

Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population.....	4
Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	7
Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population.....	10
Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population.....	13
Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age.....	16
Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	18
Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population .....	61
Immunogenicity Blood Samples Drawn – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset).....	62
Vaccine as Administered, by Vaccine Group – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) .....	63
Vaccine Administration Timing – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset).....	64
Concomitant Vaccines Received From After Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	65
E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	66
Immunogenicity Populations – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) .....	68
Safety Population – Subjects 12 Through 15 and 16 Through 25 Years of Age .....	69
Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	70
Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	74
Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	76
Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	79
Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	88
Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	94

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	100
Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), Subjects 12 Through 15 Years of Age – Safety Population .....	102
Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	103
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	113
Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	115
Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	119
Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	121
Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population.....	122
Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	124
Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	125
Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population .....	127
Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population .....	133
Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population.....	134
Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population.....	136
Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population.....	138

Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population .....	139
Summary of Geometric Mean Ratio – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population .....	140
Number (%) of Subjects Achieving a $\geq 4$ -Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population .....	141
Number (%) of Subjects Achieving a $\geq 4$ -Fold Rise From Before Vaccination to Each Subsequent Time Point 1 Month After Dose 2 – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population .....	142
Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population .....	143
Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population .....	144
Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Subjects 12 Through 15 Years of Age – Dose 1 All-Available Efficacy Population .....	145
Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population .....	146
Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	147
Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population .....	148
Geometric Mean Titers and 95% CIs: SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population .....	149

<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1867) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1903) n<sup>b</sup> (%)</b>
Sex				
Male	567 (50.1)	921 (49.3)	585 (51.8)	882 (46.3)
Female	564 (49.9)	946 (50.7)	544 (48.2)	1021 (53.7)
Race				
White	971 (85.9)	1443 (77.3)	962 (85.2)	1510 (79.3)
Black or African American	52 (4.6)	189 (10.1)	57 (5.0)	179 (9.4)
American Indian or Alaska Native	4 (0.4)	32 (1.7)	3 (0.3)	18 (0.9)
Asian	72 (6.4)	108 (5.8)	71 (6.3)	108 (5.7)
Native Hawaiian or other Pacific Islander	3 (0.3)	10 (0.5)	0	3 (0.2)
Multiracial	23 (2.0)	76 (4.1)	29 (2.6)	74 (3.9)
Not reported	6 (0.5)	9 (0.5)	7 (0.6)	11 (0.6)
Racial designation				
Japanese	5 (0.4)	3 (0.2)	2 (0.2)	6 (0.3)
Ethnicity				
Hispanic/Latino	132 (11.7)	604 (32.4)	130 (11.5)	575 (30.2)
Non-Hispanic/non-Latino	997 (88.2)	1259 (67.4)	996 (88.2)	1322 (69.5)
Not reported	2 (0.2)	4 (0.2)	3 (0.3)	6 (0.3)
Country				
Argentina	0	282 (15.1)	0	287 (15.1)



<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1867) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1903) n<sup>b</sup> (%)</b>
Brazil	0	160 (8.6)	0	142 (7.5)
Germany	0	11 (0.6)	0	20 (1.1)
South Africa	0	69 (3.7)	0	75 (3.9)
Turkey	0	12 (0.6)	0	15 (0.8)
USA	1131 (100.0)	1333 (71.4)	1129 (100.0)	1364 (71.7)
Age at vaccination (years)				
Mean (SD)	13.6 (1.11)	21.0 (2.99)	13.6 (1.11)	21.0 (2.98)
Median	14.0	22.0	14.0	21.0
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive <sup>c</sup>	46 (4.1)	100 (5.4)	47 (4.2)	104 (5.5)
Negative <sup>d</sup>	1028 (90.9)	1754 (93.9)	1023 (90.6)	1789 (94.0)
Missing	57 (5.0)	13 (0.7)	59 (5.2)	10 (0.5)
Body mass index (BMI) Obese <sup>e</sup>				
Yes	143 (12.6)	353 (18.9)	128 (11.3)	385 (20.2)
No	988 (87.4)	1514 (81.1)	1001 (88.7)	1518 (79.8)
Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.				
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.				
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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.				

Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age – Safety Population				
Vaccine Group (as Administered)				
BNT162b2 (30 µg)		Placebo		
12-15 Years (N <sup>a</sup> =1131) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =1867) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =1129) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =1903) n <sup>b</sup> (%)	
<p>d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.</p> <p>e. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at <a href="https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm">https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm</a>. For 16 through 25 years age group, obesity is defined as BMI ≥ 30.0 kg/m<sup>2</sup>.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 01APR2021 (22:23) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adsl_s005_demo_ped_saf</p>				

<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=537) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=561) n<sup>b</sup> (%)</b>
Sex				
Male	567 (50.1)	255 (47.5)	585 (51.8)	269 (48.0)
Female	564 (49.9)	282 (52.5)	544 (48.2)	292 (52.0)
Race				
White	971 (85.9)	445 (82.9)	962 (85.2)	466 (83.1)
Black or African American	52 (4.6)	47 (8.8)	57 (5.0)	50 (8.9)
American Indian or Alaska Native	4 (0.4)	7 (1.3)	3 (0.3)	1 (0.2)
Asian	72 (6.4)	22 (4.1)	71 (6.3)	21 (3.7)
Native Hawaiian or other Pacific Islander	3 (0.3)	3 (0.6)	0	1 (0.2)
Multiracial	23 (2.0)	12 (2.2)	29 (2.6)	19 (3.4)
Not reported	6 (0.5)	1 (0.2)	7 (0.6)	3 (0.5)
Racial designation				
Japanese	5 (0.4)	0	2 (0.2)	0
Ethnicity				
Hispanic/Latino	132 (11.7)	112 (20.9)	130 (11.5)	105 (18.7)
Non-Hispanic/non-Latino	997 (88.2)	423 (78.8)	996 (88.2)	456 (81.3)
Not reported	2 (0.2)	2 (0.4)	3 (0.3)	0
Country				

<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=537) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=561) n<sup>b</sup> (%)</b>
Argentina	0	20 (3.7)	0	28 (5.0)
Brazil	0	24 (4.5)	0	19 (3.4)
Germany	0	11 (2.0)	0	20 (3.6)
South Africa	0	34 (6.3)	0	45 (8.0)
Turkey	0	12 (2.2)	0	15 (2.7)
USA	1131 (100.0)	436 (81.2)	1129 (100.0)	434 (77.4)
Age at vaccination (years)				
Mean (SD)	13.6 (1.11)	19.4 (3.26)	13.6 (1.11)	19.6 (3.33)
Median	14.0	18.0	14.0	19.0
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive <sup>c</sup>	46 (4.1)	30 (5.6)	47 (4.2)	34 (6.1)
Negative <sup>d</sup>	1028 (90.9)	497 (92.6)	1023 (90.6)	522 (93.0)
Missing	57 (5.0)	10 (1.9)	59 (5.2)	5 (0.9)
Body mass index (BMI) Obese <sup>e</sup>				
Yes	143 (12.6)	80 (14.9)	128 (11.3)	101 (18.0)
No	988 (87.4)	457 (85.1)	1001 (88.7)	460 (82.0)
Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.				
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.				

**Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

Vaccine Group (as Administered)			
BNT162b2 (30 µg)		Placebo	
12-15 Years (N <sup>a</sup> =1131) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =537) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =1129) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =561) n <sup>b</sup> (%)

- 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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
- d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
- e. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at [https://www.cdc.gov/growthcharts/html\\_charts/bmiagerev.htm](https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm). For 16 through 25 years age group, obesity is defined as BMI ≥ 30.0 kg/m<sup>2</sup>.
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<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population</b>				
	<b>Vaccine Group (as Randomized)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=209) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=186) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=36) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=32) n<sup>b</sup> (%)</b>
Sex				
Male	106 (50.7)	92 (49.5)	21 (58.3)	14 (43.8)
Female	103 (49.3)	94 (50.5)	15 (41.7)	18 (56.3)
Race				
White	184 (88.0)	147 (79.0)	31 (86.1)	28 (87.5)
Black or African American	16 (7.7)	15 (8.1)	3 (8.3)	2 (6.3)
American Indian or Alaska Native	1 (0.5)	3 (1.6)	0	1 (3.1)
Asian	5 (2.4)	10 (5.4)	1 (2.8)	1 (3.1)
Native Hawaiian or other Pacific Islander	0	3 (1.6)	0	0
Multiracial	3 (1.4)	6 (3.2)	1 (2.8)	0
Not reported	0	2 (1.1)	0	0
Racial designation				
Japanese	1 (0.5)	0	0	0
Ethnicity				
Hispanic/Latino	22 (10.5)	31 (16.7)	2 (5.6)	7 (21.9)
Non-Hispanic/non-Latino	187 (89.5)	154 (82.8)	34 (94.4)	25 (78.1)
Not reported	0	1 (0.5)	0	0
Country				

<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population</b>				
	<b>Vaccine Group (as Randomized)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=209) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=186) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=36) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=32) n<sup>b</sup> (%)</b>
USA	209 (100.0)	186 (100.0)	36 (100.0)	32 (100.0)
Age at vaccination (years)				
Mean (SD)	13.5 (1.12)	20.6 (3.09)	13.4 (1.17)	20.3 (3.05)
Median	14.0	21.0	13.0	19.5
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive <sup>c</sup>	10 (4.8)	8 (4.3)	2 (5.6)	1 (3.1)
Negative <sup>d</sup>	194 (92.8)	178 (95.7)	33 (91.7)	31 (96.9)
Missing	5 (2.4)	0	1 (2.8)	0
Body mass index (BMI) Obese <sup>e</sup>				
Yes	24 (11.5)	43 (23.1)	3 (8.3)	4 (12.5)
No	185 (88.5)	143 (76.9)	33 (91.7)	28 (87.5)
Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.				
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.				
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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.				
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.				
e. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at <a href="https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm">https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm</a> . For 16 through 25 years age group, obesity is defined as BMI ≥ 30.0 kg/m <sup>2</sup> .				
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Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population			
Vaccine Group (as Randomized)			
BNT162b2 (30 µg)		Placebo	
12-15 Years (N <sup>a</sup> =209) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =186) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =36) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =32) n <sup>b</sup> (%)
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<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=210) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=191) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=36) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=34) n<sup>b</sup> (%)</b>
Sex				
Male	107 (51.0)	93 (48.7)	21 (58.3)	14 (41.2)
Female	103 (49.0)	98 (51.3)	15 (41.7)	20 (58.8)
Race				
White	185 (88.1)	151 (79.1)	31 (86.1)	30 (88.2)
Black or African American	16 (7.6)	15 (7.9)	3 (8.3)	2 (5.9)
American Indian or Alaska Native	1 (0.5)	3 (1.6)	0	1 (2.9)
Asian	5 (2.4)	10 (5.2)	1 (2.8)	1 (2.9)
Native Hawaiian or other Pacific Islander	0	4 (2.1)	0	0
Multiracial	3 (1.4)	6 (3.1)	1 (2.8)	0
Not reported	0	2 (1.0)	0	0
Racial designation				
Japanese	1 (0.5)	0	0	0
Ethnicity				
Hispanic/Latino	22 (10.5)	31 (16.2)	2 (5.6)	7 (20.6)
Non-Hispanic/non-Latino	188 (89.5)	159 (83.2)	34 (94.4)	27 (79.4)
Not reported	0	1 (0.5)	0	0
Country				

<b>Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=210) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=191) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=36) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=34) n<sup>b</sup> (%)</b>
USA	210 (100.0)	191 (100.0)	36 (100.0)	34 (100.0)
Age at vaccination (years)				
Mean (SD)	13.5 (1.12)	20.7 (3.08)	13.4 (1.17)	20.5 (3.06)
Median	14.0	21.0	13.0	20.5
Min, max	(12, 15)	(16, 25)	(12, 15)	(16, 25)
Baseline SARS-CoV-2 status				
Positive <sup>c</sup>	10 (4.8)	8 (4.2)	2 (5.6)	1 (2.9)
Negative <sup>d</sup>	195 (92.9)	183 (95.8)	33 (91.7)	33 (97.1)
Missing	5 (2.4)	0	1 (2.8)	0
Body mass index (BMI) Obese <sup>e</sup>				
Yes	24 (11.4)	43 (22.5)	3 (8.3)	5 (14.7)
No	186 (88.6)	148 (77.5)	33 (91.7)	29 (85.3)
Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.				
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.				
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. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.				
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.				
e. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at <a href="https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm">https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm</a> . For 16 through 25 years age group, obesity is defined as BMI ≥ 30.0 kg/m <sup>2</sup> .				
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 01APR2021 (23:43)				

Demographic Characteristics – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population			
Vaccine Group (as Administered)			
BNT162b2 (30 µg)		Placebo	
12-15 Years (N <sup>a</sup> =210) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =191) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =36) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =34) n <sup>b</sup> (%)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adsl_s005_demo_ped_d2_aai			

<b>Disposition of All Randomized Subjects Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age</b>				
	<b>Vaccine Group (as Randomized)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1134) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1875) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1130) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=1913) n<sup>b</sup> (%)</b>
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				
Dose 1	1131 (99.7)	1869 (99.7)	1129 (99.9)	1906 (99.6)
Dose 2	1124 (99.1)	1826 (97.4)	1117 (98.8)	1836 (96.0)
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 the study before 1-month post–Dose 2 visit	0	45 (2.4)	2 (0.2)	56 (2.9)

**Disposition of All Randomized Subjects Through 1 Month After Dose 2 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age**

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =1134) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =1875) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =1130) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =1913) n <sup>b</sup> (%)
Withdrawn after Dose 1 and before Dose 2	0	25 (1.3)	1 (0.1)	34 (1.8)
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 from the study				
Lost to follow-up	0	29 (1.5)	0	32 (1.7)
Withdrawal by subject	0	14 (0.7)	0	19 (1.0)
Protocol deviation	0	0	1 (0.1)	1 (0.1)
Withdrawal by parent/guardian	0	1 (0.1)	1 (0.1)	0
Adverse event	0	0	0	1 (0.1)
Physician decision	0	0	0	1 (0.1)
Other	0	1 (0.1)	0	2 (0.1)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.  
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.

a. N = number of randomized subjects in the specified group. This value is the denominator for the percentage calculations.

