

Summary of Clinical Data

Clinical Overview

Table A. All Clinical Trials, Participants 12 to 15 and 16 to 25 Years of Age – Randomized Subjects

Study Number/ Country	Description	BNT162b2 Participants (N)	Placebo Participants (N)	Study Status
C4591001/USA, Argentina, Brazil, Germany, South Africa, Turkey	A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals	3009	3043	Ongoing

Subject Disposition

Table B. Disposition of Immunogenicity Populations, Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Treatment Groups as Randomized

Disposition	12-15 Years BNT162b2 n ^a (%)	16-25 Years BNT162b2 n ^a (%)	12-15 Years Placebo n ^a (%)	16-25 Years Placebo n ^a (%)
Randomized ^b	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Dose 1 all-available immunogenicity population	NA	NA	NA	NA
Participants without evidence of infection before Dose 1	NA	NA	NA	NA
Participants excluded from Dose 1 all-available immunogenicity population	NA	NA	NA	NA
Reason for exclusion ^c	NA	NA	NA	NA
Did not receive at least 1 vaccination	NA	NA	NA	NA
Dose 2 all-available immunogenicity population	210 (75.0)	191 (68.2)	36 (72.0)	34 (68.0)
Participants without evidence of infection prior to 7 days after Dose 2	NA	NA	NA	NA
Participants excluded from Dose 2 all-available immunogenicity population	70 (25.0)	89 (31.8)	14 (28.0)	16 (32.0)
Reason for exclusion ^c				
Did not receive 2 vaccinations	1 (0.4)	0	0	0
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	69 (24.6)	89 (31.8)	14 (28.0)	16 (32.0)
Dose 2 Evaluable immunogenicity population	209 (74.6)	186 (66.4)	36 (72.0)	32 (64.0)
Participants excluded from evaluable immunogenicity population	71 (25.4)	94 (33.6)	14 (28.0)	18 (36.0)
Reason for exclusion ^c				
Randomized but did not meet all eligibility criteria	0	0	0	0
Did not provide informed consent	0	0	0	0
Baseline SARS-CoV-2 status was positive or not known	NA	NA	NA	NA

Disposition	12-15 Years BNT162b2 n^a (%)	16-25 Years BNT162b2 n^a (%)	12-15 Years Placebo n^a (%)	16-25 Years Placebo n^a (%)
Did not receive 2 doses of the vaccine to which they were randomly assigned	1(0.4)	0	0	0
Did not receive Dose 2 within 19-42 days after Dose 1	1 (0.4)	2(0.7)	0	2 (4.0)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	69 (24.6)	89 (31.8)	14 (28.0)	16 (32.0)
Did not have blood collection within 28-42 days after Dose 2	3 (1.1)	16 (5.7)	0	3 (6.0)
Had important protocol deviation(s) as determined by the clinician	0	0	0	1 (2.0)

^a n = Number of participants with the specified characteristic.

^b These values are the denominators for the percentage calculations.

^c Participants may have been excluded for more than 1 reason.

NA = Not Applicable

Notes: Dose 1 All-Available Immunogenicity Population is not applicable for 12-15 and 16-25 Years of age subjects in Phase 3 of the study as blood sample was collected only at Dose 1 and 1 Month after Dose 2.

Notes: Immunogenicity subset is based on a random selection of 280 subjects from BNT162b2 and 50 subjects from Placebo for each of the age groups

Table C. Disposition of Efficacy Populations, Participants 12 to 15 Years of Age, Treatment Groups as Randomized*

Disposition	BNT162b2 n^a (%)	Placebo n^a (%)	Total n^a (%)
Randomized ^b	1134 (100.0)	1130 (100.0)	2264 (100.0)
Dose 1 all-available efficacy population	1131 (99.7)	1129 (99.9)	2260 (99.8)
Participants without evidence of infection before Dose 1	1028 (90.7)	1023 (90.5)	2051 (90.6)
Participants excluded from Dose 1 all-available efficacy population	3 (0.3)	1 (0.1)	4 (0.2)
Reason for exclusion ^c			
Did not receive at least 1 vaccination	3 (0.3)	1 (0.1)	4 (0.2)
Dose 2 all-available efficacy population	1123 (99.0)	1117 (98.8)	2240 (98.9)
Participants without evidence of infection prior to 7 days after Dose 2	1008 (88.9)	983 (87.0)	1991 (87.9)
Participants excluded from Dose 2 all-available efficacy population	11 (1.0)	13 (1.2)	24 (1.1)
Reason for exclusion ^c			
Did not receive 2 vaccinations	10 (0.9)	13 (1.2)	23 (1.0)
Unblinded prior to 7 days after Dose 2	1 (0.1)	0	1 (0.0)
Evaluable efficacy (7 days) population	1119 (98.7)	1110 (98.2)	2229 (98.5)
Subjects without evidence of infection prior to 7 days after Dose 2	1005 (88.6)	978 (86.5)	1983 (87.6)
Participants excluded from evaluable efficacy (7 days) population	15 (1.3)	20 (1.8)	35 (1.5)
Reason for exclusion ^c			
Randomized but did not meet all eligibility criteria	1 (0.1)	0	1 (0.0)
Did not provide informed consent	0	0	0
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	14 (1.2)	19 (1.7)	33 (1.5)
Had other important protocol deviations on or prior to 7 days after Dose 2	0	2 (0.2)	2 (0.1)

Disposition	BNT162b2 n^a (%)	Placebo n^a (%)	Total n^a (%)
Unblinded prior to 7 days after Dose 2	1 (0.1)	0	1 (0.0)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.

^a n = Number of participants with the specified characteristic.

^b These values are the denominators for the percentage calculations.

^c Participants may have been excluded for more than 1 reason.

Table D. Disposition of All Randomized Participants 12 to 15 and 16 Through 25 Years of Age, Safety Population

Treatment Group as Randomized	12-15 Years BNT162b2 n^a (%)	16-25 Years BNT162b2 n^a (%)	12-15 Years Placebo n^a (%)	16-25 Years Placebo n^a (%)
Randomized	1134 (100.0)	1875 (100.0)	1130 (100.0)	1913 (100.0)
Not vaccinated	3 (0.3)	6 (0.3)	1 (0.1)	7 (0.4)
Vaccinated				
Completed 1 dose	1131 (99.7)	1869 (99.7)	1129 (99.9)	1906 (99.6)
Completed 2 doses	1124 (99.1)	1826 (97.4)	1117 (98.8)	1836 (96.0)
Safety Population	1131 (99.7)	1867 (99.5)	1129 (99.9)	1903 (95.9)
Reactogenicity subset	1131 (99.7)	537 (28.6)	1129 (99.9)	561 (29.3)
HIV-positive	0	1 (0.05)	0	0
Participants excluded from safety population	3 (0.26)	8 (0.42)	1 (0.08)	10 (0.52)
Reason for exclusion ^c				
Did not receive study vaccination	3 (0.26)	6 (0.32)	1 (0.08)	7 (0.36)
Unreliable data due to lack of PI oversight	0	2 (0.10)	0	3 (0.15)
Completed at least 2 months follow up after Dose 2*	660 (58.4)	1645 (88.1)	648 (57.4)	1647 (86.5)
Completed 1-month post-Dose 2 visit (vaccination period)	1118 (98.6)	1803 (96.2)	1102 (97.5)	1807 (94.5)
Discontinued from vaccination period but continue in the study up to 1-month post-Dose 2 visit	7 (0.6)	13 (0.7)	17 (1.5)	42 (2.2)
Discontinued after Dose 1 and before Dose 2	7 (0.6)	12 (0.6)	10 (0.9)	36 (1.9)
Discontinued after Dose 2 and before 1-month post-Dose 2 visit	0	1 (0.1)	7 (0.6)	6 (0.3)
Reason for discontinuation from vaccination period				
No longer meets eligibility criteria	3 (0.3)	4 (0.2)	10 (0.9)	26 (1.4)
Withdrawal by subject	0	6 (0.3)	1 (0.1)	1 (0.1)
Pregnancy	0	1 (0.1)	0	3 (0.2)
Adverse event	2 (0.2)	1 (0.1)	0	0
Physician decision	1 (0.1)	0	0	2 (0.1)
Protocol deviation	0	0	1 (0.1)	2 (0.1)
Lost to follow-up	0	0	0	1 (0.1)
Other	1 (0.1)	1 (0.1)	5 (0.4)	7 (0.4)
Withdrawn from study before 1-month post-Dose 2 visit	0	45 (2.4)	2 (0.2)	56 (2.9)
Withdrawn after Dose 1 and before Dose 2	0	25 (1.3)	1 (0.1)	34 (1.8)

Treatment Group as Randomized	12-15 Years BNT162b2 n^a (%)	16-25 Years BNT162b2 n^a (%)	12-15 Years Placebo n^a (%)	16-25 Years Placebo n^a (%)
Withdrawn after Dose 2 and before 1-month post-Dose 2 visit	0	20 (1.1)	1 (0.1)	22 (1.2)
Reason for Withdrawal				
Adverse Event	0	0	0	1 (0.1)
Death	0	0	0	0
Withdrawal by Subject	0	14 (0.7)	0	19 (1.0)
Lost to Follow-up	0	29 (1.5)	0	32 (1.7)
No longer meets eligibility criteria	0	0	0	0
Refused further study procedures	0	0	0	0
Protocol deviation	0	0	1 (0.1)	1 (0.1)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.1)	0
Physician decision	0	0	0	1 (0.1)
Other	0	1 (0.1)	0	2 (0.1)

* The numbers in this row are based on subjects who got dose 2 as administered. Duration of follow-up is based on blinded placebo-controlled follow-up period only.

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.

I. Clinical Effectiveness

Subject Demographics and Other Baseline Characteristics

Table E. Demographics and Other Baseline Characteristics, Dose 2 Evaluable Immunogenicity Population* Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset)

Characteristic	12-15 Years BNT162b2 (N= 209) n (%)	16-25 Years BNT162b2 (N= 186) n (%)	12-15 Years Placebo (N= 36) n (%)	16-25 Years Placebo (N= 32) n (%)
Sex: Female	103 (49.3)	94 (50.5)	15 (41.7)	18 (56.3)
Sex: Male	106 (50.7)	92 (49.5)	21 (58.3)	14 (43.8)
Age: Mean years (SD)	13.5 (1.12)	20.6 (3.09)	13.4 (1.17)	20.3 (3.05)
Age: Median (years)	14.0	21.0	13.0	19.5
Race: American Indian or Alaska Native	1 (0.5)	3 (1.6)	0	1 (3.1)
Race: Asian	5 (2.4)	10 (5.4)	1 (2.8)	1 (3.1)
Race: Black or African American	16 (7.7)	15 (8.1)	3 (8.3)	2 (6.3)
Race: Native Hawaiian or Other Pacific Islander	0	3 (1.6)	0	0
Race: White	184 (88.0)	147 (79.0)	31 (86.1)	28 (87.5)
Race: Multiracial	3 (1.4)	6 (3.2)	1 (2.8)	0
Race: Not reported	0	2 (1.1)	0	0
Race: Other	NA	NA	NA	NA
Ethnicity: Hispanic or Latino	22 (10.5)	31 (16.7)	2 (5.6)	7 (21.9)
Ethnicity: Not Hispanic or Latino	187 (89.5)	154 (82.8)	34 (94.4)	25 (78.1)
Ethnicity: Not reported	0	1 (0.5)	0	0
Obese ¹ : Yes	24 (11.5)	43 (23.1)	3 (8.3)	4 (12.5)
Obese: No	185 (88.5)	143 (76.9)	33 (91.7)	28 (87.5)
Comorbidities ² : Yes	45 (21.5)	56 (30.1)	7 (19.4)	9 (28.1)
Comorbidities: No	164 (78.5)	130 (69.9)	29 (80.6)	23 (71.9)

Characteristic	12-15 Years BNT162b2 (N= 209) n (%)	16-25 Years BNT162b2 (N= 186) n (%)	12-15 Years Placebo (N= 36) n (%)	16-25 Years Placebo (N= 32) n (%)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative	194 (92.8)	178 (95.7)	33 (91.7)	31 (96.9)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive	10 (4.8)	8 (4.3)	2 (5.6)	1 (3.1)
Baseline Evidence of Prior SARS-CoV-2 Infection: Unknown	5 (2.4)	0	1 (2.8)	0
Region: North America	209 (100.0)	186 (100.0)	36 (100.0)	32 (100.0)

*All eligible randomized participants who receive all vaccination(s) as randomized within the predefined window and have no other important protocol deviations as determined by the clinician.

¹ Obese is defined as BMI ≥ 30 kg/m² (≥ 16 Years of age) or BMI ≥ 95 th percentile (12-15 Years of age).

² Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥ 30 kg/m² [≥ 16 Years of age] or BMI ≥ 95 th percentile [12-15 Years of age]).

Table E.2. Demographics and Other Baseline Characteristics, Evaluable Efficacy Population, Participants 12 to 15* Years of Age

Characteristic	12-15 Years BNT162b2 (N=1119) n (%)	12-15 Years Placebo (N= 1110) n (%)
Sex: Female	560 (50.0)	536 (48.3)
Sex: Male	559 (50.0)	574 (51.7)
Age: Mean years (SD)	13.6 (1.11)	13.6 (1.11)
Age: Median (years)	14.0	14.0
Race: American Indian or Alaska Native	4 (0.4)	2 (0.2)
Race: Asian	71 (6.3)	71 (6.4)
Race: Black or African American	50 (4.5)	57 (5.1)
Race: Native Hawaiian or Other Pacific Islander	3 (0.3)	0
Race: White	962 (86.0)	944 (85.0)
Race: Multiracial	23 (2.1)	29 (2.6)
Race: Not reported	6 (0.5)	7 (0.6)
Race: Other	NA	NA
Ethnicity: Hispanic or Latino	131 (11.7)	127 (11.4)
Ethnicity: Not Hispanic or Latino	986 (88.1)	980 (88.3)
Ethnicity: Not reported	2 (0.2)	3 (0.3)
Obese ¹ : Yes	141 (12.6)	126 (11.4)
Obese: No	978 (87.4)	984 (88.6)
Comorbidities ² : Yes	243 (21.7)	235 (21.2)
Comorbidities: No	876 (78.3)	875 (78.8)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative	1018 (91.0)	1006 (90.6)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive	46 (4.1)	46 (4.1)
Baseline Evidence of Prior SARS-CoV-2 Infection: Unknown	55 (4.9)	58 (5.2)
Country: USA (add rows, as needed)	1119 (100.0)	1110 (100.0)

* All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, with Dose 2 received within the predefined window (within 19-42 days after Dose 1), have at least 1 valid and determinate immunogenicity result after Dose 2 from the blood collection within 28-42 days after Dose 2 and have no other important protocol deviations as determined by the clinician.

¹ Obese is defined as BMI ≥ 30 kg/m² (≥ 16 Years of age) or BMI ≥ 95 th percentile (12-15 Years of age).

² Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19

disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥ 30 kg/m² [≥ 16 Years of age] or BMI ≥ 95 th percentile [≥ 12 -15 Years of age]).

Immunogenicity Results – Secondary Immunogenicity Endpoints

Table F. Geometric Mean SARS-CoV-2 Neutralizing Titers (NT50) 1 Month After BNT162b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of Infection up to 1 Month After Dose 2, Dose 2 Evaluable Immunogenicity Population

Study Group	12-15 Years N=190 GMT (95% CI)	16-25 Years N=170 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion*
BNT162b2	1239.5 (1095.5, 1402.5)	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Yes

* Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is greater than 0.67.

N: Number of participants with valid and determinate assay results for the specified assay at 1 month after Dose 2.

