subject did not receive study vaccine.
	C4591001 1092 10921128	Subject did not receive study vaccine.
	C4591001 1093 10931055	Subject did not receive study vaccine.
	C4591001 1109 11091349	Subject did not receive study vaccine.
	C4591001 1112 11121229	Subject did not receive study vaccine.
	C4591001 1116 11161015	Subject did not receive study vaccine.
	C4591001 1120 11201038	Subject did not receive study vaccine.
	C4591001 1120 11201252	Subject did not receive study vaccine.
	C4591001 1120 11201299	Did not provide informed consent.
	C4591001 1122 11221006	Subject did not receive study vaccine.

16.2.3.2.4 Listing of Subjects Excluded From Safety Population – All Subjects

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1122 11221026	Subject did not receive study vaccine.
	C4591001 1123 11231027	Subject did not receive study vaccine.
	C4591001 1123 11231301	Subject did not receive study vaccine.
	C4591001 1126 11261074	Subject did not receive study vaccine.
	C4591001 1129 11291048	Subject did not receive study vaccine.
	C4591001 1133 11331162	Subject did not receive study vaccine.
	C4591001 1135 11351389	Subject did not receive study vaccine.
	C4591001 1162 11621024	Subject did not receive study vaccine.
	C4591001 1162 11621477	Subject did not receive study vaccine.
	C4591001 1167 11671003	Subject did not receive study vaccine.
	C4591001 1168 11681030	Subject did not receive study vaccine.
	C4591001 1205 12051028	Subject did not receive study vaccine.
	C4591001 1212 12121023	Subject did not receive study vaccine.
	C4591001 1223 12231200	Subject did not receive study vaccine.
	C4591001 1223 12231234	Subject did not receive study vaccine.
	C4591001 1231 12311409	Subject did not receive study vaccine.
	C4591001 1231 12311516	Subject did not receive study vaccine.
	C4591001 1231 12311926	Subject did not receive study vaccine.
	C4591001 1231 12312176	Subject did not receive study vaccine.
	C4591001 1231 12312483	Subject did not receive study vaccine.
	C4591001 1231 12313443	Subject did not receive study vaccine.
	C4591001 1231 12313527	Subject did not receive study vaccine.
	C4591001 1231 12313869	Subject did not receive study vaccine.
	C4591001 1231 12314738	Subject did not receive study vaccine.
	C4591001 1231 12315308	Subject did not receive study vaccine.
	C4591001 1232 12321037	Subject did not receive study vaccine.

16.2.3.2.4 Listing of Subjects Excluded From Safety Population – All Subjects

Age Group (Years)	Subject	Reason for Exclusion
>55	C4591001 1235 12351167	Subject did not receive study vaccine.
	C4591001 1248 12481018	Subject did not receive study vaccine.
	C4591001 1248 12481025	Subject did not receive study vaccine.
	C4591001 1248 12481060	Subject did not receive study vaccine.
	C4591001 1248 12481218	Subject did not receive study vaccine.
	C4591001 1260 12601049	Subject did not receive study vaccine.
	C4591001 1260 12601070	Subject did not receive study vaccine.
	C4591001 1264 12641018	Subject did not receive study vaccine.
	C4591001 4444 44441135	Subject did not receive study vaccine.
	C4591001 1013 10131097	Subject did not receive study vaccine.
	C4591001 1019 10191033	Subject did not receive study vaccine.
	C4591001 1019 10191300	Subject did not receive study vaccine.
	C4591001 1022 10221015	Subject did not receive study vaccine.
	C4591001 1022 10221057	Subject did not receive study vaccine.
	C4591001 1022 10221150	Subject did not receive study vaccine.
	C4591001 1037 10371057	Subject did not receive study vaccine.
	C4591001 1037 10371117	Subject did not receive study vaccine.
	C4591001 1044 10441113	Subject did not receive study vaccine.
	C4591001 1054 10541071	Subject did not receive study vaccine.
	C4591001 1054 10541175	Subject did not receive study vaccine.
	C4591001 1056 10561078	Subject did not receive study vaccine.
	C4591001 1082 10821062	Subject did not receive study vaccine.
	C4591001 1084 10841366	Subject did not receive study vaccine.
	C4591001 1084 10841446	Subject did not receive study vaccine.
	C4591001 1087 10871434	Subject did not receive study vaccine.
	C4591001 1087 10871512	Subject did not receive study vaccine.

16.2.3.2.4 Listing of Subjects Excluded From Safety Population – All Subjects

Age Group (Years)	Subject	Reason for Exclusion
	C4591001 1091 10911092	Subject did not receive study vaccine.
	C4591001 1097 10971003	Subject did not receive study vaccine.
	C4591001 1098 10981092	Subject did not receive study vaccine.
	C4591001 1098 10981109	Subject did not receive study vaccine.
	C4591001 1109 11091259	Subject did not receive study vaccine.
	C4591001 1116 11161117	Subject did not receive study vaccine.
	C4591001 1116 11161118	Subject did not receive study vaccine.
	C4591001 1128 11281023	Subject did not receive study vaccine.
	C4591001 1128 11281109	Subject did not receive study vaccine.
	C4591001 1129 11291082	Subject did not receive study vaccine.
	C4591001 1129 11291117	Subject did not receive study vaccine.
	C4591001 1133 11331197	Subject did not receive study vaccine.
	C4591001 1134 11341130	Subject did not receive study vaccine.
	C4591001 1157 11571028	Subject did not receive study vaccine.
	C4591001 1178 11781056	Subject did not receive study vaccine.
	C4591001 1185 11851006	Subject did not receive study vaccine.
	C4591001 1223 12231215	Subject did not receive study vaccine.
	C4591001 1223 12231250	Subject did not receive study vaccine.
	C4591001 1224 12241157	Subject did not receive study vaccine.
	C4591001 1231 12312222	Subject did not receive study vaccine.
	C4591001 1232 12321432	Subject did not receive study vaccine.
	C4591001 1248 12481182	Subject did not receive study vaccine.

Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (21:33)

(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: .\nda2_unblinded\C4591001_IA_P3_2MPD2\adsl_1001_excl_p3_saf_all

16.2.3.2.5 Listing of Subjects with Unknown Actual Dosing – ~38000 Subjects for Phase 2/3 Analysis

Age Group (Years)	Subject	Comments
16-55	C4591001 1163 11631006	Vaccinated per CRF but actual treatment not confirmed in IRT.
>55	C4591001 1163 11631005	Vaccinated per CRF but actual treatment not confirmed in IRT.
	C4591001 1163 11631008	Vaccinated per CRF but actual treatment not confirmed in IRT.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:52)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/sl_1001_spc_p3_saf

16.2.3.2.6 Listing of Subjects with Unknown Actual Dosing – All Subjects

Age Group (Years)	Subject	Comments
16-55	C4591001 1163 11631006	Vaccinated per CRF but actual treatment not confirmed in IRT.
>55	C4591001 1163 11631005	Vaccinated per CRF but actual treatment not confirmed in IRT.
	C4591001 1163 11631008	Vaccinated per CRF but actual treatment not confirmed in IRT.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (16:52)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/sl_1001_spc_p3_saf_all