Table.A Follow-up Duration After Dose 2 – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	**Placebo (N[a]=1129) n[b] (%)**	**Total (N[a]=2260) n[b] (%)**
Length of Blinded Placebo-controlled Follow-up			
<4 Months	345 (30.5)	356 (31.5)	701 (31.0)
≥4-<5 Months	528 (46.7)	532 (47.1)	1060 (46.9)
≥5-<6 Months	106 (9.4)	97 (8.6)	203 (9.0)
≥6 Months	152 (13.4)	144 (12.8)	296 (13.1)
Total Follow-up Period from Dose 2 to Cutoff Date September 2, 2021			
<4 Months	8 (0.7)		
≥4-<5 Months	7 (0.6)		
≥5-<6 Months	3 (0.3)		
≥6 Months	1113 (98.4)		

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.

Table.B Study Disposition of Phase 2/3 Randomized Participants 12 Through 15 Years of Age (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=1134) n^b (%)	**Placebo (N^a=1130) n^b (%)**	**Total (N^a=2264) n^b (%)**
Randomized	1134 (100.0)	1130 (100.0)	2264 (100.0)
Not vaccinated	3 (0.3)	1 (0.1)	4 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	1131 (99.7)	1129 (99.9)	2260 (99.8)
Dose 1	1131 (99.7)	1129 (99.9)	2260 (99.8)
Dose 2	1124 (99.1)	1117 (98.8)	2241 (99.0)
Discontinued from original blinded placebo-controlled vaccination period[c]	3 (0.3)	14 (1.2)	17 (0.8)
Reason for discontinuation			
No longer meets eligibility criteria	0	7 (0.6)	7 (0.3)
Protocol deviation	0	2 (0.2)	2 (0.1)
Adverse event	1 (0.1)	0	1 (0.0)
Physician decision	1 (0.1)	0	1 (0.0)
Withdrawal by subject	0	1 (0.1)	1 (0.0)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.0)
Other	1 (0.1)	3 (0.3)	4 (0.2)
Unblinded before 1-month post–Dose 2 visit	12 (1.1)	21 (1.9)	33 (1.5)
Completed 1-month post–Dose 2 visit	1113 (98.1)	1096 (97.0)	2209 (97.6)
Withdrawn from the study	5 (0.4)	14 (1.2)	19 (0.8)
Withdrawn after Dose 1 and before Dose 2	0	0	0

Table.B Study Disposition of Phase 2/3 Randomized Participants 12 Through 15 Years of Age (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=1134) n^b (%)	**Placebo (N^a=1130) n^b (%)**	**Total (N^a=2264) n^b (%)**
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.3)	3 (0.1)
Withdrawn after 1-month post–Dose 2 visit	5 (0.4)	11 (1.0)	16 (0.7)
Reason for withdrawal from the study			
Withdrawal by subject	1 (0.1)	7 (0.6)	8 (0.4)
Withdrawal by parent/guardian	1 (0.1)	5 (0.4)	6 (0.3)
Lost to follow-up	3 (0.3)	2 (0.2)	5 (0.2)
Open-label follow-up period			
Originally randomized to BNT162b2	1107 (97.6)		
Received Dose 2/unplanned dose	4 (0.4)		
Completed 1-month post–Dose 2 visit	15 (1.3)		
Completed 6-month post–Dose 2 visit	1065 (93.9)		
Withdrawn from the study	45 (4.0)		
Withdrawn before 6-month post–Dose 2 visit	25 (2.2)		
Withdrawn after 6-month post–Dose 2 visit	20 (1.8)		
Reason for withdrawal from the study			
Withdrawal by subject	7 (0.6)		
Withdrawal by parent/guardian	7 (0.6)		
Lost to follow-up	6 (0.5)		
Protocol deviation	1 (0.1)		
No longer meets eligibility criteria	1 (0.1)		
Other	23 (2.0)		