GMT: geometric mean titer

Table G. Seroconversion Rates – NT50 – 1 Month After BNT162b2 Dose 2, Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Participants Without Evidence of Infection up to 1 Month After Dose 2, Dose 2 Evaluable Immunogenicity Population

Study Group	12-15 Years N=143 n, SCR (%) (95% CI)	16-25 Years N=124 n, SCR (%) (95% CI)	Difference in Seroconversion Rates* (95% CI)	Met Predefined Success Criterion
BNT162b2	140 (97.9) (94.0, 99.6)	124 (100.0) (97.1, 100.0)	-2.1 (-6.0, 0.9)	Not Applicable

* Seroconversion is defined as achieving a ≥ 4 -fold rise from baseline (before vaccination).

N: number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2.

n: number of participants with ≥ 4 -fold rise from before vaccination to 1 month after Dose 2

SCR: Seroconversion Rate

Table H*. Subgroup Analyses of Geometric Mean SARS-CoV-2 Neutralizing Titers (NT 50) One Month After BNT162b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2 All-available Immunogenicity Population

Subgroup	12-15 Years N, GMT (95% CI)	16-25 Years N, GMT (95% CI)	GMT Ratio [definition] (95% CI)
Comorbid condition ¹ : Yes	45, 1460.3 (1218.2, 1750.5)	56, 712.4 (546.0, 929.5)	2.05 (1.49, 2.82)
Comorbid condition: No	163, 1239.7 (1075.2, 1429.3)	134, 732.1 (641.6, 835.5)	1.69 (1.40, 2.05)

Obese: Yes	24, 1596.9 (1233.2, 2067.8)	43, 802.4 (613.5, 1049.4)	1.99 (1.33, 2.97)
Obese: No	184, 1284.4 (1097.1, 1420.5)	147, 705.4 (615.9, 807.9)	1.77 (1.47, 2.14)
Baseline SARS-CoV-2: Positive	10, 2342.2 (1308.7, 4191.8)	8, 1439.2 (727.1, 2848.7)	1.63 (0.72, 3.69)
Baseline SARS-CoV-2: Negative	193, 1240.9 (1098.7, 1401.5)	182, 704.7 (624.1, 795.9)	1.76 (1.48, 2.09)
Baseline SARS-CoV-2: Unknown	5, 1458.7 (479.2, 4440.9)	0, NE (NE, NE)	NE
Sex: Female	102, 1315.5 (1123.4, 1540.3)	98, 793.4 (665.9, 945.2)	1.66 (1.31, 2.09)
Sex: Male	106, 1255.2 (1051.3, 1498.5)	92, 661.0 (560.2, 780.0)	1.90 (1.49, 2.42)
Ethnicity: Hispanic or Latino	22, 1276.2 (917.9, 1774.4)	31, 662.4 (472.3, 928.9)	1.93 (1.20, 3.11)
Ethnicity: Not Hispanic or Latino	186, 1285.4 (1132.0, 1459.4)	158, 743.4 (652.9, 846.4)	1.73 (1.44, 2.07)
Ethnicity: Not Reported	0, NE (NE, NE)	1,318.0 (NE, NE)	NE
Race: American Indian or Alaska Native	1, 908.0 (NE, NE)	3, 1130.7 (13.7, 93052.6)	0.80 (NE, NE)
Race: Asian	5, 1338.9 (625.6, 2865.8)	10, 649.6 (408.5, 1033.1)	2.06 (0.97, 4.38)
Race: Black or African American	16, 1377.3 (963.1, 1969.4)	15, 803.4 (409.7, 1575.8)	1.71 (0.82, 3.59)
Race: Native Hawaiian or Other Pacific Islander	0, NE (NE, NE)	4, 756.5 (184.9, 3094.1)	NE
Race: White	183, 1286.2 (1129.4, 1464.9)	150, 720.4 (633.2, 819.7)	1.79 (1.48, 2.15)
Race: Multiracial	3, 848.4 (224.8, 3202.1)	6, 741.5 (304.5, 1805.7)	1.14 (0.31, 4.16)
Race: Not reported	0, NE (NE, NE)	2, 486.7 (2.2, 108697.3)	NE
Others			

¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥30 kg/m² [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
N = Number of subjects with valid and determinate assay results for the specified assay at 1 month after Dose 2.
GMT: geometric mean titer

Table H. Subgroup: Subgroup Analyses of Seroconversion Rates – NT50 – One Month After BNT162b2 Dose 2, Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2 All-Available Immunogenicity Population

Subgroup	12-15 Years N n, SCR (%) (95% CI)	16-25 Years N n, SCR (%) (95% CI)	Difference in Seroconversion Rates* (95% CI)
Comorbid condition ¹ : Yes	32 31 (96.9) (83.8, 99.9)	43 42 (97.7) (87.7, 99.9)	-0.8 (-13.8, 9.5)
Comorbid condition: No	123 121 (98.4) (94.2, 99.8)	96 96 (100.0) (96.2, 100.0)	-1.6 (-5.7, 2.3)
Obese: Yes	16 15 (93.8) (69.8, 99.8)	34 33 (97.1) (84.7, 99.9)	-3.3 (-26.0, 10.0)
Obese: No	139 137 (98.6) (94.9, 99.8)	105 105 (100.0) (96.5, 100.0)	-1.4 (-5.1, 2.1)
Baseline SARS-CoV-2: Positive	8 8 (100.0) (63.1, 100.0)	5 4 (80.0) (28.4, 99.5)	20 (-18.8, 63.8)
Baseline SARS-CoV-2: Negative	146 143 (97.9) (94.1, 99.6)	134 134 (100) (97.3, 100)	-2.1 (-5.9, 0.8)
Baseline SARS-CoV-2:	1 1 (100) (2.5, 100.0)	0 0 (NE) (NE, NE)	NE
Sex: Female	78 77 (98.7) (93.1, 100.0)	72 72 (100.0) (95.0, 100.0)	-1.3 (-6.9, 3.8)
Sex: Male	77 75 (97.4) (90.9, 99.7)	67 66 (98.5) (92.0, 100.0)	-1.1 (-7.7, 5.7)
Ethnicity: Hispanic or Latino	13	21	4.8 (-19.1, 23.0)

Subgroup	12-15 Years N n, SCR (%) (95% CI)	16-25 Years N n, SCR (%) (95% CI)	Difference in Seroconversion Rates* (95% CI)
	13 (100.0) (75.3, 100.0)	20 (95.2) (76.2, 99.9)	
Ethnicity: Not Hispanic or Latino	142 139 (97.9) (94.0, 99.6)	117 117 (100.0) (96.9, 100.0)	-2.1 (-6.0, 1.1)
Ethnicity: Not Reported	0 0 (NE) (NE, NE)	1 1 (100.0) (2.5, 100.0)	NE
Race: American Indian or Alaska Native	0 0 (NE) (NE, NE)	3 3 (100.0) (29.2, 100.0)	NE
Race: Asian	5 5 (100.0) (47.8, 100.0)	3 3 (100.0) (29.2, 100.0)	0.0 (-46.8, 59.4)
Race: Black or African American	9 9 (100.0) (66.4, 100.0)	10 10 (100.0) (69.2, 100.0)	0.0 (-31.1, 28.9)
Race: Native Hawaiian or Other Pacific Islander	0 0 (NE) (NE, NE)	4 4 (100.0) (39.8, 100.0)	NE
Race: White	139 136 (97.8) (93.8, 99.6)	113 112 (99.1) (95.2, 100.0)	-1.3 (-5.4, 2.9)
Race: Multiracial	2 2 (100.0) (15.8, 100.0)	5 5 (100.0) (47.8, 100.0)	0.0 (-69.1, 47.3)
Race: Not reported	0 0 (NE) (NE, NE)	1 1 (100.0) (2.5, 100.0)	NE
Others			

¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥ 30 kg/m² [≥ 16 Years of age] or BMI ≥ 95 th percentile [12-15 Years of age]).

N = number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2

n = Number of subjects with ≥ 4 -fold rise from before vaccination to 1 month after Dose 2

SCR: Seroconversion Rate

Additional Analyses Conducted in the Individual Trial

Table I. Geometric Mean SARS-CoV-2 Neutralizing Titers (NT50) One Month After BNT162b2 Dose 2 in Participants 12 to 15 and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2 All-available Immunogenicity Population

Study Group	12-15 Years N=208 GMT (95% CI)	16-25 Years N=190 GMT (95% CI)	GMT Ratio [12-15 Years/ 16-25 Years] (95% CI)	Met Predefined Success Criterion
BNT162b2	1284.4 (1141.4, 1445.2)	726.3 (643.9, 819.1)	1.77 (1.49, 2.09)	Not Applicable

N: Number of subjects with valid and determinate assay results for the specified assay at 1 month after Dose 2

GMT: geometric mean titer

Table J. Seroconversion Rates – NT50 – One Month After BNT162b2 Dose 2 in Participants 12 to 15 Years and 16 Through 25 Years of Age (Immunogenicity Subset), Dose 2 All-available Immunogenicity Population

Study Group	12-15 Years N=155 n, SCR (%) (95% CI)	16-25 Years N=139 n, SCR (%) (95% CI)	Difference in Seroconversion Rates* (95% CI)	Met Predefined Success Criterion
BNT162b2	152 (98.1) (94.4, 99.6)	138 (99.3) (96.1, 100.0)	-1.2 (-4.9, 2.2)	Not Applicable

* Seroconversion is defined as achieving a ≥ 4 -fold rise from baseline (before vaccination).

N: number of participants with valid and determinate assay results for the specified assay both before vaccination and at 1 month after Dose 2.

n: number of participants with ≥ 4 -fold rise from before vaccination to 1 month after Dose 2

SCR: Seroconversion Rate

Efficacy Results

Table K. Vaccine Efficacy Analyses, Without Evidence of Infection Prior to 7 Days After Dose 2, Participants 12 to 15 Years of Age, Evaluable Efficacy Population

Endpoint	BNT162b2 N ^a =1005 Cases n ^{1b} Surveillance Time ^c (n ^{2d})	Placebo N ^a =978 Cases n ^{1b} Surveillance Time ^c (n ^{2d})	Vaccine Efficacy (VE) % (95% CI) ^e
First COVID-19 occurrence from 7 days after Dose 2 in subjects without evidence of prior SARS-CoV-2 infection	0, 0.154 (1001)	16, 0.147 (972)	100.0 (75.3, 100.0)
Severe COVID-19 cases	0 cases	0 cases	

^a N = number of participants in the specified group.

^b n¹ = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

^d n² = Number of participants at risk for the endpoint.

^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Table K.1 Vaccine Efficacy Analyses, With or Without Evidence of Infection Prior to 7 Days After Dose 2, Participants 12 to 15 Years, Evaluable Efficacy Population

Endpoint	BNT162b2 N^a=1119 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=1110 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy (VE) % (95% CI)^e
First COVID-19 occurrence from 7 days after Dose 2 in subjects with or without evidence of prior SARS-CoV-2 infection	0, 0.170 (1109)	18, 0.163 (1094)	100.0 (78.1, 100.0)
Severe COVID-19 cases	0 cases	0 cases	

^a N = number of participants in the specified group.

^b n1 = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

^d n2 = Number of participants at risk for the endpoint.

^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Table L. Subgroup Analyses of Vaccine Efficacy, With or Without Evidence of Infection - First COVID-19 Occurrence From 7 Days After Dose 2, Participants 12 to 15 Years of Age, Evaluable Efficacy Population

Efficacy Endpoint Subgroup	BNT162b2 N^a=1119 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=1110 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
Overall	0, 0.170(1109)	18, 0.163(1094)	100.0 (78.1,100.0)
Comorbidities ^f			
Yes	0, 0.038 (242)	7, 0.035 (230)	100.0 (36.2, 100.0)
No	0, 0.132 (867)	11, 0.129 (864)	100.0 (61.1, 100.0)
Obese ^g			
Yes	0, 0.022 (140)	4, 0.019 (124)	100.0 (-31.1, 100.0)
No	0, 0.148 (969)	14, 0.145 (970)	100.0 (70.5, 100.0)
Sex			
Female	0, 0.083 (554)	6, 0.079 (528)	100.0 (18.6, 100.0)
Male	0, 0.087 (555)	12, 0.084 (566)	100.0 (65.1, 100.0)
Ethnicity			
Hispanic or Latino	0, 0.021 (128)	5, 0.018 (125)	100.0 (6.5, 100.0)
Not Hispanic or Latino	0, 0.149 (979)	13, 0.145 (966)	100.0 (67.9, 100.0)
Race			

Efficacy Endpoint Subgroup	BNT162b2 N^a=1119 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=1110 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
American Indian or Alaska Native	0	0	NA
Asian	0	0	NA
Black or African American	0	0	NA
Native Hawaiian or other Pacific Islander	0	0	NA
White	0, 0.145 (955)	18, 0.138 (928)	100.0 (78.4, 100.0)
Multiracial	0	0	NA
Not reported	0	0	NA
Baseline SARS-CoV-2 Status			
Positive ^h	0	0	NA
Negative ⁱ	0, 0.156 (1009)	18, 0.149 (990)	100.0 (78.2, 100.0)
Unknown	0	0	NA

^a N = number of participants in the specified group.

^b n1 = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

^d n2 = Number of participants at risk for the endpoint.

^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

^f Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥30 kg/m² [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).

^g Obese is defined as BMI ≥30 kg/m² (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).

^h Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

ⁱ Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

Table L.1 Subgroup Analyses of Vaccine Efficacy, Without Evidence of Infection - First COVID-19 Occurrence From 7 Days After Dose 2, Participants 12 to 15 Years of Age, Evaluable Efficacy Population

Efficacy Endpoint Subgroup	BNT162b2 N^a=1005 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=978 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
Overall	0, 0.154 (1001)	16, 0.147 (972)	100.0 (75.3, 100.0)
Comorbidities ^f			
Yes	0, 0.034 (213)	5, 0.032 (203)	100.0 (-2.0, 100.0)
No	0, 0.121 (788)	11, 0.116 (769)	100.0 (61.9, 100.0)
Obese ^g			
Yes	0, 0.019 (123)	3, 0.016 (105)	100.0 (-104.8, 100.0)
No	0, 0.135 (878)	13, 0.131 (867)	100.0 (68.3, 100.0)
Sex			

Efficacy Endpoint Subgroup	BNT162b2 N^a=1005 Cases n¹^b Surveillance Time^c (n²^d)	Placebo N^a=978 Cases n¹^b Surveillance Time^c (n²^d)	Vaccine Efficacy % (95% CI)^e
Female	0, 0.075 (502)	6, 0.072 (473)	100.0 (19.3, 100.0)
Male	0, 0.079 (499)	10, 0.075 (499)	100.0 (57.5, 100.0)
Ethnicity			
Hispanic or Latino	0, 0.018 (109)	5, 0.015 (105)	100.0 (9.1, 100.0)
Not Hispanic or Latino	0, 0.136 (890)	11, 0.132 (864)	100.0 (61.5, 100.0)
Race			
American Indian or Alaska Native	0	0	NA
Asian	0	0	NA
Black or African American	0	0	NA
Native Hawaiian or other Pacific Islander	0	0	NA
White	0, 0.132 (865)	16, 0.124 (824)	100.0 (75.7, 100.0)
Multiracial	0	0	NA
Not reported	0	0	NA

^a N = number of participants in the specified group.

^b n1 = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

^d n2 = Number of participants at risk for the endpoint.

^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

^f Comorbidities are defined as having at least one of the Charlson comorbidity index category or obesity (BMI ≥30 kg/m² [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).

^g Obese is defined as BMI ≥30 kg/m² (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).