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (06:06)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adds\_s002\_ped\_rand

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Any medical history	848 (75.0)	373 (69.5)	826 (73.2)	381 (67.9)
Blood and lymphatic system disorders	2 (0.2)	7 (1.3)	8 (0.7)	7 (1.2)
Anaemia	0	5 (0.9)	1 (0.1)	5 (0.9)
Antiphospholipid syndrome	0	0	0	1 (0.2)
Immune thrombocytopenia	2 (0.2)	0	1 (0.1)	0
Iron deficiency anaemia	0	2 (0.4)	3 (0.3)	1 (0.2)
Lymphadenopathy	0	0	2 (0.2)	0
Thrombocytopenia	0	0	1 (0.1)	0
Cardiac disorders	5 (0.4)	6 (1.1)	3 (0.3)	6 (1.1)
Aortic valve disease	2 (0.2)	0	0	0
Arrhythmia	1 (0.1)	0	0	0
Bradycardia neonatal	0	0	0	1 (0.2)
Cardiomyopathy	0	0	0	1 (0.2)
Palpitations	0	1 (0.2)	0	2 (0.4)
Pericarditis	0	1 (0.2)	0	0
Postural orthostatic tachycardia syndrome	1 (0.1)	0	1 (0.1)	0
Pulmonary valve stenosis	1 (0.1)	0	0	0
Sinus arrhythmia	0	0	0	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Sinus tachycardia	0	2 (0.4)	0	0
Supraventricular tachycardia	0	0	1 (0.1)	1 (0.2)
Tachycardia	0	1 (0.2)	0	0
Ventricular extrasystoles	0	0	1 (0.1)	0
Wolff-Parkinson-White syndrome	0	1 (0.2)	0	0
Congenital, familial and genetic disorders	28 (2.5)	17 (3.2)	44 (3.9)	10 (1.8)
Adenomatous polyposis coli	0	0	1 (0.1)	0
Albinism	0	1 (0.2)	0	0
Anal atresia	0	1 (0.2)	0	0
Ankyloglossia congenital	0	0	1 (0.1)	0
Anorectal malformation	0	0	1 (0.1)	0
Arnold-Chiari malformation	0	1 (0.2)	0	1 (0.2)
Atrial septal defect	1 (0.1)	0	2 (0.2)	0
Bicuspid aortic valve	2 (0.2)	0	2 (0.2)	0
Birth mark	0	0	2 (0.2)	0
Cataract congenital	0	1 (0.2)	0	0
Cerebral cavernous malformation	0	0	1 (0.1)	0
Cerebral palsy	0	0	1 (0.1)	0
Chondrodystrophy	1 (0.1)	0	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Cleft lip and palate	1 (0.1)	0	0	0
Cleft palate	1 (0.1)	0	1 (0.1)	0
Colour blindness	1 (0.1)	1 (0.2)	0	0
Congenital anomaly	1 (0.1)	0	0	0
Congenital diaphragmatic hernia	1 (0.1)	0	0	0
Congenital flat feet	1 (0.1)	2 (0.4)	0	0
Congenital megacolon	0	0	1 (0.1)	0
Congenital nystagmus	2 (0.2)	0	0	0
Congenital skin dimples	0	0	1 (0.1)	0
Cryptorchism	1 (0.1)	0	0	0
Cystic fibrosis	0	0	2 (0.2)	0
Developmental hip dysplasia	0	0	1 (0.1)	2 (0.4)
Ehlers-Danlos syndrome	0	0	1 (0.1)	1 (0.2)
Factor V Leiden carrier	1 (0.1)	0	1 (0.1)	0
Factor V Leiden mutation	0	0	1 (0.1)	1 (0.2)
Factor VII deficiency	0	0	0	1 (0.2)
Fallot's tetralogy	0	1 (0.2)	0	0
Familial mediterranean fever	0	1 (0.2)	0	0
Femoral anteversion	0	1 (0.2)	0	0
Gilbert's syndrome	0	0	1 (0.1)	0