Table.B Study Disposition of Phase 2/3 Randomized Participants 12 Through 15 Years of Age (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1134) n[b] (%)	**Placebo (N[a]=1130) n[b] (%)**	**Total (N[a]=2264) n[b] (%)**
Originally randomized to placebo		1108 (98.1)	
Withdrawn from the study after unblinding and before Dose 3		47 (4.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		1010 (89.4)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		992 (87.8)	
Discontinued from open-label vaccination period[d]		5 (0.4)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		4 (0.4)	
Withdrawal by subject		1 (0.1)	
Completed 1-month post–Dose 4 visit		933 (82.6)	
Withdrawn from the study		6 (0.5)	
Withdrawn after Dose 3 and before Dose 4		5 (0.4)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		0	
Withdrawn after 1-month post–Dose 4 visit		1 (0.1)	
Reason for withdrawal from the study			
Withdrawal by subject		3 (0.3)	
Lost to follow-up		2 (0.2)	
Protocol deviation		1 (0.1)	

a. N = number of randomized 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. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1-month post–Dose 2 visit.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1-month post–Dose 4 (second dose of BNT162b2 [30 µg]) visit.

Table.C Study Disposition, Participants 12 Through 15 Years of Age, Open-label Unblinded Follow-Up Time Period

Pfizer Response: Disposition data for open-label unblinded follow-up time period is included in Table B.

Table.D Disposition of Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=1131) n^b (%)	**Placebo (N^a=1129) n^b (%)**	**Total (N^a=2260) n^b (%)**
Randomized			2264
Not vaccinated			4
Vaccinated	1131 (100.0)	1129 (100.0)	2260 (100.0)
Completed 1 dose	1131 (100.0)	1129 (100.0)	2260 (100.0)
Completed 2 doses	1124 (99.4)	1117 (98.9)	2241 (99.2)
Safety population	1131 (100.0)	1129 (100.0)	2260 (100.0)
Participants excluded from safety population			4
Reason for exclusion			
Participant did not receive study vaccine			4
Completed at least 6 months follow-up after Dose 2 in blinded placebo-controlled follow-up period	152 (13.4)	144 (12.8)	296 (13.1)
Completed at least 6 months follow-up after Dose 2 in blinded and open-label follow-up period	1113 (98.4)		
Completed 1-month post–Dose 2 visit (vaccination period)	1113 (98.4)	1096 (97.1)	2209 (97.7)
Discontinued from vaccination period but continued in the study up to 1-month post–Dose 2 visit	3 (0.3)	14 (1.2)	17 (0.8)
Discontinued after Dose 1 and before Dose 2	3 (0.3)	10 (0.9)	13 (0.6)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	0	4 (0.4)	4 (0.2)
Reason for discontinuation from vaccination period			
No longer meets eligibility criteria	0	7 (0.6)	7 (0.3)
Protocol deviation	0	2 (0.2)	2 (0.1)
Adverse event	1 (0.1)	0	1 (0.0)

Table.D Disposition of Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	**Placebo (N[a]=1129) n[b] (%)**	**Total (N[a]=2260) n[b] (%)**
Physician decision	1 (0.1)	0	1 (0.0)
Withdrawal by subject	0	1 (0.1)	1 (0.0)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.0)
Other	1 (0.1)	3 (0.3)	4 (0.2)
Withdrawn from study before 1-month post–Dose 2 visit	0	3 (0.3)	3 (0.1)
Withdrawn after Dose 1 and before Dose 2	0	0	0
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	0	3 (0.3)	3 (0.1)
Reason for withdrawal			
Withdrawal by parent/guardian	0	2 (0.2)	2 (0.1)
Withdrawal by subject	0	1 (0.1)	1 (0.0)

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.