^h Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

ⁱ Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

Table M. Demographic Characteristics, Participants 12 to 15 Years of Age With Protocol Defined COVID-19 (Without Evidence of Infection Prior to 7 Days After Dose 2)

Characteristic	BNT162b2 N^a=0 n^b (%)	Placebo N^a=16 n^b (%)	Total N^a=16 n^b (%)
Sex: Female	0	6 (37.5)	6 (37.5)
Sex: Male	0	10 (62.5)	10 (62.5)
Age at Vaccination: Mean years (SD)	0	14.1 (1.12)	14.1 (1.12)
Age at Vaccination: Median (years)	0	14.5	14.5
Age at Vaccination: Min, max (years)	0	12, 15	12, 15
Race: American Indian or Alaska Native	0	0	0
Race: Asian	0	0	0
Race: Black or African American	0	0	0
Race: Native Hawaiian or Other Pacific Islander	0	0	0

Characteristic	BNT162b2 N^a=0 n^b (%)	Placebo N^a=16 n^b (%)	Total N^a=16 n^b (%)
Race: White	0	16 (100.0)	16 (100.0)
Race: Multiracial	0	0	0
Race: Not reported	0	0	0
Ethnicity: Hispanic or Latino	0	5 (31.3)	5 (31.3)
Ethnicity: Not Hispanic or Latino	0	11 (68.8)	11 (68.8)
Ethnicity: Not reported	0	0	0
Comorbidities ^c : Yes	0	5 (31.3)	5 (31.3)
Comorbidities: No	0	11 (68.8)	11 (68.8)
Comorbidity: Obesity	0	3 (18.8)	3 (18.8)

^a N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

^b n = Number of participants with the specified characteristic.

^c Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity (BMI ≥ 30 kg/m² [≥ 16 Years of age] or BMI ≥ 95 th percentile [12-15 Years of age]).

Table M.1 Demographic Characteristics, Participants 12 to 15 Years of Age With Protocol Defined COVID-19 (With or Without Evidence of Infection Prior to 7 Days After Dose 2)

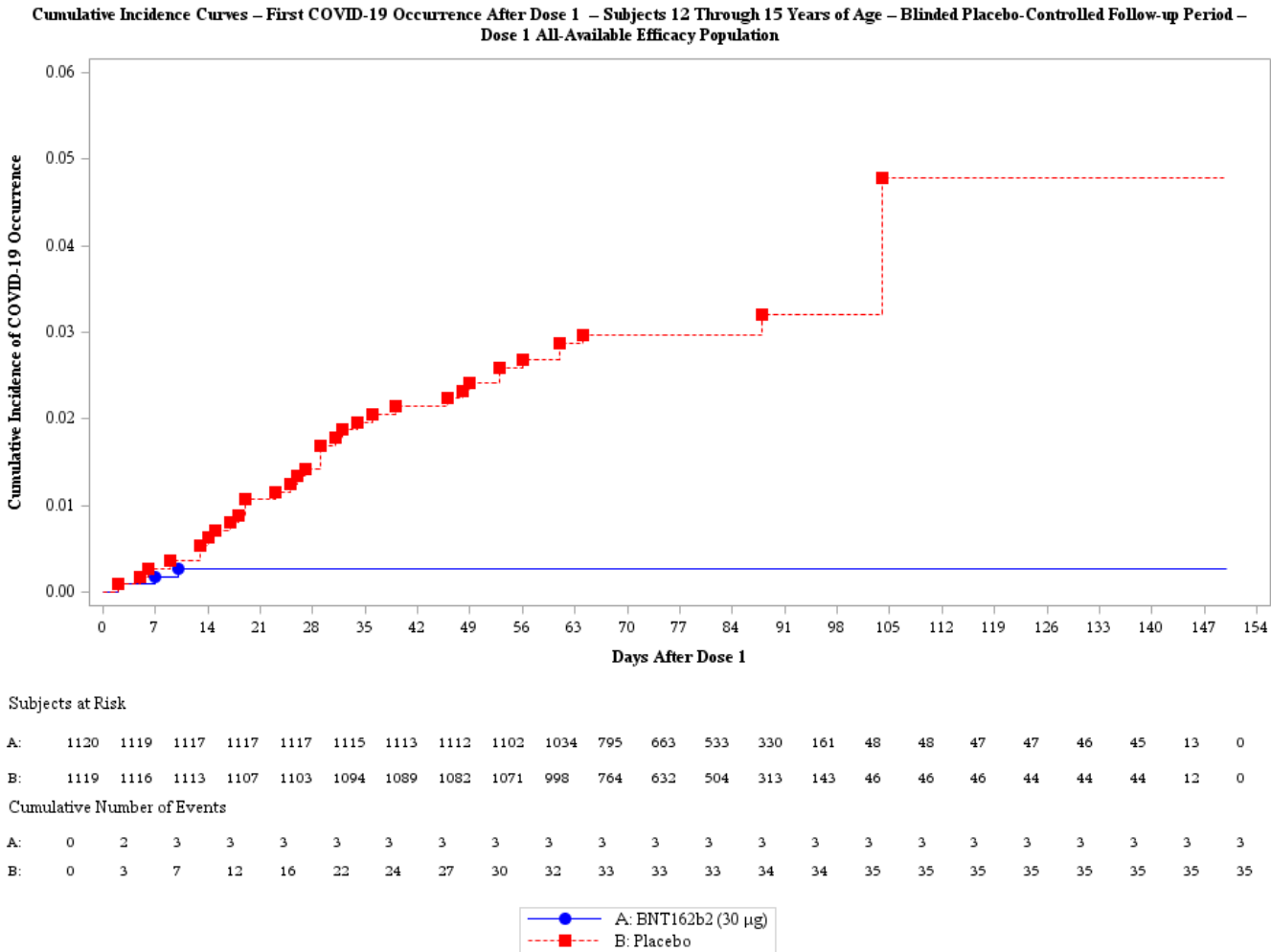
Characteristic	BNT162b2 N^a=0 n^b (%)	Placebo N^a=18 n^b (%)	Total N^a=18 n^b (%)
Sex: Female	0	6 (33.3)	6 (33.3)
Sex: Male	0	12 (66.7)	12 (66.7)
Age at Vaccination: Mean years (SD)	0	13.9 (1.16)	13.9 (1.16)
Age at Vaccination: Median (years)	0	14.0	14.0
Age at Vaccination: Min, max (years)	0	(12, 15)	(12, 15)
Race: American Indian or Alaska Native	0	0	0
Race: Asian	0	0	0
Race: Black or African American	0	0	0
Race: Native Hawaiian or Other Pacific Islander	0	0	0
Race: White	0	18 (100.0)	18 (100.0)
Race: Multiracial	0	0	0
Race: Not reported	0	0	0
Ethnicity: Hispanic or Latino	0	5 (27.8)	5 (27.8)
Ethnicity: Not Hispanic or Latino	0	13 (72.2)	13 (72.2)
Ethnicity: Not reported	0	0	0
Comorbidities ^c : Yes	0	7 (38.9)	7 (38.9)
Comorbidities: No	0	11 (61.1)	11 (61.1)
Comorbidity: Obesity	0	4 (22.2)	4 (22.2)

^a N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.

^b n = Number of participants with the specified characteristic.

^c Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only (BMI ≥ 30 kg/m² [≥ 16 Years of age] or BMI ≥ 95 th percentile [12-15 Years of age]).

Cumulative Incidence Curve of COVID-19 Cases in Participants 12 to 15 Years of Age, Over Time (Vaccine vs. Placebo)



PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adc19ef Table Generation: 02APR2021 (17:04)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA_RR/adc19ef_f001_km_d1_ped_aai

Table N. Primary Efficacy Endpoint, Participants 12 to 15 Years of Age, Dose 1 All-Available Efficacy Population

Efficacy Endpoint	BNT162b2 N^a=1131 Cases n1^b Surveillance Time^c (n2^d)	Placebo N^a=1129 Cases n1^b Surveillance Time^c (n2^d)	Vaccine Efficacy % (95% CI)^e
First COVID-19 occurrence after Dose 1	3, 0.257 (1120)	35, 0.250 (1119)	91.6, (73.5, 98.4)
After Dose 1 to before Dose 2	3	12	75.0 (7.4, 95.5)
Dose 2 to 7 days after Dose 2	0	5	100.0 (-9.1, 100.0)
≥7 Days after Dose 2	0	18	100.0 (77.3, 100.0)

^a N = number of participants in the specified group.

^b n1 = Number of participants meeting the endpoint definition.

^c Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.

^d n2 = Number of participants at risk for the endpoint.

^e Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).

II. Clinical Safety

1. Overall Exposure

The median duration of follow-up for participants aged 12-15 years was >2 months after Dose 2. Almost all (98.3%) of participants 12-15 years of age had at least 1 month of follow-up after Dose 2, and 1308 out of 2260 enrolled participants aged 12-15 years (57.9%) had at least 2 months of follow-up after Dose 2

Table O. Summary of Vaccine Exposure, Participants 12 to 25 Years of Age, Safety Population

Total Number of Doses	12-15 Years BNT162b2 (N= 1131) n (%)	16-25 Years BNT162b2 (N= 1867) n (%)	12-15 Years Placebo (N= 1129) n (%)	16-25 Years Placebo (N= 1903) n (%)
1	7 (0.62)	48 (2.57)	11 (0.97)	69 (3.63)
2	1124 (99.38)	1819 (97.43)	1118 (99.03)	1834 (96.37)

N = Total number of subjects for group

n = number of subjects in each group or in total included in the considered cohort

n/% = number/percentage of subjects receiving the specified total number of doses

2. Subject Demographics and Other Baseline Characteristics

Table P. Demographics and Other Baseline Characteristics, Participants 12 to 15 and 16 Through 25 Years of Age (Reactogenicity Subset), Safety Population*

Characteristic	12-15 Years BNT162b2 (N=1131) n (%)	16-25 Years BNT162b2 (N=537) n (%)	12-15 Years Placebo (N=1129) n (%)	16-25 Years Placebo (N=561) n (%)
Sex: Female	564(49.9)	282 (52.5)	544(48.2)	292 (52.0)
Sex: Male	567(50.1)	255 (47.5)	585(51.8)	269 (48.0)
Age: Mean years (SD)	13.6(1.11)	19.4 (3.26)	13.6(1.11)	19.6 (3.33)
Age: Median (years)	14.0	18.0	14.0	19.0

Race: American Indian or Alaska Native	4(0.4)	(16, 25)	3(0.3)	(16, 25)
Race: Asian	72(6.4)	22 (4.1)	71(6.3)	21 (3.7)
Race: Black or African American	52(4.6)	47 (8.8)	57(5.0)	50 (8.9)
Race: Native Hawaiian or Other Pacific Islander	3(0.3)	3 (0.6)	0	1 (0.2)
Race: White	971(85.9)	445 (82.9)	962(85.2)	466 (83.1)
Race: Multiracial	23 (2.0)	12 (2.2)	29 (2.6)	19 (3.4)
Race: Not reported	6 (0.5)	1 (0.2)	7 (0.6)	3 (0.5)
Race: Other	0	0	0	0
Ethnicity: Hispanic or Latino	132(11.7)	112 (20.9)	130(11.5)	105 (18.7)
Ethnicity: Not Hispanic or Latino	997(88.2)	423 (78.8)	996(88.2)	456 (81.3)
Ethnicity: Not reported	2 (0.2)	2 (0.4)	3 (0.3)	0
Obese: Yes	143(12.6)	80 (14.9)	128(11.3)	101 (18.0)
Obese: No	988(87.4)	80 (14.9)	1001(88.7)	460 (82.0)
Comorbidities ¹ : Yes	248(21.9)	126 (23.5)	240(21.3)	144 (25.7)
Comorbidities: No	883(78.1)	411 (76.5)	889(78.7)	417 (74.3)
Baseline Evidence of Prior SARS-CoV-2 Infection: Negative	1028(90.9)	497 (92.6)	1023(90.6)	522 (93.0)
Baseline Evidence of Prior SARS-CoV-2 Infection: Positive	46(4.1)	522 (93.0)	47(4.2)	522 (93.0)
Baseline Evidence of Prior SARS-CoV-2 Infection: Missing	57 (5.0)	10 (1.9)	59 (5.2)	5 (0.9)
Region: North America	1131(100.0)	436 (81.2)	1129(100.0)	434 (77.4)
Country: Argentina	0	20 (3.7)	0	28 (5.0)
Country: Brazil	0	24 (4.5)	0	19 (3.4)
Country: Germany	0	11 (2.0)	0	20 (3.6)
Country: South Africa	0	34 (6.3)	0	45 (8.0)
Country: Turkey	0	12 (2.2)	0	15 (2.7)

*All randomized participants who receive at least 1 dose of the study intervention

¹ Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as patients who had at least one of the Charlson comorbidity index category or obesity only BMI ≥ 30 kg/m² (≥ 16 Years of age) or BMI ≥ 95 th percentile (12-15 Years of age).

N = Total number of subjects for group

n = number of subjects in each group or in total included in the considered cohort

3. Safety Results:

Table Q. Safety Overview, Participants 12 to 15 Years of Age

Event	BNT162b2 n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination ^a		
Dose #1	0/1131 (0.0)	4/1129 (0.4)
Dose #2	2/1124 (0.2)	3/1117 (0.3)
Solicited injection site reaction within 7 days ^b		
Dose #1	976/1127 (86.6)	271/1127 (24.0)
Dose #2	872/1097 (79.5)	198/1078 (18.4)
Solicited systemic AE within 7 days ^b		
Dose #1	877/1127 (77.8)	636/1127 (56.4)
Dose #2	904/1097 (82.4)	439/1078 (40.7)
From Dose 1 through 1 month after Dose 2 ^a		
Unsolicited non-serious AE	66/1131 (5.8)	66/1129 (5.8)

Event	BNT162b2 n/N (%)	Placebo n/N (%)
SAE	4/1131 (0.4)	1/1129 (0.1)
From Dose 1 through cutoff date (safety population)		
SAE	5/1131 (0.4)	2/1129 (0.2)
Withdrawal due AEs	2 /1131(0.2)	0
Deaths	0	0

Table Q.1. Safety Overview, Participants 16 to 25 Years of Age (Reactogenicity Subset)

Event	BNT162b2 n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination ^a		
Dose #1	0/536 (0.0)	2/561 (0.4)
Dose #2	1/523 (0.2)	2/535 (0.4)
Solicited injection site reaction within 7 days ^b		
Dose #1	445/531 (83.8)	91/553 (16.5)
Dose #2	381/488 (78.1)	62/496 (12.5)
Solicited systemic AE within 7 days ^b		
Dose #1	403/531 (75.9)	311/553 (56.2)
Dose #2	396/488 (81.1)	183/496 (36.9)
From Dose 1 through 1 month after Dose 2 ^a		
Unsolicited non-serious AE	57/536 (10.6)	45/561 (8.0)
SAE	2/536 (0.4)	2/561 (0.4)
From Dose 1 through cutoff date (safety population)		
SAE	3/536 (0.6)	4/561 (0.7)
Withdrawal due AEs	1/536 (0.2)	2/561 (0.4)
Deaths	0	0

Solicited Adverse Events

Across age groups, median onset for all local reactions after either dose of BNT162b2 was Day 1 to Day 3 (Day 1 was the day of vaccination) and resolved with a median duration of 1-3 days.

Table R. Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity, Participants 12 to 15 Years of Age (Reactogenicity Subset)*

Event	BNT162b2 Dose 1 N ^b =1127 n ^a (%)	Placebo Dose 1 N ^b = 1127 n ^a (%)	BNT162b2 Dose 2 N ^b =1097 n ^a (%)	Placebo Dose 2 N ^b =1078 n ^a (%)
Pain at the injection site ^d				
Any	971(86.2)	263(23.3)	866(78.9)	193(17.9)
Mild	467(41.4)	227(20.1)	466(42.5)	164(15.2)
Moderate	493(43.7)	36(3.2)	393(35.8)	29(2.7)
Severe	11(1.0)	0	7(0.6)	0
Redness ^c				
Any	65(5.8)	12(1.1)	55(5.0)	10(0.9)
Mild	44(3.9)	11(1.0)	29(2.6)	8(0.7)
Moderate	20(1.8)	1(0.1)	26(2.4)	2(0.2)
Severe	1(0.1)	0	0	0

Event	BNT162b2 Dose 1 N ^b =1127 n ^a (%)	Placebo Dose 1 N ^b =1127 n ^a (%)	BNT162b2 Dose 2 N ^b =1097 n ^a (%)	Placebo Dose 2 N ^b =1078 n ^a (%)
Swelling ^d				
Any	78(6.9)	11(1.0)	54(4.9)	6(0.6)
Mild	55(4.9)	9(0.8)	36(3.3)	4(0.4)
Moderate	23(2.0)	2(0.2)	18(1.6)	2(0.2)
Severe	0	0	0	0
Any local reaction ^c	976(86.6)	271(24.0)	872(79.5)	198(18.4)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. n = Number of participants with the specified reaction.

b. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

c. Mild: 2.0 to ≤5.0 cm; moderate: 5.0 to ≤10.0 cm; severe: >10.0 cm.

d. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.

e. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

* All randomized participants who receive at least 1 dose of the study intervention.