<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Haemoglobinopathy	0	1 (0.2)	0	0
Hemivertebra	0	0	1 (0.1)	0
Hereditary motor and sensory neuropathy	0	0	1 (0.1)	0
Hereditary spherocytosis	0	0	1 (0.1)	0
Hypoplastic left heart syndrome	0	0	1 (0.1)	0
Hypospadias	0	1 (0.2)	1 (0.1)	1 (0.2)
Imperforate hymen	0	0	1 (0.1)	0
Malformation venous	1 (0.1)	0	0	0
Metabolic myopathy	1 (0.1)	0	0	0
Multiple epiphyseal dysplasia	0	0	1 (0.1)	0
Muscular dystrophy	0	1 (0.2)	0	0
Naevus flammeus	0	0	1 (0.1)	0
Neurofibromatosis	0	0	2 (0.2)	1 (0.2)
Oculoauriculovertebral dysplasia	0	0	1 (0.1)	0
Otospondylomegaepiphyseal dysplasia	1 (0.1)	0	0	0
Pectus carinatum	0	0	1 (0.1)	0
Pectus excavatum	2 (0.2)	0	1 (0.1)	0
Phimosi	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Renal dysplasia	0	0	1 (0.1)	0
Sickle cell anaemia	1 (0.1)	0	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Sickle cell trait	0	0	3 (0.3)	0
Spina bifida occulta	1 (0.1)	0	0	0
Strabismus congenital	1 (0.1)	0	0	0
Talipes	1 (0.1)	0	0	0
Thalassaemia beta	2 (0.2)	0	0	0
Thalassaemia minor	0	0	1 (0.1)	0
Thyroglossal cyst	1 (0.1)	0	0	0
Tourette's disorder	2 (0.2)	2 (0.4)	2 (0.2)	0
Transposition of the great vessels	0	0	1 (0.1)	0
Urethral valves	0	1 (0.2)	0	0
Ventricular septal defect	0	1 (0.2)	1 (0.1)	0
Vitello-intestinal duct remnant	0	0	0	1 (0.2)
Von Willebrand's disease	1 (0.1)	0	2 (0.2)	0
Ear and labyrinth disorders	11 (1.0)	4 (0.7)	10 (0.9)	1 (0.2)
Auditory disorder	1 (0.1)	0	0	0
Deafness	2 (0.2)	1 (0.2)	0	0
Deafness bilateral	1 (0.1)	0	0	1 (0.2)
Deafness unilateral	1 (0.1)	0	1 (0.1)	0
Ear pain	0	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Eustachian tube disorder	1 (0.1)	0	0	0
Eustachian tube dysfunction	2 (0.2)	0	0	0
Hypoacusis	1 (0.1)	1 (0.2)	2 (0.2)	0
Meniere's disease	0	1 (0.2)	0	0
Middle ear adhesions	0	0	1 (0.1)	0
Motion sickness	0	1 (0.2)	1 (0.1)	0
Tinnitus	1 (0.1)	0	2 (0.2)	0
Tympanic membrane perforation	1 (0.1)	0	1 (0.1)	0
Vestibular disorder	0	0	1 (0.1)	0
Endocrine disorders	7 (0.6)	7 (1.3)	7 (0.6)	14 (2.5)
Autoimmune thyroiditis	0	1 (0.2)	1 (0.1)	1 (0.2)
Growth hormone deficiency	1 (0.1)	0	3 (0.3)	2 (0.4)
Hyperprolactinaemia	0	0	0	1 (0.2)
Hyperthyroidism	0	1 (0.2)	0	1 (0.2)
Hypopituitarism	1 (0.1)	0	0	0
Hypothyroidism	3 (0.3)	4 (0.7)	1 (0.1)	10 (1.8)
Precocious puberty	2 (0.2)	0	2 (0.2)	0
Thyroid mass	0	1 (0.2)	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Eye disorders	46 (4.1)	28 (5.2)	59 (5.2)	33 (5.9)
Amblyopia	1 (0.1)	0	2 (0.2)	0
Amblyopia strabismic	1 (0.1)	0	0	0
Anisometropia	1 (0.1)	0	0	0
Astigmatism	1 (0.1)	1 (0.2)	6 (0.5)	3 (0.5)
Blepharitis	2 (0.2)	0	0	0
Blindness	0	1 (0.2)	0	0
Blindness unilateral	0	0	1 (0.1)	0
Borderline glaucoma	0	0	0	1 (0.2)
Cataract	1 (0.1)	0	0	0
Chalazion	0	0	1 (0.1)	0
Conjunctivitis allergic	1 (0.1)	0	0	0
Dacryostenosis acquired	0	0	1 (0.1)	0
Dry eye	0	1 (0.2)	0	0
Eyelid ptosis	1 (0.1)	0	0	1 (0.2)
Hypermetropia	5 (0.4)	4 (0.7)	7 (0.6)	4 (0.7)
Iridodialysis	0	0	0	1 (0.2)
Iritis	0	0	0	1 (0.2)
Myopia	20 (1.8)	17 (3.2)	27 (2.4)	20 (3.6)
Optic atrophy	0	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Optic nerve cupping	0	0	1 (0.1)	0
Presbyopia	1 (0.1)	2 (0.4)	0	1 (0.2)
Punctate keratitis	1 (0.1)	0	0	0
Pupils unequal	0	0	1 (0.1)	0
Recession of chamber angle of eye	0	0	1 (0.1)	0
Refraction disorder	0	0	0	2 (0.4)
Refractive amblyopia	0	0	1 (0.1)	0
Retinoschisis	0	0	0	1 (0.2)
Strabismus	4 (0.4)	2 (0.4)	4 (0.4)	0
Visual acuity reduced	8 (0.7)	1 (0.2)	12 (1.1)	2 (0.4)
Gastrointestinal disorders	42 (3.7)	41 (7.6)	40 (3.5)	36 (6.4)
Abdominal hernia	1 (0.1)	1 (0.2)	0	0
Abdominal migraine	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Abdominal pain	1 (0.1)	0	2 (0.2)	0
Abdominal pain lower	0	1 (0.2)	0	0
Abdominal pain upper	1 (0.1)	2 (0.4)	1 (0.1)	0
Aphthous ulcer	0	1 (0.2)	0	0
Chronic gastritis	0	1 (0.2)	0	0
Coeliac disease	4 (0.4)	1 (0.2)	4 (0.4)	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Colitis ulcerative	0	1 (0.2)	0	1 (0.2)
Constipation	9 (0.8)	3 (0.6)	11 (1.0)	2 (0.4)
Crohn's disease	0	0	0	1 (0.2)
Cyclic vomiting syndrome	1 (0.1)	0	0	0
Diaphragmatic hernia	0	2 (0.4)	0	0
Diarrhoea	1 (0.1)	0	2 (0.2)	1 (0.2)
Dyspepsia	3 (0.3)	3 (0.6)	0	4 (0.7)
Dysphagia	0	0	1 (0.1)	0
Enterocolitis	1 (0.1)	0	0	0
Eosinophilic oesophagitis	1 (0.1)	0	3 (0.3)	1 (0.2)
Flatulence	0	0	0	1 (0.2)
Food poisoning	0	0	0	1 (0.2)
Gastritis	0	1 (0.2)	0	0
Gastroesophageal reflux disease	12 (1.1)	15 (2.8)	13 (1.2)	10 (1.8)
Gingival discomfort	0	0	0	1 (0.2)
Haemorrhoids	0	1 (0.2)	0	0
Hiatus hernia	0	1 (0.2)	1 (0.1)	0
Inguinal hernia	1 (0.1)	0	1 (0.1)	2 (0.4)
Intussusception	2 (0.2)	0	0	0
Irritable bowel syndrome	2 (0.2)	5 (0.9)	2 (0.2)	5 (0.9)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Malabsorption	1 (0.1)	0	0	0
Oesophagitis	1 (0.1)	0	0	1 (0.2)
Pancreatitis	0	0	0	1 (0.2)
Rectal prolapse	0	0	0	1 (0.2)
Salivary gland disorder	0	0	0	1 (0.2)
Short-bowel syndrome	0	1 (0.2)	0	0
Tooth impacted	0	2 (0.4)	0	3 (0.5)
Toothache	0	0	1 (0.1)	1 (0.2)
Umbilical hernia	2 (0.2)	2 (0.4)	3 (0.3)	1 (0.2)
Volvulus	0	1 (0.2)	0	0
General disorders and administration site conditions	10 (0.9)	5 (0.9)	10 (0.9)	3 (0.5)
Adverse food reaction	1 (0.1)	0	0	0
Cyst	1 (0.1)	0	1 (0.1)	1 (0.2)
Developmental delay	0	0	2 (0.2)	0
Drug intolerance	1 (0.1)	1 (0.2)	2 (0.2)	0
Fatigue	0	0	0	1 (0.2)
Hernia	0	1 (0.2)	0	0
Medical device pain	1 (0.1)	0	1 (0.1)	0
Pain	5 (0.4)	1 (0.2)	3 (0.3)	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Peripheral swelling	1 (0.1)	1 (0.2)	0	0
Pyrexia	0	1 (0.2)	1 (0.1)	0
Hepatobiliary disorders	4 (0.4)	1 (0.2)	0	5 (0.9)
Cholelithiasis	2 (0.2)	0	0	4 (0.7)
Cholelithiasis obstructive	0	1 (0.2)	0	0
Hepatic steatosis	1 (0.1)	0	0	1 (0.2)
Non-alcoholic steatohepatitis	1 (0.1)	0	0	0
Immune system disorders	398 (35.2)	137 (25.5)	386 (34.2)	139 (24.8)
Allergy to animal	24 (2.1)	4 (0.7)	19 (1.7)	6 (1.1)
Allergy to arthropod bite	1 (0.1)	0	2 (0.2)	0
Allergy to arthropod sting	2 (0.2)	1 (0.2)	4 (0.4)	1 (0.2)
Allergy to chemicals	1 (0.1)	0	0	1 (0.2)
Allergy to metals	0	0	2 (0.2)	0
Allergy to plants	4 (0.4)	0	2 (0.2)	0
Anaphylactic reaction	1 (0.1)	0	0	0
Cockroach allergy	1 (0.1)	0	1 (0.1)	0
Drug hypersensitivity	129 (11.4)	37 (6.9)	97 (8.6)	47 (8.4)
Dust allergy	0	0	0	2 (0.4)