Table.E Disposition of Participants 12 Through 15 Years of Age – Efficacy Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) 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)
Subjects without evidence of infection before Dose 1	1083 (95.5)	1078 (95.4)	2161 (95.5)
Subjects 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)
Subjects without evidence of infection prior to 7 days after Dose 2	1061 (93.6)	1037 (91.8)	2098 (92.7)
Subjects 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)	1109 (98.1)	2228 (98.4)
Subjects without evidence of infection prior to 7 days after Dose 2	1057 (93.2)	1030 (91.2)	2087 (92.2)
Subjects excluded from evaluable efficacy (7 days) population	15 (1.3)	21 (1.9)	36 (1.6)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	1 (0.1)	1 (0.1)	2 (0.1)
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)
Unblinded prior to 7 days after Dose 2	1 (0.1)	0	1 (0.0)

Table.E Disposition of Participants 12 Through 15 Years of Age – Efficacy Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	**Placebo n[a] (%)**	**Total n[a] (%)**
Had other important protocol deviations on or prior to 7 days after Dose 2	0	3 (0.3)	3 (0.1)

a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.

Table.F Demographics and Other Baseline Characteristics – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)	Total (N[a]=2260) n[b] (%)
Sex: Female	564 (49.9)	544 (48.2)	1108 (49.0)
Sex: Male	567 (50.1)	585 (51.8)	1152 (51.0)
Age at Vaccination: Mean years (SD)	13.6 (1.11)	13.6 (1.11)	13.6 (1.11)
Age at Vaccination: Median (years)	14.0	14.0	14.0
Age at Vaccination: Min, max (years)	(12, 15)	(12, 15)	(12, 15)
Race: American Indian or Alaska Native	4 (0.4)	3 (0.3)	7 (0.3)
Race: Asian	72 (6.4)	71 (6.3)	143 (6.3)
Race: Black or African American	52 (4.6)	57 (5.0)	109 (4.8)
Race: Native Hawaiian or Other Pacific Islander	3 (0.3)	0	3 (0.1)
Race: White	970 (85.8)	962 (85.2)	1932 (85.5)
Race: Multiracial	24 (2.1)	29 (2.6)	53 (2.3)
Race: Not reported	6 (0.5)	7 (0.6)	13 (0.6)
Ethnicity: Hispanic or Latino	132 (11.7)	130 (11.5)	262 (11.6)
Ethnicity: Not Hispanic or Latino	997 (88.2)	996 (88.2)	1993 (88.2)
Ethnicity: Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Obesity: Yes[c]	143 (12.6)	128 (11.3)	271 (12.0)
Obesity: No	988 (87.4)	1001 (88.7)	1989 (88.0)
Comorbidities: Yes[d]	249 (22.0)	242 (21.4)	491 (21.7)

Table.F Demographics and Other Baseline Characteristics – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=1131) n[b] (%)	Placebo (N[a]=1129) n[b] (%)	Total (N[a]=2260) n[b] (%)
Comorbidities: No	882 (78.0)	887 (78.6)	1769 (78.3)
Baseline evidence of prior SARS-CoV-2 infection: Negative[e]	1083 (95.8)	1078 (95.5)	2161 (95.6)
Baseline evidence of prior SARS-CoV-2 infection: Positive[f]	46 (4.1)	50 (4.4)	96 (4.2)
Baseline evidence of prior SARS-CoV-2 infection: Missing	2 (0.2)	1 (0.1)	3 (0.1)
Country: United States of America	1131 (100.0)	1129 (100.0)	2260 (100.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

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

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

c. Subjects who had a BMI at or above the 95th percentile from the CDC growth chart.

d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.