Table R.1 Frequency of Solicited Local Reactions Within 7 Days After Each Dose, by Maximum Severity, Participants 16 to 25 Years of Age (Reactogenicity Subset)*

Event	BNT162b2 Dose 1 N ^b =531 n ^a (%)	Placebo Dose 1 N ^b =553 n ^a (%)	BNT162b2 Dose 2 N ^b =488 n ^a (%)	Placebo Dose 2 N ^b =496 n ^a (%)
Pain at the injection site ^d				
Any	443(83.4)	88(15.9)	378(77.5)	60(12.1)
Mild	204(38.4)	81(14.6)	202(41.4)	53(10.7)
Moderate	227(42.7)	7(1.3)	169(34.6)	7(1.4)
Severe	12(2.3)	0	7(1.4)	0
Redness ^c				
Any	34(6.4)	5(0.9)	28(5.7)	1(0.2)
Mild	25(4.7)	4(0.7)	18(3.7)	1(0.2)
Moderate	7(1.3)	1(0.2)	9(1.8)	0
Severe	2(0.4)	0	1(0.2)	0
Swelling ^d				
Any	44(8.3)	6(1.1)	33(6.8)	1(0.2)
Mild	31(5.8)	3(0.5)	23(4.7)	1(0.2)
Moderate	12(2.3)	3(0.5)	10(2.0)	0
Severe	1(0.2)	0	0	0
Any local reaction ^c	445(83.8)	91(16.5)	381(78.1)	62(12.5)

Note: Reactions were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. n = Number of participants with the specified reaction.

b. N = number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.

c. Mild: 2.0 to ≤5.0 cm; moderate: 5.0 to ≤10.0 cm; severe: >10.0 cm.

d. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity.

e. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.

* All randomized participants who receive at least 1 dose of the study intervention.

Across age groups, median onset for all systemic events after either dose of BNT162b2 was Day 1 to Day 4 (Day 1 was the day of vaccination). Systemic events resolved post each dose with a median duration of 1 day, except fatigue and chills which resolved within a median of 1-2 days.

Table S. Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity, Participants 12 to 15 Years of Age *

Event	BNT162b2 Dose 1 N^a=1127 n^b (%)	Placebo Dose 1 N^a=1127 n^b(%)	BNT162b2 Dose 2 N^a=1097 n^b (%)	Placebo Dose 2 N^a=1078 n^b (%)
Fever				
≥38.0°C	114(10.1)	12(1.1)	215(19.6)	7(0.6)
≥38.0°C to 38.4°C	74(6.6)	8(0.7)	107(9.8)	5(0.5)
>38.4°C to 38.9°C	29(2.6)	2(0.2)	83(7.6)	1(0.1)
>38.9°C to 40.0°C	10(0.9)	2(0.2)	25(2.3)	1(0.1)
≥40.0°C	1(0.1)	0	0	0
Fatigue^c				
Any	677(60.1)	457(40.6)	726(66.2)	264(24.5)
Mild	278(24.7)	250(22.2)	232(21.1)	133(12.3)
Moderate	384(34.1)	199(17.7)	468(42.7)	127(11.8)
Severe	15(1.3)	8(0.7)	26(2.4)	4(0.4)
Headache^c				
Any	623(55.3)	396(35.1)	708(64.5)	263(24.4)
Mild	361(32.0)	256(22.7)	302(27.5)	169(15.7)
Moderate	251(22.3)	131(11.6)	384(35.0)	93(8.6)
Severe	11(1.0)	9(0.8)	22(2.0)	1(0.1)
Chills^c				
Any	311(27.6)	109(9.7)	455(41.5)	73(6.8)
Mild	195(17.3)	82(7.3)	221(20.1)	52(4.8)
Moderate	111(9.8)	25(2.2)	214(19.5)	21(1.9)
Severe	5(0.4)	2(0.2)	20(1.8)	0
Vomiting^d				
Any	31(2.8)	10(0.9)	29(2.6)	12(1.1)
Mild	30(2.7)	8(0.7)	25(2.3)	11(1.0)
Moderate	0	2(0.2)	4(0.4)	1(0.1)
Severe	1(0.1)	0	0	0
Diarrhea^c				
Any	90(8.0)	82(7.3)	65(5.9)	43(4.0)
Mild	77(6.8)	72(6.4)	59(5.4)	38(3.5)
Moderate	13(1.2)	10(0.9)	6(0.5)	5(0.5)
Severe	0	0	0	0
New or worsened muscle pain^d				
Any	272(24.1)	148(13.1)	355(32.4)	90(8.3)
Mild	125(11.1)	88(7.8)	152(13.9)	51(4.7)
Moderate	145(12.9)	60(5.3)	197(18.0)	37(3.4)
Severe	2(0.2)	0	6(0.5)	2(0.2)
New or worsened joint pain^d				
Any	109(9.7)	77(6.8)	173(15.8)	51(4.7)
Mild	66(5.9)	50(4.4)	91(8.3)	30(2.8)
Moderate	42(3.7)	27(2.4)	78(7.1)	21(1.9)
Severe	1(0.1)	0	4(0.4)	0
Any systemic event ^f	877(77.8)	636(56.4)	904(82.4)	439(40.7)

Event	BNT162b2 Dose 1 N ^a =1127 n ^b (%)	Placebo Dose 1 N ^a =1127 n ^b (%)	BNT162b2 Dose 2 N ^a =1097 n ^b (%)	Placebo Dose 2 N ^a =1078 n ^b (%)
Use of antipyretic or pain medication ^g	413(36.6)	111(9.8)	557(50.8)	95(8.8)

Note: Events were collected in the electronic diary (e-diary) from Day 1 to Day 7 after vaccination.

a. N = number of participants reporting at least 1 yes or no response for the specified event after the specified dose.

b. n = Number of participants with the specified characteristic.

c. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity.

d. Mild: 1 to 2 times in 24 hours; moderate: >2 times in 24 hours; severe: requires intravenous hydration.

e. Mild: 2 to 3 loose stools in 24 hours; moderate: 4 to 5 loose stools in 24 hours; severe: 6 or more loose stools in 24 hours.

f. Any systemic event: any fever $\geq 38.0^{\circ}\text{C}$, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.

g. Severity was not collected for use of antipyretic or pain medication.

*All randomized participants who receive at least 1 dose of the study intervention.

Table S.1 Frequency of Solicited Systemic Adverse Events Within 7 Days After Each Dose, by Maximum Severity, Participants 16 to 25 Years of Age (Reactogenicity Subset)*

Event	BNT162b2 Dose 1 N ^a =531 n ^b (%)	Placebo Dose 1 N ^a =553 n ^b (%)	BNT162b2 Dose 2 N ^a =488 n ^b (%)	Placebo Dose 2 N ^a =496 n ^b (%)
Fever				
$\geq 38.0^{\circ}\text{C}$	39(7.3)	8(1.4)	84(17.2)	2(0.4)
$\geq 38.0^{\circ}\text{C}$ to 38.4°C	24(4.5)	5(0.9)	45(9.2)	1(0.2)
$>38.4^{\circ}\text{C}$ to 38.9°C	12(2.3)	2(0.4)	32(6.6)	0
$>38.9^{\circ}\text{C}$ to 40.0°C	3(0.6)	1(0.2)	7(1.4)	1(0.2)
$\geq 40.0^{\circ}\text{C}$	0	0	0	0
Fatigue ^c				
Any	318(59.9)	213(38.5)	320(65.6)	115(23.2)
Mild	134(25.2)	118(21.3)	98(20.1)	51(10.3)
Moderate	173(32.6)	89(16.1)	199(40.8)	62(12.5)
Severe	11(2.1)	6(1.1)	23(4.7)	2(0.4)
Headache ^c				
Any	286(53.9)	205(37.1)	297(60.9)	118(23.8)
Mild	151(28.4)	138(25.0)	119(24.4)	67(13.5)
Moderate	124(23.4)	63(11.4)	157(32.2)	46(9.3)
Severe	11(2.1)	4(0.7)	21(4.3)	5(1.0)
Chills ^c				
Any	133(25.0)	47(8.5)	195(40.0)	22(4.4)
Mild	91(17.1)	31(5.6)	82(16.8)	17(3.4)
Moderate	37(7.0)	15(2.7)	101(20.7)	5(1.0)
Severe	5(0.9)	1(0.2)	12(2.5)	0
Vomiting ^d				
Any	9(1.7)	9(1.6)	13(2.7)	9(1.8)
Mild	9(1.7)	8(1.4)	10(2.0)	5(1.0)
Moderate	0	0	3(0.6)	4(0.8)
Severe	0	1(0.2)	0	0
Diarrhea ^c				
Any	57(10.7)	62(11.2)	39(8.0)	26(5.2)

*All randomized participants who receive at least 1 dose of the study intervention.

	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Event				
Any solicited local reaction				
Day of onset: n, median (min, max)	976, 1 (1, 7)	271, 1 (1, 7)	872, 1.0 (1, 6)	198, 1.0 (1, 7)
Duration: n, median (min, max)	NA	NA	NA	NA
Persisted beyond 7 days	NA	NA	NA	NA
Redness				
Day of onset: n, median (min, max)	65, 2.0 (1,4)	12, 1.5 (1, 4)	55, 2.0 (1,5)	10, 1.0 (1, 2)
Duration: n, median (min, max)	65, 2.0 (1, 16)	12, 1.0 (1, 3)	55, 2.0 (1, 5)	10, 1.0 (1, 4)
Persisted beyond 7 days	2	0	0	0
Swelling				

Event	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Day of onset: n, median (min, max)	78, 2.0 (1,5)	11, 1.0 (1, 4)	54, 2.0 (1,4)	6, 1.0 (1, 7)
Duration: n, median (min, max)	78, 2.0 (1, 5)	11, 1.0 (1, 5)	54, 1.0 (1, 5)	6, 1.5 (1,2)
Persisted beyond 7 days	0	0	0	0
Pain at the injection site				
Day of onset: n, median (min, max)	971, 1.0 (1,7)	263, 1.0 (1, 7)	866, 1.0 (1, 6)	193, 1.0 (1,7)
Duration: n, median (min, max)	971, 2.0 (1, 10)	263, 1.0 (1, 10)	866, 2.0 (1,11)	193, 1.0 (1, 8)
Persisted beyond 7 days	9	6	8	4
Any solicited systemic reaction				
Day of onset: n, median (min, max)	877, 2.0 (1, 7)	636, 1.0 (1, 7)	904, 2.0 (1, 7)	439, 2.0 (1, 7)
Duration: n, median (min, max)	NA	NA	NA	NA
Persisted beyond 7 days	NA	NA	NA	NA
Fever ($\geq 38.0^{\circ}\text{C}$)				
Day of onset: n, median (min, max)	114, 2.0 (1, 5)	12, 3.0 (1, 7)	215, 2.0 (1, 4)	7, 2.0 (1, 7)
Duration: n, median (min, max)	114, 1.0 (1, 4)	12, 1.0 (1, 5)	215, 1.0 (1, 6)	7, 1.0 (1, 14)
Persisted beyond 7 days	0	0	0	1
Fatigue				
Day of onset: n, median (min, max)	677, 2.0 (1, 7)	457, 1.0 (1, 7)	726, 2.0 (1, 7)	264, 2.0 (1, 7)
Duration: n, median (min, max)	677, 2.0 (1, 45)	457, 2.0 (1, 22)	726, 1.0 (1, 23)	264, 2.0 (1, 37)
Persisted beyond 7 days	25	34	24	15
Headache				
Day of onset: n, median (min, max)	623, 2.0 (1, 7)	396, 2.0 (1, 7)	708, 2.0 (1, 7)	263, 2.0 (1, 7)
Duration: n, median (min, max)	623, 1.0 (1, 24)	396, 1.0 (1, 21)	708, 1.0 (1, 36)	263, 1.0 (1, 23)
Persisted beyond 7 days	18	19	18	8
Chills				
Day of onset: n, median (min, max)	311, 2.0 (1, 7)	109, 2.0 (1, 7)	455, 2.0 (1, 7)	73, 2.0 (1, 7)
Duration: n, median (min, max)	311, 1.0 (1, 15)	109, 1.0 (1, 22)	455, 1.0 (1, 9)	73, 1.0 (1, 8)
Persisted beyond 7 days	6	5	2	2
Vomiting				
Day of onset: n, median (min, max)	31, 2.0 (1, 7)	10, 2.0 (1, 6)	29, 2.0 (1, 7)	12, 4.0 (2, 7)
Duration: n, median (min, max)	31, 1.0 (1, 5)	10, 1.0 (1, 2)	29, 1.0 (1, 2)	12, 1.0 (1, 4)
Persisted beyond 7 days	0	0	0	0
Diarrhea				
Day of onset: n, median (min, max)	90, 3.0 (1, 7)	82, 3.0 (1, 7)	65, 3.0 (1, 7)	43, 4.0 (1, 7)

Event	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Duration: n, median (min, max)	90, 1.0 (1, 7)	82, 1.0 (1, 8)	65, 1.0 (1, 35)	43, 1.0 (1, 5)
Persisted beyond 7 days	0	1	2	0
New or worsened muscle pain				
Day of onset: n, median (min, max)	272, 2.0 (1, 7)	148, 2.0 (1, 7)	355, 2.0 (1, 7)	90, 2.0 (1, 7)
Duration: n, median (min, max)	272, 1.0 (1, 9)	148, 1.0 (1, 22)	355, 1.0 (1, 17)	90, 1.0 (1, 9)
Persisted beyond 7 days	3	6	4	3
New or worsened joint pain				
Day of onset: n, median (min, max)	109, 2.0 (1, 7)	77, 2.0 (1, 7)	173, 2.0 (1, 6)	51, 2.0 (1, 7)
Duration: n, median (min, max)	109, 1.0 (1, 8)	77, 1.0 (1, 22)	173, 1.0 (1, 8)	51, 1.0 (1, 12)
Persisted beyond 7 days	1	2	2	2
Use of antipyretic or pain medication				
Day of onset: n, median (min, max)	413, 2.0 (1, 7)	111, 3.0 (1, 7)	557, 2.0 (1, 7)	95, 3.0 (1, 7)
Duration: n, median (min, max)	413, 1.0 (1, 20)	111, 1.0 (1, 19)	557, 1.0 (1, 12)	95, 1.0 (1, 23)
Persisted beyond 7 days	413	111	557	95

Table T.1 Characteristics of Solicited Local and Systemic Adverse Reactions, Participants 16 to 25 Years of Age, Safety Population (Reactogenicity Subset)

Event	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Any solicited local reaction				
Day of onset: n, median (min, max)	445, 1.0 (1,4)	91, 1.0(1,7)	381, 1.0(1,6)	62, 1.0(1,6)
Duration: n, median (min, max)	NA	NA	NA	NA
Persisted beyond 7 days	NA	NA	NA	NA
Redness				
Day of onset: n, median (min, max)	34, 2.0(1,5)	5, 1.0(1,4)	28,3.0(1,4)	1,1.0(1,1)
Duration: n, median (min, max)	34,2.0(1,5)	5,1.0(1,2)	28,1.5(1,8)	1,1.0(1,1)
Persisted beyond 7 days	0	0	1	0
Swelling				
Day of onset: n, median (min, max)	44,2.0(1,5)	6,1.0(1,3)	33,2.0(1,4)	1,3.0(3,3,)
Duration: n, median (min, max)	44,1.0(1,7)	6,1.0(1,3)	33,2.0(1,7)	1,3.0(3,3)
Persisted beyond 7 days	0	0	0	0
Pain at the injection site				