<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Flour sensitivity	0	0	0	1 (0.2)
Food allergy	31 (2.7)	15 (2.8)	39 (3.5)	11 (2.0)
Hypersensitivity	22 (1.9)	7 (1.3)	15 (1.3)	6 (1.1)
Milk allergy	3 (0.3)	0	5 (0.4)	1 (0.2)
Mite allergy	1 (0.1)	1 (0.2)	4 (0.4)	0
Multiple allergies	0	0	1 (0.1)	0
Mycotic allergy	0	0	1 (0.1)	0
Oral allergy syndrome	0	0	4 (0.4)	0
Perennial allergy	2 (0.2)	0	3 (0.3)	0
Perfume sensitivity	1 (0.1)	0	0	0
Reaction to colouring	1 (0.1)	0	0	1 (0.2)
Reaction to food additive	0	0	1 (0.1)	0
Rubber sensitivity	6 (0.5)	1 (0.2)	5 (0.4)	3 (0.5)
Seasonal allergy	240 (21.2)	90 (16.8)	244 (21.6)	83 (14.8)
Selective IgA immunodeficiency	0	0	1 (0.1)	0
Serum sickness	1 (0.1)	0	0	0
Infections and infestations	72 (6.4)	39 (7.3)	52 (4.6)	36 (6.4)
Abscess limb	0	0	1 (0.1)	0
Adenoiditis	11 (1.0)	0	6 (0.5)	1 (0.2)

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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Appendicitis	6 (0.5)	4 (0.7)	9 (0.8)	1 (0.2)
Bacterial vaginosis	0	0	0	1 (0.2)
Bacterial vulvovaginitis	0	1 (0.2)	0	0
Body tinea	1 (0.1)	0	0	0
Cellulitis	1 (0.1)	1 (0.2)	0	1 (0.2)
Chlamydial infection	0	1 (0.2)	0	1 (0.2)
Cholecystitis infective	0	0	0	1 (0.2)
Chronic sinusitis	2 (0.2)	2 (0.4)	1 (0.1)	0
Chronic tonsillitis	2 (0.2)	1 (0.2)	3 (0.3)	0
Conjunctivitis	1 (0.1)	0	1 (0.1)	0
Croup infectious	1 (0.1)	0	1 (0.1)	0
Dermatophytosis of nail	1 (0.1)	0	0	0
Ear infection	12 (1.1)	3 (0.6)	8 (0.7)	3 (0.5)
Escherichia infection	0	0	0	1 (0.2)
Folliculitis	0	1 (0.2)	0	2 (0.4)
Gastrointestinal viral infection	1 (0.1)	0	0	0
Genital herpes	0	0	0	1 (0.2)
Gingivitis	0	0	0	1 (0.2)
Herpes simplex	1 (0.1)	2 (0.4)	0	2 (0.4)
Herpes virus infection	0	1 (0.2)	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Histoplasmosis	1 (0.1)	0	0	0
Impetigo	1 (0.1)	0	0	0
Infectious mononucleosis	0	1 (0.2)	1 (0.1)	1 (0.2)
Kidney infection	1 (0.1)	0	0	1 (0.2)
Labyrinthitis	0	1 (0.2)	0	0
Lyme disease	2 (0.2)	1 (0.2)	0	0
Mastitis	0	0	0	1 (0.2)
Mastoiditis	0	0	0	1 (0.2)
Meningitis	1 (0.1)	0	0	0
Meningitis viral	1 (0.1)	0	0	0
Molluscum contagiosum	0	0	1 (0.1)	0
Nail infection	1 (0.1)	0	0	0
Oral herpes	1 (0.1)	3 (0.6)	0	3 (0.5)
Osteomyelitis	2 (0.2)	0	0	0
Otitis externa	0	0	0	1 (0.2)
Otitis media	3 (0.3)	0	1 (0.1)	0
Otitis media acute	1 (0.1)	0	0	0
Otitis media chronic	1 (0.1)	1 (0.2)	2 (0.2)	0
Papilloma viral infection	0	1 (0.2)	0	0
Paronychia	1 (0.1)	0	0	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Pharyngeal abscess	0	0	1 (0.1)	0
Pharyngitis	2 (0.2)	1 (0.2)	0	1 (0.2)
Pharyngitis streptococcal	1 (0.1)	0	3 (0.3)	0
Pneumonia	6 (0.5)	3 (0.6)	4 (0.4)	0
Pneumonia viral	0	1 (0.2)	0	0
Pulmonary tuberculosis	0	0	0	1 (0.2)
Respiratory syncytial virus bronchiolitis	0	0	1 (0.1)	0
Respiratory syncytial virus infection	1 (0.1)	1 (0.2)	0	0
Rhinitis	1 (0.1)	0	1 (0.1)	0
Rotavirus infection	0	0	1 (0.1)	0
Scarlet fever	1 (0.1)	0	1 (0.1)	0
Sinusitis	4 (0.4)	0	1 (0.1)	1 (0.2)
Staphylococcal scalded skin syndrome	1 (0.1)	0	0	0
Tinea infection	0	0	1 (0.1)	0
Tinea pedis	0	1 (0.2)	0	0
Tinea versicolour	0	0	0	1 (0.2)
Tonsillitis	11 (1.0)	7 (1.3)	8 (0.7)	6 (1.1)
Urinary tract infection	0	2 (0.4)	2 (0.2)	4 (0.7)
Viral infection	1 (0.1)	0	0	0
Vulvovaginal mycotic infection	1 (0.1)	0	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Injury, poisoning and procedural complications	58 (5.1)	37 (6.9)	47 (4.2)	26 (4.6)
Ankle fracture	5 (0.4)	3 (0.6)	1 (0.1)	0
Back injury	0	0	0	1 (0.2)
Cartilage injury	0	1 (0.2)	0	0
Cataract traumatic	0	0	0	1 (0.2)
Chest injury	1 (0.1)	0	0	0
Chillblains	1 (0.1)	0	0	0
Clavicle fracture	2 (0.2)	2 (0.4)	3 (0.3)	3 (0.5)
Concussion	5 (0.4)	5 (0.9)	3 (0.3)	2 (0.4)
Contusion	1 (0.1)	0	0	0
Epicondylitis	0	1 (0.2)	0	0
Epiphyseal fracture	1 (0.1)	0	0	1 (0.2)
Exposure to communicable disease	0	1 (0.2)	0	0
Eye injury	0	0	0	1 (0.2)
Facial bones fracture	1 (0.1)	0	2 (0.2)	1 (0.2)
Fall	1 (0.1)	0	0	0
Femur fracture	0	1 (0.2)	1 (0.1)	0
Fibula fracture	1 (0.1)	1 (0.2)	0	1 (0.2)
Foot fracture	8 (0.7)	4 (0.7)	3 (0.3)	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Forearm fracture	0	0	0	1 (0.2)
Foreign body in ear	0	0	1 (0.1)	0
Hand fracture	8 (0.7)	4 (0.7)	5 (0.4)	1 (0.2)
Hip fracture	0	0	0	1 (0.2)
Humerus fracture	0	0	1 (0.1)	1 (0.2)
Hyphaema	0	0	0	1 (0.2)
Injury to brachial plexus due to birth trauma	0	0	0	1 (0.2)
Jaw fracture	0	0	1 (0.1)	0
Joint dislocation	0	3 (0.6)	1 (0.1)	1 (0.2)
Joint injury	0	0	2 (0.2)	1 (0.2)
Ligament injury	1 (0.1)	0	0	0
Ligament rupture	1 (0.1)	2 (0.4)	0	1 (0.2)
Ligament sprain	0	2 (0.4)	2 (0.2)	0
Limb fracture	2 (0.2)	0	0	0
Limb injury	1 (0.1)	2 (0.4)	0	1 (0.2)
Limb traumatic amputation	0	1 (0.2)	0	0
Lower limb fracture	1 (0.1)	0	1 (0.1)	0
Meniscus injury	2 (0.2)	1 (0.2)	0	0
Muscle injury	0	1 (0.2)	0	0
Muscle strain	4 (0.4)	0	1 (0.1)	1 (0.2)