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

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

Table.G Demographics and Other Baseline Characteristics – Participants 12 Through 15 Years of Age With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=1119) n[b] (%)	Placebo (N[a]=1109) n[b] (%)	Total (N[a]=2228) n[b] (%)
Sex: Female	560 (50.0)	536 (48.3)	1096 (49.2)
Sex: Male	559 (50.0)	573 (51.7)	1132 (50.8)
Age at Vaccination: Mean years (SD)	13.6 (1.11)	13.6 (1.11)	13.6 (1.11)
Age at Vaccination: Median (years)	14.0	14.0	14.0
Age at Vaccination: Min, max (years)	(12, 15)	(12, 15)	(12, 15)
Race: American Indian or Alaska Native	4 (0.4)	2 (0.2)	6 (0.3)
Race: Asian	71 (6.3)	71 (6.4)	142 (6.4)
Race: Black or African American	50 (4.5)	57 (5.1)	107 (4.8)
Race: Native Hawaiian or Other Pacific Islander	3 (0.3)	0	3 (0.1)
Race: White	961 (85.9)	943 (85.0)	1904 (85.5)
Race: Multiracial	24 (2.1)	29 (2.6)	53 (2.4)
Race: Not reported	6 (0.5)	7 (0.6)	13 (0.6)
Ethnicity: Hispanic or Latino	131 (11.7)	127 (11.5)	258 (11.6)
Ethnicity: Not Hispanic or Latino	986 (88.1)	979 (88.3)	1965 (88.2)
Ethnicity: Not reported	2 (0.2)	3 (0.3)	5 (0.2)
Obesity: Yes[c]	141 (12.6)	125 (11.3)	266 (11.9)
Obesity: No	978 (87.4)	984 (88.7)	1962 (88.1)
Comorbidities: Yes[d]	244 (21.8)	236 (21.3)	480 (21.5)

Table.G Demographics and Other Baseline Characteristics – Participants 12 Through 15 Years of Age With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=1119) n[b] (%)	Placebo (N[a]=1109) n[b] (%)	Total (N[a]=2228) n[b] (%)
Comorbidities: No	875 (78.2)	873 (78.7)	1748 (78.5)
Baseline evidence of prior SARS-CoV-2 infection: Negative[e]	1071 (95.7)	1059 (95.5)	2130 (95.6)
Baseline evidence of prior SARS-CoV-2 infection: Positive[f]	46 (4.1)	49 (4.4)	95 (4.3)
Baseline evidence of prior SARS-CoV-2 infection: Missing	2 (0.2)	1 (0.1)	3 (0.1)
Country: United States of America	1119 (100.0)	1109 (100.0)	2228 (100.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

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

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

c. Subjects who had a BMI at or above the 95th percentile from the CDC growth chart.

d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥95th percentile.

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

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

Table.H Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff March, 2021)

Endpoint	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]
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)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects 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 subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Table.I Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

Endpoint	BNT162b2 (N[a]=1057) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=1030) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First COVID-19 occurrence from 7 days after Dose 2 in subjects without evidence of prior SARS-CoV-2 infection	0 0.343 (1043)	28 0.322 (1019)	100.0 (86.8, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects 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 subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Table.J Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age With or Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

Endpoint	BNT162b2 (N[a]=1119) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=1109) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First COVID-19 occurrence from 7 days after Dose 2	0 0.362 (1098)	30 0.345 (1088)	100.0 (87.5, 100.0)

Abbreviations: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects 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 subjects at risk for the endpoint.

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

Figure A. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1, Participants 12 Through 15 Years of Age, Dose 1 All-Available Efficacy Population