Event	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Day of onset: n, median (min, max)	443,1.0(1,4)	88,1.0(1,7)	378,1.0(1,6)	60,1.0(1,6)
Duration: n, median (min, max)	443,2.0(1,9)	88,1.0(1,11)	378,2.0(1,70)	60,1.0(1,35)
Persisted beyond 7 days	3	1	7	1
Any solicited systemic reaction				
Day of onset: n, median (min, max)	403,2.0(1,7)	311,2.0(1,7)	396,2.0(1,7)	183,2.0(1,7)
Duration: n, median (min, max)	NA	NA	NA	NA
Persisted beyond 7 days	NA	NA	NA	NA
Fever ($\geq 38.0^{\circ}\text{C}$)				
Day of onset: n, median (min, max)	39,2.0(1,7)	8,2.5(1,7)	84,2.0(1,6)	2,1.5(1,2)
Duration: n, median (min, max)	39,1.0(1,4)	8,1.0(1,7)	84,1.0(1,2)	2,1.0(1,1)
Persisted beyond 7 days	0	0	0	0
Fatigue				
Day of onset: n, median (min, max)	318,2.0(1,7)	213,2.0(1,7)	320,2.0(1,7)	115,2.0(1,7)
Duration: n, median (min, max)	318,2.0(1,11)	213,2.0(1,15)	320,1.0(1,28)	115,2.0(1,38)
Persisted beyond 7 days	12	17	11	9
Headache				
Day of onset: n, median (min, max)	286,2.0(1,7)	205,2.0(1,7)	297,2.0(1,7)	118,2.0(1,7)
Duration: n, median (min, max)	286,1.0(1,25)	205,1.0(1,22)	297,1.0(1,24)	118,1.0(1,35)
Persisted beyond 7 days	10	14	6	8
Chills				
Day of onset: n, median (min, max)	133,2.0(1,7)	47,2.0(1,7)	195,2.0(1,4)	22,3.0(1,7)
Duration: n, median (min, max)	133,1.0(1,8)	47,2.0(1,7)	195,1.0(1,11)	22,2.0(1,6)
Persisted beyond 7 days	1	0	1	0
Vomiting				
Day of onset: n, median (min, max)	9,2.0(1,7)	9,3.0(1,5)	13,2.0(2,5)	9,3.0(1,7)
Duration: n, median (min, max)	9,1.0(1,5)	9,1.0(1,4)	13,1.0(1,2)	9,1.0(1,6)
Persisted beyond 7 days	0	0	0	0
Diarrhea				
Day of onset: n, median (min, max)	57,3.0(1,7)	62,3.0(1,7)	39,3.0(1,7)	26,3.0(1,7)
Duration: n, median (min, max)	57,1.0(1,9)	62,1.0(1,7)	39,1.0(1,5)	26,1.0(1,33)
Persisted beyond 7 days	1	0	0	2
New or worsened muscle pain				

Event	BNT162b2 Dose 1	Placebo Dose 1	BNT162b2 Dose 2	Placebo Dose 2
Day of onset: n, median (min, max)	143,2.0(1,7)	78,2.0(1,7)	199,2.0(1,7)	48,2.0(1,7)
Duration: n, median (min, max)	143,1.0(1,10)	78,1.0(1,13)	199,1.0(1,23)	48,1.0(1,9)
Persisted beyond 7 days	3	2	1	2
New or worsened joint pain				
Day of onset: n, median (min, max)	70,2.0(1,7)	28,3.0(1,7)	107,2.0(1,7)	20,4.0(1,7)
Duration: n, median (min, max)	70,1.0(1,24)	28,1.5(1,12)	107,1.0(1,28)	20,1.0(1,8)
Persisted beyond 7 days	1	1	2	1
Use of antipyretic or pain medication				
Day of onset: n, median (min, max)	167,2.0(1,7)	62,3.0(1,7)	223,2.0(1,7)	59,3.0(1,7)
Duration: n, median (min, max)	167,1.0(1,10)	62,1.0(1,23)	223,1.0(1,28)	59,1.0(1,15)
Persisted beyond 7 days	167	62	223	59

Table U. Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in Any Treatment Group From Dose 1 to One Month After Dose 2, Participants 12 to 15 Years of Age, Safety Population

Primary System Organ Class (CODE)	Preferred Term (CODE)	BNT162b2 (N=1131) Any % (Severe %)	Placebo (N=1129) Any % (Severe %)
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)	0	0
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)	0	0

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

N = number of subjects included in the considered cohort in each group

n/% = number/percentage of subjects reporting the adverse event at least once

[n] = number of events reported

*All randomized participants who receive at least 1 dose of the study intervention.

Table U.1 Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in Any Treatment Group From Dose 1 to One Month After Dose 2, Participants 16 to 25 Years of Age (Reactogenicity Subset), Safety Population

Primary System Organ Class (CODE)	Preferred Term (CODE)	BNT162b2 (N=536) Any % (Severe %)	Placebo (N=561) Any % (Severe %)
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)	0	0
Each SOC	Adverse events in any PT Any PT (% severe) Any PT (% severe)	0	0

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

N = number of subjects included in the considered cohort in each group

n/% = number/percentage of subjects reporting the adverse event at least once

[n] = number of events reported

*All randomized participants who receive at least 1 dose of the study intervention.

In participants aged 12-15 years, 5 (0.4%) in the BNT162b2 group and 2 (0.02%) in the placebo group reported any SAE up to the data cutoff date. In participants aged 16-25 years, 3 (0.6%) in the BNT162b2 group and 4 (0.7%) in the placebo group reported any SAE up to the data cutoff date.

Table V. Percentage of Subjects Reporting SAEs From Dose 1 Through Cutoff Date (13MAR2021), by MedDRA Primary System Organ Class and Preferred Term, Participants 12 to 15 Years of Age, Safety Population*

Primary System Organ Class (CODE) Preferred Term (CODE)	BNT162b2 (N=1131) n(%)	Placebo (N=1129) n(%)
Any Event	5(0.4)	2(0.2)
GASTROINTESTINAL DISORDERS	1(0.1)	0
Abdominal pain	1(0.1)	0
Constipation	1(0.1)	0
INFECTIONS AND INFESTATIONS	0	2(0.2)
Appendicitis	0	2(0.2)
Focal peritonitis	0	1(0.1)
NERVOUS SYSTEM DISORDERS	1(0.1)	0
Neuralgia	1(0.1)	0
PSYCHIATRIC DISORDERS	4(0.4)	0
Depression	3(0.3)	0
Anxiety	1(0.1)	0
Suicidal ideation	1(0.1)	0

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

N = number of subjects included in the considered cohort in each group

n/% = number/percentage of subjects reporting the adverse event at least once

[n] = number of events reported

*All randomized participants who receive at least 1 dose of the study intervention.

Table V.1 Percentage of Subjects Reporting SAEs From Dose 1 Through Cutoff Date (13MAR2021), by MedDRA Primary System Organ Class and Preferred Term, Participants 16 to 25 Years of Age (Reactogenicity Subset), Safety Population*

Primary System Organ Class (CODE) Preferred Term (CODE)	BNT162b2 (N=536) n (%)	Placebo (N=561) n (%)
Any Event	3(0.6)	4(0.7)
GASTROINTESTINAL DISORDERS	1(0.2)	1(0.2)
Abdominal pain	1(0.2)	0
Inguinal hernia	0	1(0.2)
INFECTIONS AND INFESTATIONS	1(0.2)	1(0.2)
Appendicitis	1(0.2)	0
Urinary tract infection	0	1(0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	1(0.2)
Flail chest	0	1(0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	0	1(0.2)
Psoriatic arthropathy	0	1(0.2)
PSYCHIATRIC DISORDERS	1(0.2)	0
Depression	1(0.2)	0

Adverse events in any PT = at least one adverse event experienced (regardless of the MedDRA Preferred Term)

N = number of subjects included in the considered cohort in each group

n/% = number/percentage of subjects reporting the adverse event at least once

[n] = number of events reported

*All randomized participants who receive at least 1 dose of the study intervention.

SMQ analyses

***narrow SMQs: vasculitis, hypersensitivity, arthritis, angioedema, peripheral neuropathy, demyelinating disease of central nervous system, convulsions

We may send additional SMQ requests as we review the data.

Table W. Name of Standard MedDRA Queries From Dose 1 to 1 Month After Dose 2, Participants 12 to 15 Years of Age, Safety Population

Overall SMQ (unsolicited adverse events)	BNT162b2	Placebo
System Organ Class	(N^a=1131)	(N^a=1129)
Preferred Term	n^b (%)	n^b (%)
Subjects with any unsolicited adverse events within SMQ	6 (0.53)	10 (0.89)
Angioedema (SMQ)	3 (0.27)	4 (0.35)
Congenital, familial and genetic disorders	0	0
Hereditary angioedema	0	0
Hereditary angioedema with C1 esterase inhibitor deficiency	0	0
Eye disorders	0	0
Conjunctival oedema	0	0
Corneal oedema	0	0
Eye oedema	0	0
Eye swelling	0	0
Eyelid oedema	0	0
Limbic swelling	0	0
Oculorespiratory syndrome	0	0
Periorbital oedema	0	0
Periorbital swelling	0	0
Scleral oedema	0	0
Swelling of eyelid	0	0
Gastrointestinal disorders	1 (0.09)	0
Gingival oedema	0	0
Gingival swelling	0	0
Intestinal angioedema	0	0
Lip oedema	0	0
Lip swelling	1 (0.09)	0
Mouth swelling	1 (0.09)	0
Oedema mouth	0	0
Palatal oedema	0	0
Palatal swelling	0	0
Swollen tongue	0	0
Tongue oedema	0	0
General disorders and administration site conditions	0	0
Face oedema	0	0
Swelling face	0	0
Immune system disorders	0	0
Allergic oedema	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Epiglottic oedema	0	0
Laryngeal oedema	0	0
Laryngotracheal oedema	0	0
Oropharyngeal oedema	0	0

Oropharyngeal swelling	0	0
Pharyngeal oedema	0	0
Pharyngeal swelling	0	0
Tracheal oedema	0	0
Skin and subcutaneous tissue disorders	2 (0.18)	4 (0.35)
Acquired C1 inhibitor deficiency	0	0
Angioedema	0	0
Circumoral oedema	0	0
Circumoral swelling	0	0
Gleich's syndrome	0	0
Idiopathic angioedema	0	0
Idiopathic urticaria	0	0
Urticaria	2 (0.18)	4 (0.35)
Urticaria cholinergic	0	0
Urticaria chronic	0	0
Urticaria papular	0	0
Arthritis (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
COPA syndrome	0	0
Otospondylomegaepiphyseal dysplasia	0	0
Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome	0	0
General disorders and administration site conditions	0	0
Infusion site joint inflammation	0	0
Injection site joint inflammation	0	0
Infections and infestations	0	0
Arthritis bacterial	0	0
Arthritis fungal	0	0
Arthritis gonococcal	0	0
Arthritis helminthic	0	0
Arthritis infective	0	0
Arthritis rubella	0	0
Arthritis salmonella	0	0
Arthritis viral	0	0
Epidemic polyarthritis	0	0
Infected gouty tophus	0	0
Infusion site joint infection	0	0
Injection site joint infection	0	0
Medical device site joint infection	0	0
Septic arthritis haemophilus	0	0
Septic arthritis neisserial	0	0
Septic arthritis staphylococcal	0	0

Septic arthritis streptobacillus	0	0
Septic arthritis streptococcal	0	0
Vaccination site joint infection	0	0
Injury, poisoning and procedural complications	0	0
Traumatic arthritis	0	0
Metabolism and nutrition disorders	0	0
Gout	0	0
Periarthritis calcarea	0	0
Musculoskeletal and connective tissue disorders	0	0
Ankylosing spondylitis	0	0
Arthritis	0	0
Arthritis allergic	0	0
Arthritis climacteric	0	0
Arthritis enteropathic	0	0
Arthritis reactive	0	0
Autoimmune arthritis	0	0
Axial spondyloarthritis	0	0
Bursitis	0	0
Carcinomatous polyarthritis	0	0
Chondrocalcinosis	0	0
Chondrocalcinosis pyrophosphate	0	0
Chondromalacia	0	0
Chondronecrosis	0	0
Diffuse idiopathic skeletal hyperostosis	0	0
Enteropathic spondylitis	0	0
Facet joint syndrome	0	0
Felty's syndrome	0	0
Gouty arthritis	0	0
Gouty tophus	0	0
Haemophilic arthropathy	0	0
Idiopathic condylar resorption	0	0
Immune-mediated arthritis	0	0
Juvenile idiopathic arthritis	0	0
Juvenile psoriatic arthritis	0	0
Juvenile spondyloarthritis	0	0
Nodal osteoarthritis	0	0
Oligoarthritis	0	0
Osteoarthritis	0	0
Palindromic rheumatism	0	0
Paraneoplastic arthritis	0	0
Patellofemoral pain syndrome	0	0
Periarthritis	0	0

Plica syndrome	0	0
Polyarthritis	0	0
Rapidly progressive osteoarthritis	0	0
Rheumatic disorder	0	0
Rheumatic fever	0	0
Rheumatoid arthritis	0	0
SLE arthritis	0	0
Sacroiliac joint dysfunction	0	0
Sacroiliitis	0	0
Seronegative arthritis	0	0
Spinal osteoarthritis	0	0
Spondylitis	0	0
Still's disease	0	0
Synovitis	0	0
Temporomandibular joint syndrome	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Caplan's syndrome	0	0
Laryngeal rheumatoid arthritis	0	0
Convulsions (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
1p36 deletion syndrome	0	0
2-Hydroxyglutaric aciduria	0	0
Alpers disease	0	0
Aspartate-glutamate-transporter deficiency	0	0
Baltic myoclonic epilepsy	0	0
Benign familial neonatal convulsions	0	0
Biotinidase deficiency	0	0
CDKL5 deficiency disorder	0	0
CEC syndrome	0	0
Congenital bilateral perisylvian syndrome	0	0
Double cortex syndrome	0	0
Epilepsy with myoclonic-atonic seizures	0	0
GM2 gangliosidosis	0	0
Glucose transporter type 1 deficiency syndrome	0	0
Grey matter heterotopia	0	0
Hemimegalencephaly	0	0
Lafora's myoclonic epilepsy	0	0
Molybdenum cofactor deficiency	0	0
Myoclonic epilepsy and ragged-red fibres	0	0
Polymicrogyria	0	0
Schizencephaly	0	0
Severe myoclonic epilepsy of infancy	0	0

Tuberous sclerosis complex	0	0
General disorders and administration site conditions	0	0
Sudden unexplained death in epilepsy	0	0
Nervous system disorders	0	0
Acquired epileptic aphasia	0	0
Acute encephalitis with refractory, repetitive partial seizures	0	0
Alcoholic seizure	0	0
Atonic seizures	0	0
Atypical benign partial epilepsy	0	0
Autonomic seizure	0	0
Benign rolandic epilepsy	0	0
CSWS syndrome	0	0
Change in seizure presentation	0	0
Clonic convulsion	0	0
Convulsion in childhood	0	0
Convulsions local	0	0
Convulsive threshold lowered	0	0
Dreamy state	0	0
Drug withdrawal convulsions	0	0
Early infantile epileptic encephalopathy with burst-suppression	0	0
Epilepsy	0	0
Epileptic aura	0	0
Faciobrachial dystonic seizure	0	0
Febrile convulsion	0	0
Febrile infection-related epilepsy syndrome	0	0
Focal dyscognitive seizures	0	0
Frontal lobe epilepsy	0	0
Gelastic seizure	0	0
Generalised onset non-motor seizure	0	0
Generalised tonic-clonic seizure	0	0
Hyperglycaemic seizure	0	0
Hypocalcaemic seizure	0	0
Hypoglycaemic seizure	0	0
Hyponatraemic seizure	0	0
Idiopathic generalised epilepsy	0	0
Infantile spasms	0	0
Jeavons syndrome	0	0
Juvenile myoclonic epilepsy	0	0
Lennox-Gastaut syndrome	0	0
Migraine-triggered seizure	0	0
Myoclonic epilepsy	0	0