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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Nasal injury	0	0	1 (0.1)	0
Pelvic fracture	0	1 (0.2)	0	0
Post concussion syndrome	0	0	1 (0.1)	0
Radius fracture	5 (0.4)	2 (0.4)	1 (0.1)	1 (0.2)
Rib fracture	0	0	0	1 (0.2)
Scar	0	1 (0.2)	0	0
Skeletal injury	0	0	0	2 (0.4)
Skin laceration	0	0	1 (0.1)	0
Stress fracture	1 (0.1)	0	2 (0.2)	2 (0.4)
Tibia fracture	3 (0.3)	1 (0.2)	5 (0.4)	0
Torus fracture	0	0	2 (0.2)	0
Traumatic arthritis	0	1 (0.2)	0	0
Ulna fracture	0	1 (0.2)	0	1 (0.2)
Upper limb fracture	12 (1.1)	2 (0.4)	11 (1.0)	4 (0.7)
VIIth nerve injury	1 (0.1)	0	0	0
Wrist fracture	10 (0.9)	3 (0.6)	6 (0.5)	2 (0.4)
Investigations	14 (1.2)	7 (1.3)	8 (0.7)	14 (2.5)
Arthroscopy	0	1 (0.2)	0	2 (0.4)
Biopsy liver	0	0	0	1 (0.2)

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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Blood cholesterol increased	0	1 (0.2)	0	0
Blood pressure increased	1 (0.1)	0	2 (0.2)	0
Body height decreased	1 (0.1)	0	0	0
Body mass index increased	0	0	0	1 (0.2)
Bronchoscopy	0	0	0	1 (0.2)
Cardiac murmur	9 (0.8)	1 (0.2)	4 (0.4)	1 (0.2)
Cardiac murmur functional	0	0	0	1 (0.2)
Endoscopy	1 (0.1)	1 (0.2)	0	0
Endoscopy upper gastrointestinal tract	0	0	1 (0.1)	0
HIV test positive	0	1 (0.2)	0	0
Heart rate increased	0	0	0	1 (0.2)
Heart rate irregular	0	1 (0.2)	0	1 (0.2)
Human papilloma virus test positive	0	1 (0.2)	0	1 (0.2)
Menstruation normal	1 (0.1)	0	1 (0.1)	0
Progesterone decreased	0	0	0	1 (0.2)
Serum ferritin decreased	1 (0.1)	0	0	0
Thyroid function test abnormal	0	0	0	1 (0.2)
Vitamin D decreased	0	0	0	2 (0.4)
Weight decreased	1 (0.1)	0	0	0