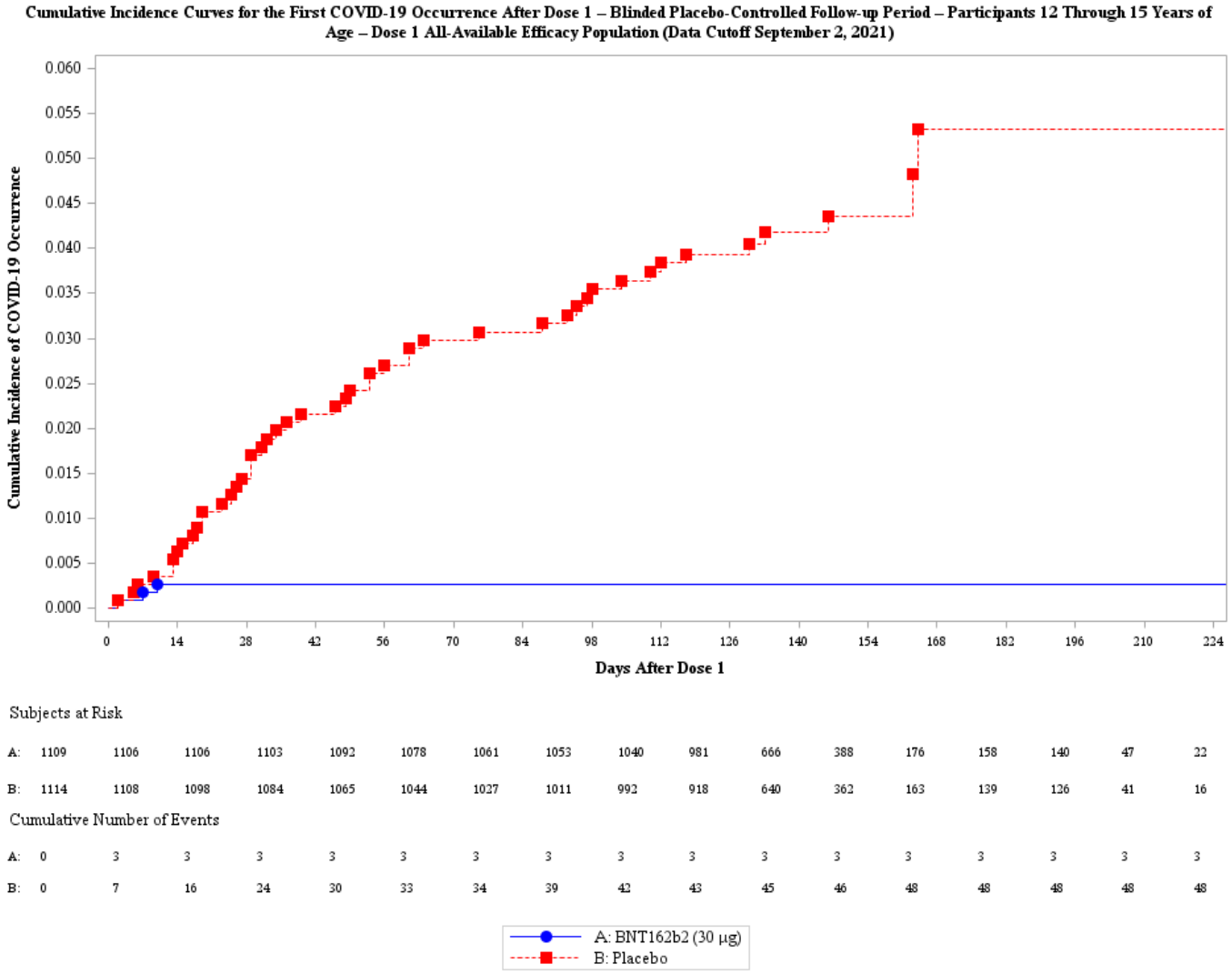

Table.K Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age – Dose 1 All-Available Efficacy Population (Data Cutoff September 2, 2021)

Efficacy Endpoint Subgroup	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 0.450 (1109)	48 0.434 (1114)	94.0 (81.3, 98.8)
After Dose 1 to before Dose 2	3 0.065 (1109)	12 0.065 (1114)	75.1 (7.6, 95.5)
Dose 2 to 7 days after Dose 2	0 0.021 (1103)	5 0.021 (1100)	100.0 (-8.7, 100.0)
≥7 Days after Dose 2	0 0.364 (1102)	31 0.348 (1095)	100.0 (87.9, 100.0)
≥7 days after Dose 2 to <2 Months after Dose 2	0 0.146 (1102)	17 0.143 (1095)	100.0 (76.3, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0 0.156 (1065)	10 0.149 (1029)	100.0 (57.3, 100.0)
≥4 Months after Dose 2 to <6 Months after Dose 2	0 0.053 (770)	4 0.049 (732)	100.0 (-40.7, 100.0)
≥6 Months after Dose 2	0	0	NE

Table.K Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age – Dose 1 All-Available Efficacy Population (Data Cutoff September 2, 2021)

Efficacy Endpoint Subgroup	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]
	0.009 (149)	0.007 (133)	

Abbreviation: VE = vaccine efficacy.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects 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 for the overall row and from start to the end of the range stated for each time interval.

d. n2 = Number of subjects at risk for the endpoint.