Neonatal epileptic seizure	0	0
Neonatal seizure	0	0
Partial seizures	0	0
Partial seizures with secondary generalisation	0	0
Petit mal epilepsy	0	0
Post stroke epilepsy	0	0
Post stroke seizure	0	0
Post-traumatic epilepsy	0	0
Postictal headache	0	0
Postictal paralysis	0	0
Postictal state	0	0
Seizure	0	0
Seizure anoxic	0	0
Seizure cluster	0	0
Seizure like phenomena	0	0
Simple partial seizures	0	0
Status epilepticus	0	0
Temporal lobe epilepsy	0	0
Tonic clonic movements	0	0
Tonic convulsion	0	0
Tonic posturing	0	0
Transient epileptic amnesia	0	0
Uncinate fits	0	0
Pregnancy, puerperium and perinatal conditions	0	0
Eclampsia	0	0
Psychiatric disorders	0	0
Automatism epileptic	0	0
Deja vu	0	0
Epileptic psychosis	0	0
Postictal psychosis	0	0
Surgical and medical procedures	0	0
Epilepsy surgery	0	0
Multiple subpial transection	0	0
Topectomy	0	0
Demyelination (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
Myoclonic epilepsy and ragged-red fibres	0	0
MELAS syndrome	0	0
Neuropathy, ataxia, retinitis pigmentosa syndrome	0	0
Infections and infestations	0	0
Encephalomyelitis	0	0
Progressive multifocal leukoencephalopathy	0	0

Zika virus associated Guillain Barre syndrome	0	0
Investigations	0	0
Expanded disability status scale score decreased	0	0
Expanded disability status scale score increased	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0
Hypergammaglobulinaemia benign monoclonal	0	0
Nervous system disorders	0	0
Acute disseminated encephalomyelitis	0	0
Acute haemorrhagic leukoencephalitis	0	0
Anti-myelin-associated glycoprotein associated polyneuropathy	0	0
Autoimmune demyelinating disease	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy	0	0
Clinically isolated syndrome	0	0
Concentric sclerosis	0	0
Demyelinating polyneuropathy	0	0
Demyelination	0	0
Encephalitis periaxialis diffusa	0	0
Guillain-Barre syndrome	0	0
Immune-mediated neuropathy	0	0
Leukoencephalomyelitis	0	0
Leukoencephalopathy	0	0
Lewis-Sumner syndrome	0	0
Marburg's variant multiple sclerosis	0	0
Marchiafava-Bignami disease	0	0
Multiple sclerosis	0	0
Multiple sclerosis relapse	0	0
Myelitis transverse	0	0
Neuromyelitis optica pseudo relapse	0	0
Neuromyelitis optica spectrum disorder	0	0
Noninfectious myelitis	0	0
Noninfective encephalomyelitis	0	0
Optic neuritis	0	0
Osmotic demyelination syndrome	0	0
Primary progressive multiple sclerosis	0	0
Progressive multiple sclerosis	0	0
Progressive relapsing multiple sclerosis	0	0
Relapsing multiple sclerosis	0	0
Relapsing-remitting multiple sclerosis	0	0
Secondary progressive multiple sclerosis	0	0
Subacute inflammatory demyelinating polyneuropathy	0	0

Toxic leukoencephalopathy	0	0
Tumefactive multiple sclerosis	0	0
Surgical and medical procedures	0	0
Multiple sclerosis relapse prophylaxis	0	0
Hypersensitivity (SMQ)	6 (0.53)	10 (0.89)
Blood and lymphatic system disorders	0	0
Allergic eosinophilia	0	0
Heparin-induced thrombocytopenia	0	0
Immune thrombocytopenia	0	0
Cardiac disorders	0	0
Hypersensitivity myocarditis	0	0
Kounis syndrome	0	0
Congenital, familial and genetic disorders	0	0
Hereditary angioedema	0	0
Hereditary angioedema with C1 esterase inhibitor deficiency	0	0
Epidermolysis bullosa	0	0
Ear and labyrinth disorders	0	0
Allergic otitis externa	0	0
Allergic otitis media	0	0
Eye disorders	0	0
Conjunctival oedema	0	0
Corneal oedema	0	0
Eye oedema	0	0
Eye swelling	0	0
Eyelid oedema	0	0
Limbal swelling	0	0
Oculorespiratory syndrome	0	0
Periorbital oedema	0	0
Periorbital swelling	0	0
Scleral oedema	0	0
Swelling of eyelid	0	0
Allergic keratitis	0	0
Blepharitis allergic	0	0
Conjunctivitis allergic	0	0
Eye allergy	0	0
Giant papillary conjunctivitis	0	0
Scleritis allergic	0	0
Vernal keratoconjunctivitis	0	0
Gastrointestinal disorders	1 (0.09)	0
Gingival oedema	0	0
Gingival swelling	0	0
Intestinal angioedema	0	0

Lip oedema	0	0
Lip swelling	1 (0.09)	0
Mouth swelling	1 (0.09)	0
Oedema mouth	0	0
Palatal oedema	0	0
Palatal swelling	0	0
Swollen tongue	0	0
Tongue oedema	0	0
Allergic colitis	0	0
Allergic gastroenteritis	0	0
Allergic stomatitis	0	0
Anal eczema	0	0
Contact stomatitis	0	0
Oral mucosal eruption	0	0
General disorders and administration site conditions	0	0
Face oedema	0	0
Swelling face	0	0
Administration site dermatitis	0	0
Administration site eczema	0	0
Administration site hypersensitivity	0	0
Administration site rash	0	0
Administration site recall reaction	0	0
Administration site urticaria	0	0
Administration site vasculitis	0	0
Application site dermatitis	0	0
Application site eczema	0	0
Application site hypersensitivity	0	0
Application site rash	0	0
Application site recall reaction	0	0
Application site urticaria	0	0
Application site vasculitis	0	0
Catheter site dermatitis	0	0
Catheter site eczema	0	0
Catheter site hypersensitivity	0	0
Catheter site rash	0	0
Catheter site urticaria	0	0
Catheter site vasculitis	0	0
Immediate post-injection reaction	0	0
Implant site dermatitis	0	0
Implant site hypersensitivity	0	0
Implant site rash	0	0
Implant site urticaria	0	0

Infusion site dermatitis	0	0
Infusion site eczema	0	0
Infusion site hypersensitivity	0	0
Infusion site rash	0	0
Infusion site recall reaction	0	0
Infusion site urticaria	0	0
Infusion site vasculitis	0	0
Injection site dermatitis	0	0
Injection site eczema	0	0
Injection site hypersensitivity	0	0
Injection site rash	0	0
Injection site recall reaction	0	0
Injection site urticaria	0	0
Injection site vasculitis	0	0
Instillation site hypersensitivity	0	0
Instillation site rash	0	0
Instillation site urticaria	0	0
Medical device site dermatitis	0	0
Medical device site eczema	0	0
Medical device site hypersensitivity	0	0
Medical device site rash	0	0
Medical device site recall reaction	0	0
Medical device site urticaria	0	0
Vaccination site dermatitis	0	0
Vaccination site eczema	0	0
Vaccination site exfoliation	0	0
Vaccination site hypersensitivity	0	0
Vaccination site rash	0	0
Vaccination site recall reaction	0	0
Vaccination site urticaria	0	0
Vaccination site vasculitis	0	0
Vaccination site vesicles	0	0
Vessel puncture site rash	0	0
Vessel puncture site vesicles	0	0
Hepatobiliary disorders	0	0
Allergic hepatitis	0	0
Immune system disorders	0	0
Allergic oedema	0	0
Allergic reaction to excipient	0	0
Allergy to immunoglobulin therapy	0	0
Allergy to surgical sutures	0	0
Allergy to vaccine	0	0

Anaphylactic reaction	0	0
Anaphylactic shock	0	0
Anaphylactoid reaction	0	0
Anaphylactoid shock	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	0	0
Atopy	0	0
Contrast media allergy	0	0
Contrast media reaction	0	0
Device allergy	0	0
Dialysis membrane reaction	0	0
Drug hypersensitivity	0	0
Eosinophilic granulomatosis with polyangiitis	0	0
Hypersensitivity	0	0
Immune-mediated adverse reaction	0	0
Infusion related hypersensitivity reaction	0	0
Iodine allergy	0	0
Multiple allergies	0	0
Nutritional supplement allergy	0	0
Oral allergy syndrome	0	0
Reaction to azo-dyes	0	0
Reaction to colouring	0	0
Reaction to excipient	0	0
Reaction to food additive	0	0
Reaction to preservatives	0	0
Serum sickness	0	0
Serum sickness-like reaction	0	0
Solvent sensitivity	0	0
Therapeutic product cross-reactivity	0	0
Type I hypersensitivity	0	0
Type II hypersensitivity	0	0
Type III immune complex mediated reaction	0	0
Type IV hypersensitivity reaction	0	0
Infections and infestations	0	0
Dermatitis infected	0	0
Eczema vaccinatum	0	0
Kaposi's varicelliform eruption	0	0
Pustule	0	0
Rash pustular	0	0
Injury, poisoning and procedural complications	0	0
Administration related reaction	0	0
Allergic transfusion reaction	0	0
Anaphylactic transfusion reaction	0	0

Documented hypersensitivity to administered product	0	0
Incision site dermatitis	0	0
Incision site rash	0	0
Infusion related reaction	0	0
Injection related reaction	0	0
Procedural shock	0	0
Stoma site hypersensitivity	0	0
Stoma site rash	0	0
Investigations	0	0
Allergy alert test positive	0	0
Allergy test positive	0	0
Antiendomysial antibody positive	0	0
Blood immunoglobulin E abnormal	0	0
Blood immunoglobulin E increased	0	0
Drug provocation test	0	0
Mast cell degranulation present	0	0
Radioallergosorbent test positive	0	0
Skin test positive	0	0
Musculoskeletal and connective tissue disorders	0	0
Arthritis allergic	0	0
Nervous system disorders	0	0
Encephalitis allergic	0	0
Encephalopathy allergic	0	0
Renal and urinary disorders	0	0
Allergic cystitis	0	0
Henoch-Schonlein purpura nephritis	0	0
Nephritis allergic	0	0
Reproductive system and breast disorders	0	0
Scrotal dermatitis	0	0
Scrotal oedema	0	0
Vaginal ulceration	0	0
Vulval eczema	0	0
Vulval ulceration	0	0
Vulvovaginal rash	0	0
Vulvovaginal ulceration	0	0
Vulvovaginitis allergic	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Epiglottic oedema	0	0
Laryngeal oedema	0	0
Laryngotracheal oedema	0	0
Oropharyngeal oedema	0	0
Oropharyngeal swelling	0	0

Pharyngeal oedema	0	0
Pharyngeal swelling	0	0
Tracheal oedema	0	0
Allergic bronchitis	0	0
Allergic cough	0	0
Allergic pharyngitis	0	0
Allergic respiratory disease	0	0
Allergic respiratory symptom	0	0
Allergic sinusitis	0	0
Aspirin-exacerbated respiratory disease	0	0
Atopic cough	0	0
Bronchospasm	0	0
Chronic eosinophilic rhinosinusitis	0	0
Chronic hyperplastic eosinophilic sinusitis	0	0
Hypersensitivity pneumonitis	0	0
Immune-mediated pneumonitis	0	0
Laryngitis allergic	0	0
Laryngospasm	0	0
Oropharyngeal blistering	0	0
Oropharyngeal spasm	0	0
Rhinitis allergic	0	0
Skin and subcutaneous tissue disorders	5 (0.44)	10 (0.89)
Acquired C1 inhibitor deficiency	0	0
Angioedema	0	0
Circumoral oedema	0	0
Circumoral swelling	0	0
Gleich's syndrome	0	0
Idiopathic urticaria	0	0
Urticaria	2 (0.18)	4 (0.35)
Urticaria cholinergic	0	0
Urticaria chronic	0	0
Urticaria papular	0	0
Acute generalised exanthematous pustulosis	0	0
Bromoderma	0	0
Bullous haemorrhagic dermatosis	0	0
Cutaneous vasculitis	0	0
Dennie-Morgan fold	0	0
Dermatitis	0	0
Dermatitis acneiform	0	0
Dermatitis allergic	0	0
Dermatitis atopic	0	0
Dermatitis bullous	0	0

Dermatitis contact	1 (0.09)	1 (0.09)
Dermatitis exfoliative	0	0
Dermatitis exfoliative generalised	0	0
Dermatitis herpetiformis	0	0
Dermatitis psoriasiform	0	0
Drug eruption	0	0
Drug reaction with eosinophilia and systemic symptoms	0	0
Dry skin	0	0
Eczema	0	0
Eczema infantile	0	0
Eczema nummular	0	0
Eczema vesicular	0	0
Eczema weeping	0	0
Epidermal necrosis	0	0
Epidermolysis	0	0
Erythema multiforme	0	0
Erythema nodosum	0	0
Exfoliative rash	0	0
Fixed eruption	0	0
Haemorrhagic urticaria	0	0
Hand dermatitis	0	0
Henoch-Schonlein purpura	0	0
Hypersensitivity vasculitis	0	0
Interstitial granulomatous dermatitis	0	0
Mucocutaneous rash	0	0
Nikolsky's sign	0	0
Nodular rash	0	0
Oculomucocutaneous syndrome	0	0
Palisaded neutrophilic granulomatous dermatitis	0	0
Palpable purpura	0	0
Pathergy reaction	0	0
Perioral dermatitis	0	0
Pruritus allergic	0	0
Rash	2 (0.18)	4 (0.35)
Rash erythematous	0	0
Rash follicular	0	0
Rash macular	0	0
Rash maculo-papular	0	1 (0.09)
Rash maculovesicular	0	0
Rash morbilliform	0	0
Rash neonatal	0	0
Rash papular	0	0

Rash papulosquamous	0	0
Rash pruritic	0	0
Rash rubelliform	0	0
Rash scarlatiniform	0	0
Rash vesicular	0	0
Red man syndrome	0	0
SJS-TEN overlap	0	0
Skin necrosis	0	0
Skin reaction	0	0
Solar urticaria	0	0
Stevens-Johnson syndrome	0	0
Symmetrical drug-related intertriginous and flexural exanthema	0	0
Systemic lupus erythematosus rash	0	0
Toxic epidermal necrolysis	0	0
Toxic skin eruption	0	0
Urticaria contact	0	0
Urticaria physical	0	0
Urticaria pigmentosa	0	0
Urticaria vesiculosa	0	0
Urticarial dermatitis	0	0
Urticarial vasculitis	0	0
Vasculitic rash	0	0
Surgical and medical procedures	0	0
Anaphylaxis treatment	0	0
Antiallergic therapy	0	0
Immune tolerance induction	0	0
Vascular disorders	0	0
Circulatory collapse	0	0
Distributive shock	0	0
Shock	0	0
Shock symptom	0	0
Any unsolicited adverse events within Peripheral neuropathy (SMQ)	1 (0.09)	0
Congenital, familial and genetic disorders	0	0
Paroxysmal extreme pain disorder	0	0
Sensory neuropathy hereditary	0	0
Injury, poisoning and procedural complications	0	0
Radiation neuropathy	0	0
Investigations	0	0
Biopsy peripheral nerve abnormal	0	0
Joint position sense decreased	0	0
Nerve conduction studies abnormal	0	0