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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Metabolism and nutrition disorders	39 (3.4)	31 (5.8)	51 (4.5)	30 (5.3)
Calcium deficiency	0	0	1 (0.1)	0
Dairy intolerance	1 (0.1)	0	1 (0.1)	0
Decreased appetite	2 (0.2)	0	1 (0.1)	0
Dehydration	1 (0.1)	0	0	0
Dyslipidaemia	1 (0.1)	0	2 (0.2)	0
Food intolerance	2 (0.2)	0	2 (0.2)	0
Fructose intolerance	1 (0.1)	0	1 (0.1)	0
Glucose tolerance impaired	1 (0.1)	0	0	1 (0.2)
Gluten sensitivity	0	3 (0.6)	2 (0.2)	1 (0.2)
Hypercholesterolaemia	0	2 (0.4)	0	1 (0.2)
Hyperglycaemia	1 (0.1)	0	0	0
Hyperlipidaemia	4 (0.4)	1 (0.2)	0	0
Hypertriglyceridaemia	1 (0.1)	0	1 (0.1)	0
Hypoglycaemia	0	0	0	1 (0.2)
Insulin resistance	0	1 (0.2)	0	0
Iron deficiency	0	1 (0.2)	2 (0.2)	2 (0.4)
Lactose intolerance	5 (0.4)	5 (0.9)	7 (0.6)	2 (0.4)
Obesity	15 (1.3)	12 (2.2)	20 (1.8)	18 (3.2)
Overweight	1 (0.1)	1 (0.2)	4 (0.4)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Type 1 diabetes mellitus	2 (0.2)	1 (0.2)	5 (0.4)	2 (0.4)
Type 2 diabetes mellitus	0	2 (0.4)	0	1 (0.2)
Underweight	1 (0.1)	1 (0.2)	0	1 (0.2)
Vitamin D deficiency	4 (0.4)	2 (0.4)	6 (0.5)	1 (0.2)
Musculoskeletal and connective tissue disorders	55 (4.9)	29 (5.4)	48 (4.3)	19 (3.4)
Arthralgia	12 (1.1)	3 (0.6)	8 (0.7)	5 (0.9)
Back pain	1 (0.1)	4 (0.7)	1 (0.1)	2 (0.4)
Deformity thorax	0	1 (0.2)	0	0
Discoid meniscus	0	0	1 (0.1)	0
Exostosis	1 (0.1)	1 (0.2)	0	0
Fibromyalgia	0	0	0	1 (0.2)
Foot deformity	2 (0.2)	3 (0.6)	2 (0.2)	0
Growing pains	1 (0.1)	0	0	0
Growth retardation	1 (0.1)	0	0	0
Hypermobility syndrome	0	0	1 (0.1)	0
Intervertebral disc protrusion	0	3 (0.6)	0	0
Juvenile idiopathic arthritis	0	0	1 (0.1)	0
Knee deformity	2 (0.2)	0	0	0
Kyphosis	1 (0.1)	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Lordosis	1 (0.1)	0	0	0
Muscle tightness	0	1 (0.2)	0	0
Myalgia	1 (0.1)	0	5 (0.4)	2 (0.4)
Neck pain	0	1 (0.2)	0	0
Osteitis	1 (0.1)	0	1 (0.1)	0
Osteochondrosis	3 (0.3)	2 (0.4)	4 (0.4)	1 (0.2)
Pain in extremity	2 (0.2)	0	3 (0.3)	1 (0.2)
Pain in jaw	1 (0.1)	0	0	0
Patellofemoral pain syndrome	0	2 (0.4)	2 (0.2)	0
Plantar fascial fibromatosis	0	0	1 (0.1)	0
Plantar fasciitis	0	0	0	1 (0.2)
Rotator cuff syndrome	1 (0.1)	0	0	0
Scapular dyskinesis	0	1 (0.2)	0	0
Scoliosis	21 (1.9)	5 (0.9)	12 (1.1)	4 (0.7)
Short stature	6 (0.5)	0	2 (0.2)	0
Shoulder deformity	0	0	1 (0.1)	0
Spinal osteoarthritis	0	1 (0.2)	0	0
Spondylolisthesis	0	1 (0.2)	0	0
Spondylolysis	0	1 (0.2)	0	0
Synovial cyst	0	1 (0.2)	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Temporomandibular joint syndrome	2 (0.2)	0	1 (0.1)	2 (0.4)
Tendon disorder	0	0	1 (0.1)	0
Tendonitis	1 (0.1)	0	3 (0.3)	0
Toe walking	1 (0.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (0.8)	4 (0.7)	14 (1.2)	7 (1.2)
Benign ear neoplasm	1 (0.1)	0	0	0
Benign neoplasm of skin	0	1 (0.2)	0	1 (0.2)
Cholesteatoma	0	0	1 (0.1)	1 (0.2)
Colon adenoma	0	0	0	1 (0.2)
Eyelid haemangioma	1 (0.1)	0	0	0
Fibroadenoma of breast	0	1 (0.2)	1 (0.1)	0
Fibroma	0	0	1 (0.1)	0
Haemangioma	1 (0.1)	0	0	0
Lipoma	0	0	1 (0.1)	0
Melanocytic naevus	1 (0.1)	0	3 (0.3)	2 (0.4)
Nephroblastoma	0	0	1 (0.1)	0
Ovarian neoplasm	0	0	0	1 (0.2)
Pituitary tumour benign	0	1 (0.2)	0	0
Skin papilloma	5 (0.4)	1 (0.2)	6 (0.5)	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Nervous system disorders	94 (8.3)	58 (10.8)	67 (5.9)	58 (10.3)
Apraxia	1 (0.1)	0	0	0
Arachnoid cyst	1 (0.1)	0	0	0
Benign rolandic epilepsy	1 (0.1)	0	0	0
Central auditory processing disorder	0	1 (0.2)	0	0
Cluster headache	0	2 (0.4)	0	0
Convulsion in childhood	1 (0.1)	0	0	0
Disturbance in attention	4 (0.4)	0	0	0
Dizziness	2 (0.2)	1 (0.2)	0	0
Dysgraphia	0	0	2 (0.2)	0
Dyslexia	1 (0.1)	2 (0.4)	6 (0.5)	1 (0.2)
Epilepsy	4 (0.4)	0	1 (0.1)	1 (0.2)
Essential tremor	0	1 (0.2)	0	0
Facial paralysis	0	0	0	1 (0.2)
Febrile convulsion	3 (0.3)	1 (0.2)	0	0
Headache	38 (3.4)	19 (3.5)	29 (2.6)	24 (4.3)
Hydrocephalus	0	0	1 (0.1)	0
Hypersomnia	0	0	0	1 (0.2)
Idiopathic intracranial hypertension	0	0	1 (0.1)	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Mental impairment	2 (0.2)	0	0	0
Migraine	30 (2.7)	30 (5.6)	25 (2.2)	20 (3.6)
Migraine with aura	2 (0.2)	1 (0.2)	2 (0.2)	0
Migraine without aura	0	1 (0.2)	2 (0.2)	0
Narcolepsy	0	1 (0.2)	0	1 (0.2)
Neuropathy peripheral	0	0	0	2 (0.4)
Nystagmus	1 (0.1)	1 (0.2)	0	0
Paroxysmal choreoathetosis	0	0	0	1 (0.2)
Petit mal epilepsy	0	0	0	1 (0.2)
Restless legs syndrome	0	0	0	1 (0.2)
Retinal migraine	1 (0.1)	0	0	0
Seizure	1 (0.1)	0	1 (0.1)	0
Sensory disturbance	0	0	1 (0.1)	0
Sensory processing disorder	1 (0.1)	0	1 (0.1)	0
Speech disorder	2 (0.2)	0	0	0
Syncope	1 (0.1)	0	1 (0.1)	0
Tension headache	1 (0.1)	7 (1.3)	0	3 (0.5)
Tethered cord syndrome	1 (0.1)	0	0	0
Tremor	0	1 (0.2)	0	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Pregnancy, puerperium and perinatal conditions	2 (0.2)	3 (0.6)	1 (0.1)	2 (0.4)
Delivery	0	2 (0.4)	0	1 (0.2)
Premature baby	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Product issues	0	0	1 (0.1)	0
Device breakage	0	0	1 (0.1)	0
Psychiatric disorders	290 (25.6)	119 (22.2)	281 (24.9)	130 (23.2)
Adjustment disorder	0	0	0	2 (0.4)
Adjustment disorder with depressed mood	1 (0.1)	1 (0.2)	1 (0.1)	0
Adjustment disorder with mixed anxiety and depressed mood	0	1 (0.2)	1 (0.1)	0
Affective disorder	0	1 (0.2)	0	0
Aggression	1 (0.1)	0	1 (0.1)	0
Anger	0	0	1 (0.1)	1 (0.2)
Anxiety	104 (9.2)	52 (9.7)	93 (8.2)	49 (8.7)
Anxiety disorder	4 (0.4)	3 (0.6)	3 (0.3)	6 (1.1)
Attention deficit hyperactivity disorder	182 (16.1)	39 (7.3)	165 (14.6)	53 (9.4)
Autism spectrum disorder	10 (0.9)	4 (0.7)	10 (0.9)	4 (0.7)
Behaviour disorder	2 (0.2)	0	1 (0.1)	0
Bipolar disorder	2 (0.2)	5 (0.9)	0	3 (0.5)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Bulimia nervosa	0	0	0	2 (0.4)
Childhood depression	1 (0.1)	0	0	0
Chronic tic disorder	0	0	2 (0.2)	0
Depression	49 (4.3)	48 (8.9)	45 (4.0)	43 (7.7)
Depressive symptom	0	0	1 (0.1)	0
Disruptive mood dysregulation disorder	3 (0.3)	0	2 (0.2)	0
Eating disorder	1 (0.1)	0	2 (0.2)	0
Encopresis	0	1 (0.2)	0	0
Enuresis	3 (0.3)	0	2 (0.2)	0
Gender dysphoria	2 (0.2)	0	0	0
Generalised anxiety disorder	8 (0.7)	9 (1.7)	14 (1.2)	5 (0.9)
Hallucination, auditory	1 (0.1)	0	0	0
Impulse-control disorder	2 (0.2)	0	0	0
Impulsive behaviour	0	0	1 (0.1)	0
Insomnia	27 (2.4)	14 (2.6)	28 (2.5)	11 (2.0)
Irritability	0	0	0	1 (0.2)
Learning disorder	0	0	1 (0.1)	0
Major depression	4 (0.4)	2 (0.4)	5 (0.4)	3 (0.5)
Mental disorder	0	1 (0.2)	0	0
Neurodevelopmental disorder	1 (0.1)	0	0	0