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

Table.L Subgroup Analyses of The Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age With or Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
Efficacy Endpoint Subgroup	**BNT162b2 (30 µg) (N[a]=1119) Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo (N[a]=1109) Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy (%) (95% CI[e])**
First COVID-19 occurrence from 7 days after Dose 2			
Overall	0 0.362 (1098)	30 0.345 (1088)	100.0 (87.5, 100.0)
Age group: 12 to 13 years	0 0.180 (521)	13 0.168 (503)	100.0 (69.3, 100.0)
Age group: 14 to 15 years	0 0.183 (577)	17 0.178 (585)	100.0 (76.5, 100.0)
At risk: Yes[f]	0 0.082 (241)	11 0.073 (228)	100.0 (64.6, 100.0)
At risk: No	0 0.280 (857)	19 0.273 (860)	100.0 (79.2, 100.0)
Obese: Yes[g]	0 0.048 (140)	7 0.039 (122)	100.0 (43.1, 100.0)
Obese: No	0	23	100.0

Table.L Subgroup Analyses of The Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age With or Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=1119) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Group (as Randomized) Placebo (N[a]=1109) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy (%) (95% CI[e])
	0.314 (958)	0.306 (966)	(83.1, 100.0)
Sex: Female	0 0.179 (548)	12 0.169 (527)	100.0 (66.1, 100.0)
Sex: Male	0 0.183 (550)	18 0.177 (561)	100.0 (78.0, 100.0)
Ethnicity: Hispanic or Latino	0 0.045 (127)	7 0.040 (125)	100.0 (37.8, 100.0)
Ethnicity: Not Hispanic or Latino	0 0.317 (969)	23 0.304 (960)	100.0 (83.3, 100.0)
Race: Black or African American	0 0.019 (47)	2 0.021 (56)	100.0 (-492.9, 100.0)
Race: White	0 0.309 (945)	28 0.291 (926)	100.0 (86.8, 100.0)
Baseline SARS-CoV-2 Status:Negative[i]	0	30	100.0

Table.L Subgroup Analyses of The Updated Vaccine Efficacy – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age With or Without Evidence of Prior SARS-CoV-2 Infection – Evaluable Efficacy Population (Data Cutoff September 2, 2021)

	Vaccine Group (as Randomized)		
Efficacy Endpoint Subgroup	**BNT162b2 (30 µg) (N[a]=1119) Cases n1[b] Surveillance Time[c] (n2[d])**	**Placebo (N[a]=1109) Cases n1[b] Surveillance Time[c] (n2[d])**	**Vaccine Efficacy (%) (95% CI[e])**
	0.347 (1051)	0.328 (1038)	(87.6, 100.0)
Country: United States	0 0.362 (1098)	30 0.345 (1088)	100.0 (87.5, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects 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 subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥95th percentile).
g. Subjects who had a BMI at or above the 95th percentile from the CDC growth chart.
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 and negative NAAT result at Visit 1 and no medical history of COVID-19.

Table.M Demographic Characteristics – Participants 12 Through 15 Years of Age With Protocol-Defined COVID-19 Without Evidence of Infection Prior to 7 Days After Dose 2 (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=0) n[b] (%)	Placebo (N[a]=28) n[b] (%)	Total (N[a]=28) n[b] (%)
Age at Vaccination: Mean years (SD)	- (-)	13.8 (1.08)	13.8 (1.08)
Age at Vaccination: Median (years)	-	14.0	14.0
Age Group: 12-13 years	0	12 (42.9)	12 (42.9)
Age Group: 14-15 years	0	16 (57.1)	16 (57.1)
Race: Black or African American	0	2 (7.1)	2 (7.1)
Race: White	0	26 (92.9)	26 (92.9)
Sex: Female	0	12 (42.9)	12 (42.9)
Sex: Male	0	16 (57.1)	16 (57.1)
Ethnicity: Hispanic or Latino	0	7 (25.0)	7 (25.0)
Ethnicity: Not Hispanic or Latino	0	21 (75.0)	21 (75.0)
Comorbidities: Yes[c]	0	9 (32.1)	9 (32.1)
Comorbidities: No	0	19 (67.9)	19 (67.9)
Obesity: Yes[d]	0	6 (21.4)	6 (21.4)
Obesity: No	0	22 (78.6)	22 (78.6)
Country: United States	0	28 (100.0)	28 (100.0)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of