Peripheral nervous system function test abnormal	0	0
Musculoskeletal and connective tissue disorders	0	0
Amyotrophy	0	0
Neuropathic muscular atrophy	0	0
Nervous system disorders	1 (0.09)	0
Anti-myelin-associated glycoprotein associated polyneuropathy	0	0
Demyelinating polyneuropathy	0	0
Guillain-Barre syndrome	0	0
Immune-mediated neuropathy	0	0
Acute painful neuropathy of rapid glycaemic control	0	0
Acute polyneuropathy	0	0
Angiopathic neuropathy	0	0
Autoimmune neuropathy	0	0
Axonal and demyelinating polyneuropathy	0	0
Axonal neuropathy	0	0
Central pain syndrome	0	0
Decreased vibratory sense	0	0
Ischaemic neuropathy	0	0
Loss of proprioception	0	0
Miller Fisher syndrome	0	0
Multifocal motor neuropathy	0	0
Myelopathy	0	0
Neuralgia	1 (0.09)	0
Neuritis	0	0
Neuronal neuropathy	0	0
Neuropathy peripheral	0	0
Notalgia paraesthetica	0	0
Peripheral motor neuropathy	0	0
Peripheral sensorimotor neuropathy	0	0
Peripheral sensory neuropathy	0	0
Polyneuropathy	0	0
Polyneuropathy chronic	0	0
Polyneuropathy idiopathic progressive	0	0
Sensorimotor disorder	0	0
Sensory disturbance	0	0
Sensory loss	0	0
Small fibre neuropathy	0	0
Tick paralysis	0	0
Toxic neuropathy	0	0
Any unsolicited adverse events within Vasculitis (SMQ)	0	0
Cardiac disorders	0	0

Arteritis coronary	0	0
Eye disorders	0	0
Cogan's syndrome	0	0
Ocular vasculitis	0	0
Retinal vasculitis	0	0
Gastrointestinal disorders	0	0
Vasculitis gastrointestinal	0	0
General disorders and administration site conditions	0	0
Administration site vasculitis	0	0
Application site vasculitis	0	0
Infusion site vasculitis	0	0
Injection site vasculitis	0	0
Vaccination site vasculitis	0	0
Medical device site vasculitis	0	0
Immune system disorders	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	0	0
Eosinophilic granulomatosis with polyangiitis	0	0
Infections and infestations	0	0
Erythema induratum	0	0
Type 2 lepra reaction	0	0
Viral vasculitis	0	0
Injury, poisoning and procedural complications	0	0
Radiation vasculitis	0	0
Musculoskeletal and connective tissue disorders	0	0
Polymyalgia rheumatica	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0
Langerhans' cell histiocytosis	0	0
Nervous system disorders	0	0
Central nervous system vasculitis	0	0
Cerebral arteritis	0	0
Renal and urinary disorders	0	0
Henoch-Schonlein purpura nephritis	0	0
Renal arteritis	0	0
Renal vasculitis	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Pulmonary vasculitis	0	0
Skin and subcutaneous tissue disorders	0	0
Cutaneous vasculitis	0	0
Henoch-Schonlein purpura	0	0
Hypersensitivity vasculitis	0	0
Urticarial vasculitis	0	0

Vasculitic rash	0	0
Acute haemorrhagic oedema of infancy	0	0
Capillaritis	0	0
Chronic pigmented purpura	0	0
Nodular vasculitis	0	0
Segmented hyalinising vasculitis	0	0
Vascular purpura	0	0
Vascular disorders	0	0
Aortitis	0	0
Arteritis	0	0
Behcet's syndrome	0	0
Diabetic arteritis	0	0
Diffuse vasculitis	0	0
Giant cell arteritis	0	0
Granulomatosis with polyangiitis	0	0
Haemorrhagic vasculitis	0	0
Kawasaki's disease	0	0
Lupus vasculitis	0	0
MAGIC syndrome	0	0
Microscopic polyangiitis	0	0
Polyarteritis nodosa	0	0
Pseudovasculitis	0	0
Rheumatoid vasculitis	0	0
Takayasu's arteritis	0	0
Thromboangiitis obliterans	0	0
Vasculitis	0	0
Vasculitis necrotising	0	0

- a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.

Table W.1 Name of Standard MedDRA Query From Dose 1 to 1 Month After Dose 2, Participants 16 to 25 Years of Age (Reactogenicity Subset), Safety Population

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Subjects with any unsolicited adverse events within SMQ	6 (1.12)	0
Angioedema (SMQ)	1 (0.19)	0
Congenital, familial and genetic disorders	0	0
Hereditary angioedema	0	0
Hereditary angioedema with C1 esterase inhibitor deficiency	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Eye disorders	0	0
Conjunctival oedema	0	0
Corneal oedema	0	0
Eye oedema	0	0
Eye swelling	0	0
Eyelid oedema	0	0
Limb swelling	0	0
Oculorespiratory syndrome	0	0
Periorbital oedema	0	0
Periorbital swelling	0	0
Scleral oedema	0	0
Swelling of eyelid	0	0
Gastrointestinal disorders	1 (0.19)	0
Gingival oedema	0	0
Gingival swelling	0	0
Intestinal angioedema	0	0
Lip oedema	0	0
Lip swelling	1 (0.19)	0
Mouth swelling	0	0
Oedema mouth	0	0
Palatal oedema	0	0
Palatal swelling	0	0
Swollen tongue	0	0
Tongue oedema	0	0
General disorders and administration site conditions	0	0
Face oedema	0	0
Swelling face	0	0
Immune system disorders	0	0
Allergic oedema	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Epiglottic oedema	0	0
Laryngeal oedema	0	0
Laryngotracheal oedema	0	0
Oropharyngeal oedema	0	0
Oropharyngeal swelling	0	0
Pharyngeal oedema	0	0
Pharyngeal swelling	0	0
Tracheal oedema	0	0
Skin and subcutaneous tissue disorders	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Acquired C1 inhibitor deficiency	0	0
Angioedema	0	0
Circumoral oedema	0	0
Circumoral swelling	0	0
Gleich's syndrome	0	0
Idiopathic angioedema	0	0
Idiopathic urticaria	0	0
Urticaria	0	0
Urticaria cholinergic	0	0
Urticaria chronic	0	0
Urticaria papular	0	0
Arthritis (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
COPA syndrome	0	0
Otospondylomegaepiphyseal dysplasia	0	0
Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome	0	0
General disorders and administration site conditions	0	0
Infusion site joint inflammation	0	0
Injection site joint inflammation	0	0
Infections and infestations	0	0
Arthritis bacterial	0	0
Arthritis fungal	0	0
Arthritis gonococcal	0	0
Arthritis helminthic	0	0
Arthritis infective	0	0
Arthritis rubella	0	0
Arthritis salmonella	0	0
Arthritis viral	0	0
Epidemic polyarthritis	0	0
Infected gouty tophus	0	0
Infusion site joint infection	0	0
Injection site joint infection	0	0
Medical device site joint infection	0	0
Septic arthritis haemophilus	0	0
Septic arthritis neisserial	0	0
Septic arthritis staphylococcal	0	0
Septic arthritis streptobacillus	0	0
Septic arthritis streptococcal	0	0
Vaccination site joint infection	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Injury, poisoning and procedural complications	0	0
Traumatic arthritis	0	0
Metabolism and nutrition disorders	0	0
Gout	0	0
Periarthritis calcarea	0	0
Musculoskeletal and connective tissue disorders	0	0
Ankylosing spondylitis	0	0
Arthritis	0	0
Arthritis allergic	0	0
Arthritis climacteric	0	0
Arthritis enteropathic	0	0
Arthritis reactive	0	0
Autoimmune arthritis	0	0
Axial spondyloarthritis	0	0
Bursitis	0	0
Carcinomatous polyarthritis	0	0
Chondrocalcinosis	0	0
Chondrocalcinosis pyrophosphate	0	0
Chondromalacia	0	0
Chondronecrosis	0	0
Diffuse idiopathic skeletal hyperostosis	0	0
Enteropathic spondylitis	0	0
Facet joint syndrome	0	0
Felty's syndrome	0	0
Gouty arthritis	0	0
Gouty tophus	0	0
Haemophilic arthropathy	0	0
Idiopathic condylar resorption	0	0
Immune-mediated arthritis	0	0
Juvenile idiopathic arthritis	0	0
Juvenile psoriatic arthritis	0	0
Juvenile spondyloarthritis	0	0
Nodal osteoarthritis	0	0
Oligoarthritis	0	0
Osteoarthritis	0	0
Palindromic rheumatism	0	0
Paraneoplastic arthritis	0	0
Patellofemoral pain syndrome	0	0
Periarthritis	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Plica syndrome	0	0
Polyarthritis	0	0
Rapidly progressive osteoarthritis	0	0
Rheumatic disorder	0	0
Rheumatic fever	0	0
Rheumatoid arthritis	0	0
SLE arthritis	0	0
Sacroiliac joint dysfunction	0	0
Sacroiliitis	0	0
Seronegative arthritis	0	0
Spinal osteoarthritis	0	0
Spondylitis	0	0
Still's disease	0	0
Synovitis	0	0
Temporomandibular joint syndrome	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Caplan's syndrome	0	0
Laryngeal rheumatoid arthritis	0	0
Convulsions (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
1p36 deletion syndrome	0	0
2-Hydroxyglutaric aciduria	0	0
Alpers disease	0	0
Aspartate-glutamate-transporter deficiency	0	0
Baltic myoclonic epilepsy	0	0
Benign familial neonatal convulsions	0	0
Biotinidase deficiency	0	0
CDKL5 deficiency disorder	0	0
CEC syndrome	0	0
Congenital bilateral perisylvian syndrome	0	0
Double cortex syndrome	0	0
Epilepsy with myoclonic-atonic seizures	0	0
GM2 gangliosidosis	0	0
Glucose transporter type 1 deficiency syndrome	0	0
Grey matter heterotopia	0	0
Hemimegalencephaly	0	0
Lafora's myoclonic epilepsy	0	0
Molybdenum cofactor deficiency	0	0
Myoclonic epilepsy and ragged-red fibres	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Polymicrogyria	0	0
Schizencephaly	0	0
Severe myoclonic epilepsy of infancy	0	0
Tuberous sclerosis complex	0	0
General disorders and administration site conditions	0	0
Sudden unexplained death in epilepsy	0	0
Nervous system disorders	0	0
Acquired epileptic aphasia	0	0
Acute encephalitis with refractory, repetitive partial seizures	0	0
Alcoholic seizure	0	0
Atonic seizures	0	0
Atypical benign partial epilepsy	0	0
Autonomic seizure	0	0
Benign rolandic epilepsy	0	0
CSWS syndrome	0	0
Change in seizure presentation	0	0
Clonic convulsion	0	0
Convulsion in childhood	0	0
Convulsions local	0	0
Convulsive threshold lowered	0	0
Dreamy state	0	0
Drug withdrawal convulsions	0	0
Early infantile epileptic encephalopathy with burst-suppression	0	0
Epilepsy	0	0
Epileptic aura	0	0
Faciobrachial dystonic seizure	0	0
Febrile convulsion	0	0
Febrile infection-related epilepsy syndrome	0	0
Focal dyscognitive seizures	0	0
Frontal lobe epilepsy	0	0
Gelastic seizure	0	0
Generalised onset non-motor seizure	0	0
Generalised tonic-clonic seizure	0	0
Hyperglycaemic seizure	0	0
Hypocalcaemic seizure	0	0
Hypoglycaemic seizure	0	0
Hyponatraemic seizure	0	0
Idiopathic generalised epilepsy	0	0
Infantile spasms	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Jeavons syndrome	0	0
Juvenile myoclonic epilepsy	0	0
Lennox-Gastaut syndrome	0	0
Migraine-triggered seizure	0	0
Myoclonic epilepsy	0	0
Neonatal epileptic seizure	0	0
Neonatal seizure	0	0
Partial seizures	0	0
Partial seizures with secondary generalisation	0	0
Petit mal epilepsy	0	0
Post stroke epilepsy	0	0
Post stroke seizure	0	0
Post-traumatic epilepsy	0	0
Postictal headache	0	0
Postictal paralysis	0	0
Postictal state	0	0
Seizure	0	0
Seizure anoxic	0	0
Seizure cluster	0	0
Seizure like phenomena	0	0
Simple partial seizures	0	0
Status epilepticus	0	0
Temporal lobe epilepsy	0	0
Tonic clonic movements	0	0
Tonic convulsion	0	0
Tonic posturing	0	0
Transient epileptic amnesia	0	0
Uncinate fits	0	0
Pregnancy, puerperium and perinatal conditions	0	0
Eclampsia	0	0
Psychiatric disorders	0	0
Automatism epileptic	0	0
Deja vu	0	0
Epileptic psychosis	0	0
Postictal psychosis	0	0
Surgical and medical procedures	0	0
Epilepsy surgery	0	0
Multiple subpial transection	0	0
Topectomy	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Any unsolicited adverse events within Demyelination (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
Myoclonic epilepsy and ragged-red fibres	0	0
MELAS syndrome	0	0
Neuropathy, ataxia, retinitis pigmentosa syndrome	0	0
Infections and infestations	0	0
Encephalomyelitis	0	0
Progressive multifocal leukoencephalopathy	0	0
Zika virus associated Guillain Barre syndrome	0	0
Investigations	0	0
Expanded disability status scale score decreased	0	0
Expanded disability status scale score increased	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0
Hypergammaglobulinaemia benign monoclonal	0	0
Nervous system disorders	0	0
Acute disseminated encephalomyelitis	0	0
Acute haemorrhagic leukoencephalitis	0	0
Anti-myelin-associated glycoprotein associated polyneuropathy	0	0
Autoimmune demyelinating disease	0	0
Chronic inflammatory demyelinating polyradiculoneuropathy	0	0
Clinically isolated syndrome	0	0
Concentric sclerosis	0	0
Demyelinating polyneuropathy	0	0
Demyelination	0	0
Encephalitis periaxialis diffusa	0	0
Guillain-Barre syndrome	0	0
Immune-mediated neuropathy	0	0
Leukoencephalomyelitis	0	0
Leukoencephalopathy	0	0
Lewis-Sumner syndrome	0	0
Marburg's variant multiple sclerosis	0	0
Marchiafava-Bignami disease	0	0
Multiple sclerosis	0	0
Multiple sclerosis relapse	0	0
Myelitis transverse	0	0
Neuromyelitis optica pseudo relapse	0	0
Neuromyelitis optica spectrum disorder	0	0
Noninfectious myelitis	0	0
Noninfective encephalomyelitis	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Optic neuritis	0	0
Osmotic demyelination syndrome	0	0
Primary progressive multiple sclerosis	0	0
Progressive multiple sclerosis	0	0
Progressive relapsing multiple sclerosis	0	0
Relapsing multiple sclerosis	0	0
Relapsing-remitting multiple sclerosis	0	0
Secondary progressive multiple sclerosis	0	0
Subacute inflammatory demyelinating polyneuropathy	0	0
Toxic leukoencephalopathy	0	0
Tumefactive multiple sclerosis	0	0
Surgical and medical procedures	0	0
Multiple sclerosis relapse prophylaxis	0	0
Hypersensitivity (SMQ)	6 (1.12)	0
Blood and lymphatic system disorders	0	0
Allergic eosinophilia	0	0
Heparin-induced thrombocytopenia	0	0
Immune thrombocytopenia	0	0
Cardiac disorders	0	0
Hypersensitivity myocarditis	0	0
Kounis syndrome	0	0
Congenital, familial and genetic disorders	0	0
Hereditary angioedema	0	0
Hereditary angioedema with C1 esterase inhibitor deficiency	0	0
Epidermolysis bullosa	0	0
Ear and labyrinth disorders	0	0
Allergic otitis externa	0	0
Allergic otitis media	0	0
Eye disorders	0	0
Conjunctival oedema	0	0
Corneal oedema	0	0
Eye oedema	0	0
Eye swelling	0	0
Eyelid oedema	0	0
Limbic swelling	0	0
Oculorespiratory syndrome	0	0
Periorbital oedema	0	0
Periorbital swelling	0	0
Scleral oedema	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Swelling of eyelid	0	0
Allergic keratitis	0	0
Blepharitis allergic	0	0
Conjunctivitis allergic	0	0
Eye allergy	0	0
Giant papillary conjunctivitis	0	0
Scleritis allergic	0	0
Vernal keratoconjunctivitis	0	0
Gastrointestinal disorders	1 (0.19)	0
Gingival oedema	0	0
Gingival swelling	0	0
Intestinal angioedema	0	0
Lip oedema	0	0
Lip swelling	1 (0.19)	0
Mouth swelling	0	0
Oedema mouth	0	0
Palatal oedema	0	0
Palatal swelling	0	0
Swollen tongue	0	0
Tongue oedema	0	0
Allergic colitis	0	0
Allergic gastroenteritis	0	0
Allergic stomatitis	0	0
Anal eczema	0	0
Contact stomatitis	0	0
Oral mucosal eruption	0	0
General disorders and administration site conditions	0	0
Face oedema	0	0
Swelling face	0	0
Administration site dermatitis	0	0
Administration site eczema	0	0
Administration site hypersensitivity	0	0
Administration site rash	0	0
Administration site recall reaction	0	0
Administration site urticaria	0	0
Administration site vasculitis	0	0
Application site dermatitis	0	0
Application site eczema	0	0
Application site hypersensitivity	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Application site rash	0	0
Application site recall reaction	0	0
Application site urticaria	0	0
Application site vasculitis	0	0
Catheter site dermatitis	0	0
Catheter site eczema	0	0
Catheter site hypersensitivity	0	0
Catheter site rash	0	0
Catheter site urticaria	0	0
Catheter site vasculitis	0	0
Immediate post-injection reaction	0	0
Implant site dermatitis	0	0
Implant site hypersensitivity	0	0
Implant site rash	0	0
Implant site urticaria	0	0
Infusion site dermatitis	0	0
Infusion site eczema	0	0
Infusion site hypersensitivity	0	0
Infusion site rash	0	0
Infusion site recall reaction	0	0
Infusion site urticaria	0	0
Infusion site vasculitis	0	0
Injection site dermatitis	0	0
Injection site eczema	0	0
Injection site hypersensitivity	0	0
Injection site rash	0	0
Injection site recall reaction	0	0
Injection site urticaria	0	0
Injection site vasculitis	0	0
Instillation site hypersensitivity	0	0
Instillation site rash	0	0
Instillation site urticaria	0	0
Medical device site dermatitis	0	0
Medical device site eczema	0	0
Medical device site hypersensitivity	0	0
Medical device site rash	0	0
Medical device site recall reaction	0	0
Medical device site urticaria	0	0
Vaccination site dermatitis	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N ^a =536)	(N ^a =561)
Preferred Term	n ^b (%)	n ^b (%)
Vaccination site eczema	0	0
Vaccination site exfoliation	0	0
Vaccination site hypersensitivity	0	0
Vaccination site rash	0	0
Vaccination site recall reaction	0	0
Vaccination site urticaria	0	0
Vaccination site vasculitis	0	0
Vaccination site vesicles	0	0
Vessel puncture site rash	0	0
Vessel puncture site vesicles	0	0
Hepatobiliary disorders	0	0
Allergic hepatitis	0	0
Immune system disorders	0	0
Allergic oedema	0	0
Allergic reaction to excipient	0	0
Allergy to immunoglobulin therapy	0	0
Allergy to surgical sutures	0	0
Allergy to vaccine	0	0
Anaphylactic reaction	0	0
Anaphylactic shock	0	0
Anaphylactoid reaction	0	0
Anaphylactoid shock	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	0	0
Atopy	0	0
Contrast media allergy	0	0
Contrast media reaction	0	0
Device allergy	0	0
Dialysis membrane reaction	0	0
Drug hypersensitivity	0	0
Eosinophilic granulomatosis with polyangiitis	0	0
Hypersensitivity	0	0
Immune-mediated adverse reaction	0	0
Infusion related hypersensitivity reaction	0	0
Iodine allergy	0	0
Multiple allergies	0	0
Nutritional supplement allergy	0	0
Oral allergy syndrome	0	0
Reaction to azo-dyes	0	0
Reaction to colouring	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Reaction to excipient	0	0
Reaction to food additive	0	0
Reaction to preservatives	0	0
Serum sickness	0	0
Serum sickness-like reaction	0	0
Solvent sensitivity	0	0
Therapeutic product cross-reactivity	0	0
Type I hypersensitivity	0	0
Type II hypersensitivity	0	0
Type III immune complex mediated reaction	0	0
Type IV hypersensitivity reaction	0	0
Infections and infestations	0	0
Dermatitis infected	0	0
Eczema vaccinatum	0	0
Kaposi's varicelliform eruption	0	0
Pustule	0	0
Rash pustular	0	0
Injury, poisoning and procedural complications	0	0
Administration related reaction	0	0
Allergic transfusion reaction	0	0
Anaphylactic transfusion reaction	0	0
Documented hypersensitivity to administered product	0	0
Incision site dermatitis	0	0
Incision site rash	0	0
Infusion related reaction	0	0
Injection related reaction	0	0
Procedural shock	0	0
Stoma site hypersensitivity	0	0
Stoma site rash	0	0
Investigations	0	0
Allergy alert test positive	0	0
Allergy test positive	0	0
Antiendomysial antibody positive	0	0
Blood immunoglobulin E abnormal	0	0
Blood immunoglobulin E increased	0	0
Drug provocation test	0	0
Mast cell degranulation present	0	0
Radioallergosorbent test positive	0	0
Skin test positive	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Musculoskeletal and connective tissue disorders	0	0
Arthritis allergic	0	0
Nervous system disorders	0	0
Encephalitis allergic	0	0
Encephalopathy allergic	0	0
Renal and urinary disorders	0	0
Allergic cystitis	0	0
Henoch-Schonlein purpura nephritis	0	0
Nephritis allergic	0	0
Reproductive system and breast disorders	0	0
Scrotal dermatitis	0	0
Scrotal oedema	0	0
Vaginal ulceration	0	0
Vulval eczema	0	0
Vulval ulceration	0	0
Vulvovaginal rash	0	0
Vulvovaginal ulceration	0	0
Vulvovaginitis allergic	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Epiglottic oedema	0	0
Laryngeal oedema	0	0
Laryngotracheal oedema	0	0
Oropharyngeal oedema	0	0
Oropharyngeal swelling	0	0
Pharyngeal oedema	0	0
Pharyngeal swelling	0	0
Tracheal oedema	0	0
Allergic bronchitis	0	0
Allergic cough	0	0
Allergic pharyngitis	0	0
Allergic respiratory disease	0	0
Allergic respiratory symptom	0	0
Allergic sinusitis	0	0
Aspirin-exacerbated respiratory disease	0	0
Atopic cough	0	0
Bronchospasm	0	0
Chronic eosinophilic rhinosinusitis	0	0
Chronic hyperplastic eosinophilic sinusitis	0	0
Hypersensitivity pneumonitis	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Immune-mediated pneumonitis	0	0
Laryngitis allergic	0	0
Laryngospasm	0	0
Oropharyngeal blistering	0	0
Oropharyngeal spasm	0	0
Rhinitis allergic	0	0
Skin and subcutaneous tissue disorders	5 (0.93)	0
Acquired C1 inhibitor deficiency	0	0
Angioedema	0	0
Circumoral oedema	0	0
Circumoral swelling	0	0
Gleich's syndrome	0	0
Idiopathic urticaria	0	0
Urticaria	0	0
Urticaria cholinergic	0	0
Urticaria chronic	0	0
Urticaria papular	0	0
Acute generalised exanthematous pustulosis	0	0
Bromoderma	0	0
Bullous haemorrhagic dermatosis	0	0
Cutaneous vasculitis	0	0
Dennie-Morgan fold	0	0
Dermatitis	0	0
Dermatitis acneiform	0	0
Dermatitis allergic	0	0
Dermatitis atopic	0	0
Dermatitis bullous	0	0
Dermatitis contact	1 (0.19)	0
Dermatitis exfoliative	0	0
Dermatitis exfoliative generalised	0	0
Dermatitis herpetiformis	0	0
Dermatitis psoriasiform	0	0
Drug eruption	0	0
Drug reaction with eosinophilia and systemic symptoms	0	0
Dry skin	0	0
Eczema	0	0
Eczema infantile	0	0
Eczema nummular	0	0
Eczema vesicular	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N ^a =536)	(N ^a =561)
Preferred Term	n ^b (%)	n ^b (%)
Eczema weeping	0	0
Epidermal necrosis	0	0
Epidermolysis	0	0
Erythema multiforme	0	0
Erythema nodosum	0	0
Exfoliative rash	0	0
Fixed eruption	0	0
Haemorrhagic urticaria	0	0
Hand dermatitis	0	0
Henoch-Schonlein purpura	0	0
Hypersensitivity vasculitis	0	0
Interstitial granulomatous dermatitis	0	0
Mucocutaneous rash	0	0
Nikolsky's sign	0	0
Nodular rash	0	0
Oculomucocutaneous syndrome	0	0
Palisaded neutrophilic granulomatous dermatitis	0	0
Palpable purpura	0	0
Pathergy reaction	0	0
Perioral dermatitis	0	0
Pruritus allergic	0	0
Rash	3 (0.56)	0
Rash erythematous	1 (0.19)	0
Rash follicular	0	0
Rash macular	0	0
Rash maculo-papular	0	0
Rash maculovesicular	0	0
Rash morbilliform	0	0
Rash neonatal	0	0
Rash papular	0	0
Rash papulosquamous	0	0
Rash pruritic	0	0
Rash rubelliform	0	0
Rash scarlatiniform	0	0
Rash vesicular	0	0
Red man syndrome	0	0
SJS-TEN overlap	0	0
Skin necrosis	0	0
Skin reaction	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Solar urticaria	0	0
Stevens-Johnson syndrome	0	0
Symmetrical drug-related intertriginous and flexural exanthema	0	0
Systemic lupus erythematosus rash	0	0
Toxic epidermal necrolysis	0	0
Toxic skin eruption	0	0
Urticaria contact	0	0
Urticaria physical	0	0
Urticaria pigmentosa	0	0
Urticaria vesiculosa	0	0
Urticarial dermatitis	0	0
Urticarial vasculitis	0	0
Vasculitic rash	0	0
Surgical and medical procedures	0	0
Anaphylaxis treatment	0	0
Antiallergic therapy	0	0
Immune tolerance induction	0	0
Vascular disorders	0	0
Circulatory collapse	0	0
Distributive shock	0	0
Shock	0	0
Shock symptom	0	0
Peripheral neuropathy (SMQ)	0	0
Congenital, familial and genetic disorders	0	0
Paroxysmal extreme pain disorder	0	0
Sensory neuropathy hereditary	0	0
Injury, poisoning and procedural complications	0	0
Radiation neuropathy	0	0
Investigations	0	0
Biopsy peripheral nerve abnormal	0	0
Joint position sense decreased	0	0
Nerve conduction studies abnormal	0	0
Peripheral nervous system function test abnormal	0	0
Musculoskeletal and connective tissue disorders	0	0
Amyotrophy	0	0
Neuropathic muscular atrophy	0	0
Nervous system disorders	0	0
Anti-myelin-associated glycoprotein associated polyneuropathy	0	0
Demyelinating polyneuropathy	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Guillain-Barre syndrome	0	0
Immune-mediated neuropathy	0	0
Acute painful neuropathy of rapid glycaemic control	0	0
Acute polyneuropathy	0	0
Angiopathic neuropathy	0	0
Autoimmune neuropathy	0	0
Axonal and demyelinating polyneuropathy	0	0
Axonal neuropathy	0	0
Central pain syndrome	0	0
Decreased vibratory sense	0	0
Ischaemic neuropathy	0	0
Loss of proprioception	0	0
Miller Fisher syndrome	0	0
Multifocal motor neuropathy	0	0
Myelopathy	0	0
Neuralgia	0	0
Neuritis	0	0
Neuronal neuropathy	0	0
Neuropathy peripheral	0	0
Notalgia paraesthetica	0	0
Peripheral motor neuropathy	0	0
Peripheral sensorimotor neuropathy	0	0
Peripheral sensory neuropathy	0	0
Polyneuropathy	0	0
Polyneuropathy chronic	0	0
Polyneuropathy idiopathic progressive	0	0
Sensorimotor disorder	0	0
Sensory disturbance	0	0
Sensory loss	0	0
Small fibre neuropathy	0	0
Tick paralysis	0	0
Toxic neuropathy	0	0
Vasculitis (SMQ)	0	0
Cardiac disorders	0	0
Arteritis coronary	0	0
Eye disorders	0	0
Cogan's syndrome	0	0
Ocular vasculitis	0	0
Retinal vasculitis	0	0

Overall SMQ	BNT162b2	Placebo
System Organ Class	(N^a=536)	(N^a=561)
Preferred Term	n^b (%)	n^b (%)
Gastrointestinal disorders	0	0
Vasculitis gastrointestinal	0	0
General disorders and administration site conditions	0	0
Administration site vasculitis	0	0
Application site vasculitis	0	0
Infusion site vasculitis	0	0
Injection site vasculitis	0	0
Vaccination site vasculitis	0	0
Medical device site vasculitis	0	0
Immune system disorders	0	0
Anti-neutrophil cytoplasmic antibody positive vasculitis	0	0
Eosinophilic granulomatosis with polyangiitis	0	0
Infections and infestations	0	0
Erythema induratum	0	0
Type 2 lepra reaction	0	0
Viral vasculitis	0	0
Injury, poisoning and procedural complications	0	0
Radiation vasculitis	0	0
Musculoskeletal and connective tissue disorders	0	0
Polymyalgia rheumatica	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	0
Langerhans' cell histiocytosis	0	0
Nervous system disorders	0	0
Central nervous system vasculitis	0	0
Cerebral arteritis	0	0
Renal and urinary disorders	0	0
Henoch-Schonlein purpura nephritis	0	0
Renal arteritis	0	0
Renal vasculitis	0	0
Respiratory, thoracic and mediastinal disorders	0	0
Pulmonary vasculitis	0	0
Skin and subcutaneous tissue disorders	0	0
Cutaneous vasculitis	0	0
Henoch-Schonlein purpura	0	0
Hypersensitivity vasculitis	0	0
Urticarial vasculitis	0	0
Vasculitic rash	0	0
Acute haemorrhagic oedema of infancy	0	0
Capillaritis	0	0

- a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
- b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event", n = the number of subjects reporting at least 1 occurrence of any event.

Table X. SAEs Considered Related by Investigator From Dose 1 Through Cutoff Date - Participants 12 to 15 Years of Age, Safety Population

Product (Vaccine or Placebo)	SAE	Onset (Days After Vaccination)	Demographics/Risk Factors	Resolution	Related per Investigator/ Pfizer
No events meeting criteria.					

Table X.1 SAEs Considered Related by Investigator From Dose 1 Through Cutoff Date - Participants 16 to 25 Years of Age, Safety Population

Product (Vaccine or Placebo)	SAE	Onset (Days After Vaccination)	Demographics/Risk Factors	Resolution	Related per Investigator/ Pfizer
Placebo crossover to BNT162b2	anaphylactoid reaction	Day 69 (2 days after receiving the first dose of BNT162b2)	17 F; asthma and eczema, food allergy, seasonal allergy, drug hypersensitivity	Resolved	Yes/Yes

Table Y. Deaths, Participants 12 Through 25 Years of Age, Safety Population

Product (Vaccine or Placebo)	Cause of Death	Onset (Days After Vaccination)	Demographics/Risk Factors
	No deaths have been reported in participants 12 through 25 years of age.		

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