Table.M Demographic Characteristics – Participants 12 Through 15 Years of Age With Protocol-Defined COVID-19 Without Evidence of Infection Prior to 7 Days After Dose 2 (Data Cutoff September 2, 2021)

Characteristic	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N^a=0) n^b (%)	Placebo (N^a=28) n^b (%)	Total (N^a=28) n^b (%)

the Charlson comorbidity index category or BMI ≥95th percentile.

d. Subjects who had a BMI at or above the 95th percentile from the CDC growth chart.

Table.N Updated Vaccine Efficacy Against Severe COVID-19, Participants Without Evidence of Prior SARS-CoV-2 Infection, Evaluable Efficacy Population

Pfizer Response: No Severe COVID-19 cases occurred in participants 12 through 15 years of age.

Table.O Updated Vaccine Efficacy Against First Occurrence of Severe COVID-19 After Dose 1, Dose 1 All-Available Efficacy Population

Pfizer Response: No Severe COVID-19 cases occurred in participants 12 through 15 years of age.

Table.P Safety Overview – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

	BNT162b2 (30 µg) n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination		
Dose1	0/1131 (0.0)	4/1129 (0.4)
Dose2	2/1124 (0.2)	3/1117 (0.3)
From Dose 1 through 1 month after Dose 2		
Any unsolicited AE	74/1131 (6.5)	77/1129 (6.8)
Unsolicited non-serious AE	72/1131 (6.4)	76/1129 (6.7)
SAE	4/1131 (0.4)	1/1129 (<0.1)
Withdrawal due to unsolicited AE	1/1131 (<0.1)	0/1129 (0.0)
Death	0/1131 (0.0)	0/1129 (0.0)
Dose 1 to Data Cutoff (September 2, 2021) or participant unblinding (whichever is earlier)		
Any unsolicited AE	95/1131 (8.4)	113/1129 (10.0)
Unsolicited non-serious AE	89/1131 (7.9)	111/1129 (9.8)
SAE	10/1131 (0.9)	2/1129 (0.2)
Withdrawal due to unsolicited AE	1/1131 (<0.1)	0/1129 (0.0)
Death	0/1131 (0.0)	0/1129 (0.0)

Note: MedDRA (v24.0) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.

Table.Q Unsolicited Adverse Events, Blinded Placebo-controlled Follow-up Period, Participants 12 Through 15 Years of Age and 16-25 Years of Age, Safety Population

Pfizer Response: Table Q data is reported in Table P.

Table.R Frequency of Solicited Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 12 Through 15 Years of Age – Reactogenicity Subset of the Safety Population

Pfizer Response: Please refer to EUA 12-15 508 document. No new e-diary data is reported.

Table.S Frequency of Solicited Systemic Reactions, by Maximum Severity, Within 7 Days After Each Dose – Participants 12 Through 15 Years of Age – Reactogenicity Subset of the Safety Population

Pfizer Response: Please refer to EUA 12-15 508 document. No new e-diary data is reported.

Table.T Frequency of Unsolicited Adverse Events Occurring in ≥1% of Participants in Any Treatment Group From Dose 1 to 1 Month After Dose 2, Safety Population

Pfizer Response: No unsolicited adverse events are reported occurring in ≥1% of participants 12 through 15 years of age from dose 1 to 1 month after dose 2.

Table.U Frequency of Unsolicited Adverse Events Occurring in ≥1% of Participants in Any Treatment Group From Dose 1 to Data Cutoff or Date of Unblinding (Whichever is Earlier), Safety Population

Pfizer Response: No unsolicited adverse events are reported occurring in ≥1% of participants 12 through 15 years of age from dose 1 to data cutoff or date of unblinding.

Table.V Frequency of Unsolicited Adverse Events Occurring in ≥1% of Participants in Any Treatment Group From Date of Unblinding to Data Cutoff Date, Safety Population

Pfizer Response: No unsolicited adverse events are reported occurring in ≥1% of participants 12 through 15 years of age from date of unblinding to data cutoff date.

Table.W Frequency of Unsolicited AEs with Occurrence in ≥1% From Dose 1 to 6 Months After Dose 2, Participants Who Originally Received BNT162b2 With at Least 6 Months of Follow-up Time, Safety Population

Pfizer Response: No unsolicited adverse events are reported occurring in ≥1% of participants 12 through 15 years of age and who originally received BNT162b2 with at least 6 months of follow-up time.

Table.X Frequency of Unsolicited AEs with Occurrence in ≥1% of Participants From Dose 3 to Cutoff Date (September 2, 2021) – Open-Label Follow-up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Participants 12 Through 15 Years of Age – Safety Population

	BNT162b2 (30 µg) (N=1010)	
SYSTEM ORGAN CLASS and Preferred Term	**Any n (%)**	**Severe n (%)**
GASTROINTESTINAL DISORDERS		
Nausea	12(1.2)	0 (0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
Chills	45(4.5)	0 (0.0)
Fatigue	104(10.3)	2 (0.2)
Injection site pain	157(15.5)	0 (0.0)
Pain	35(3.5)	0 (0.0)
Pyrexia	64(6.3)	3 (0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Myalgia	38(3.8)	1 (0.1)
NERVOUS SYSTEM DISORDERS		
Headache	71(7.0)	0 (0.0)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
MedDRA v24.0 coding dictionary applied.

Table.Y Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=1131)	Placebo (N[a]=1129)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Subjects with any unsolicited adverse events within SMQ	8 (0.71)	12 (1.06)
Angioedema (SMQ)	Any unsolicited adverse events within Angioedema (SMQ)	3 (0.27)	5 (0.44)
	Gastrointestinal disorders	1 (0.09)	0
	Lip swelling	1 (0.09)	0
	Mouth swelling	1 (0.09)	0
	Skin and subcutaneous tissue disorders	2 (0.18)	5 (0.44)
	Urticaria	2 (0.18)	5 (0.44)
Hypersensitivity (SMQ)	Any unsolicited adverse events within Hypersensitivity (SMQ)	8 (0.71)	12 (1.06)
	Gastrointestinal disorders	1 (0.09)	0
	Lip swelling	1 (0.09)	0
	Mouth swelling	1 (0.09)	0
	Skin and subcutaneous tissue disorders	7 (0.62)	12 (1.06)
	Dermatitis contact	2 (0.18)	1 (0.09)
	Eczema	0	1 (0.09)
	Rash	3 (0.27)	5 (0.44)
	Rash maculo-papular	0	1 (0.09)
	Urticaria	2 (0.18)	5 (0.44)

Table.Y Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=1131)	Placebo (N[a]=1129)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)

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

Table.Z SAEs considered related by Investigator – Phase 2/3 – Participants 12 Through 15 Years of Age – Safety Population (Data Cutoff September 2, 2021)

Product (Vaccine or Placebo)	SAE	Dose/Rel Day[a]	Demographics: Age/Sex/Risk Factors from Charlson Index	Resolution	Related per Investigator
Placebo crossover to BNT162b2	Appendicitis	4*/4#	12 F; no relevant medical history	Resolved	Yes

Note: MedDRA (v24.0) coding dictionary applied.
Note: # = SAE occurring on or after unblinding.
Note: * indicates Dose 3 = first dose of BNT162b2 (30 μg), Dose 4 = second dose of BNT162b2 (30 μg).
a. Relative day (Rel Day) = date of SAE - date of last vaccination + 1.