<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Nightmare	1 (0.1)	0	0	0
Obsessive-compulsive disorder	5 (0.4)	4 (0.7)	8 (0.7)	2 (0.4)
Oppositional defiant disorder	2 (0.2)	0	3 (0.3)	0
Paediatric autoimmune neuropsychiatric disorders associated with streptococcal infection	0	0	1 (0.1)	0
Panic attack	0	0	0	2 (0.4)
Panic disorder	0	2 (0.4)	0	1 (0.2)
Persistent depressive disorder	1 (0.1)	0	0	1 (0.2)
Post-traumatic stress disorder	4 (0.4)	1 (0.2)	5 (0.4)	0
Reactive attachment disorder of infancy or early childhood	0	0	1 (0.1)	0
Reading disorder	0	0	1 (0.1)	0
Selective eating disorder	0	1 (0.2)	0	0
Separation anxiety disorder	1 (0.1)	0	0	0
Sleep disorder	0	1 (0.2)	3 (0.3)	0
Social anxiety disorder	0	0	1 (0.1)	1 (0.2)
Speech sound disorder	1 (0.1)	0	0	0
Suicidal ideation	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Tic	3 (0.3)	2 (0.4)	2 (0.2)	1 (0.2)
Renal and urinary disorders	5 (0.4)	5 (0.9)	6 (0.5)	2 (0.4)
Dysuria	0	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Haematuria	1 (0.1)	0	1 (0.1)	0
Hydronephrosis	1 (0.1)	1 (0.2)	0	0
Hypertonic bladder	0	2 (0.4)	0	0
Nephrolithiasis	1 (0.1)	1 (0.2)	0	2 (0.4)
Nephrotic syndrome	0	1 (0.2)	0	0
Renal cyst	0	0	1 (0.1)	0
Renal disorder	1 (0.1)	0	0	0
Single functional kidney	0	0	1 (0.1)	0
Urinary retention	0	0	1 (0.1)	0
Urinary tract disorder	1 (0.1)	0	0	0
Vesicoureteric reflux	1 (0.1)	0	1 (0.1)	0
Reproductive system and breast disorders	32 (2.8)	33 (6.1)	35 (3.1)	27 (4.8)
Amenorrhoea	0	1 (0.2)	0	0
Breast cyst	1 (0.1)	1 (0.2)	0	0
Dysfunctional uterine bleeding	1 (0.1)	0	1 (0.1)	0
Dysmenorrhoea	11 (1.0)	17 (3.2)	15 (1.3)	12 (2.1)
Endometriosis	0	2 (0.4)	0	1 (0.2)
Epididymal cyst	1 (0.1)	1 (0.2)	0	0
Erectile dysfunction	0	0	0	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Gynaecomastia	0	0	1 (0.1)	0
Menorrhagia	7 (0.6)	7 (1.3)	9 (0.8)	4 (0.7)
Menstrual disorder	0	0	0	1 (0.2)
Menstruation irregular	4 (0.4)	1 (0.2)	6 (0.5)	4 (0.7)
Metrorrhagia	0	0	1 (0.1)	0
Ovarian cyst	0	1 (0.2)	0	3 (0.5)
Ovulation disorder	1 (0.1)	0	0	0
Polycystic ovaries	3 (0.3)	4 (0.7)	1 (0.1)	3 (0.5)
Premenstrual dysphoric disorder	0	0	2 (0.2)	0
Testicular torsion	1 (0.1)	2 (0.4)	0	1 (0.2)
Uterine haemorrhage	1 (0.1)	0	0	0
Vaginal disorder	1 (0.1)	0	0	0
Varicocele	1 (0.1)	0	1 (0.1)	0
Respiratory, thoracic and mediastinal disorders	178 (15.7)	75 (14.0)	178 (15.8)	79 (14.1)
Adenoidal hypertrophy	1 (0.1)	1 (0.2)	0	0
Asthma	107 (9.5)	43 (8.0)	109 (9.7)	46 (8.2)
Asthma exercise induced	11 (1.0)	9 (1.7)	16 (1.4)	5 (0.9)
Bronchial hyperreactivity	6 (0.5)	1 (0.2)	4 (0.4)	0
Bronchitis chronic	0	0	1 (0.1)	0

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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Bronchospasm	0	1 (0.2)	1 (0.1)	2 (0.4)
Epistaxis	6 (0.5)	2 (0.4)	5 (0.4)	0
Infantile apnoea	0	0	0	1 (0.2)
Nasal inflammation	1 (0.1)	0	0	0
Nasal polyps	0	0	1 (0.1)	0
Nasal septum deviation	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
Nasal turbinate hypertrophy	3 (0.3)	0	0	0
Oropharyngeal pain	1 (0.1)	0	1 (0.1)	0
Pneumothorax spontaneous	0	1 (0.2)	0	0
Rhinitis allergic	41 (3.6)	22 (4.1)	46 (4.1)	25 (4.5)
Rhinitis perennial	1 (0.1)	0	0	0
Sinus congestion	0	1 (0.2)	0	1 (0.2)
Sinus disorder	0	1 (0.2)	0	0
Sleep apnoea syndrome	5 (0.4)	1 (0.2)	3 (0.3)	2 (0.4)
Snoring	2 (0.2)	0	0	1 (0.2)
Thoracic insufficiency syndrome	0	1 (0.2)	0	0
Tonsillar hypertrophy	2 (0.2)	0	1 (0.1)	1 (0.2)
Tonsillolith	1 (0.1)	0	0	0
Tracheomalacia	0	0	1 (0.1)	0
Vasomotor rhinitis	1 (0.1)	0	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
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	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Vocal cord disorder	1 (0.1)	0	0	0
Vocal cord dysfunction	0	0	0	1 (0.2)
Vocal cord thickening	1 (0.1)	0	0	0
Wheezing	2 (0.2)	0	0	0
Skin and subcutaneous tissue disorders	169 (14.9)	70 (13.0)	180 (15.9)	73 (13.0)
Acanthosis nigricans	0	0	1 (0.1)	0
Acne	95 (8.4)	49 (9.1)	97 (8.6)	47 (8.4)
Acne cosmetica	1 (0.1)	0	0	0
Acne cystic	0	3 (0.6)	1 (0.1)	0
Actinic keratosis	1 (0.1)	0	1 (0.1)	0
Alopecia	1 (0.1)	1 (0.2)	0	2 (0.4)
Alopecia areata	1 (0.1)	0	0	0
Blister	1 (0.1)	0	0	0
Chronic spontaneous urticaria	0	0	0	1 (0.2)
Dermatitis	4 (0.4)	2 (0.4)	1 (0.1)	0
Dermatitis allergic	0	0	1 (0.1)	0
Dermatitis atopic	10 (0.9)	2 (0.4)	12 (1.1)	5 (0.9)
Dermatitis contact	5 (0.4)	1 (0.2)	4 (0.4)	1 (0.2)
Drug eruption	0	1 (0.2)	3 (0.3)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Dry skin	0	0	1 (0.1)	0
Dyshidrotic eczema	0	0	0	1 (0.2)
Eczema	35 (3.1)	6 (1.1)	44 (3.9)	15 (2.7)
Erythema annulare	0	1 (0.2)	0	0
Granuloma annulare	0	0	0	1 (0.2)
Hand dermatitis	8 (0.7)	0	2 (0.2)	0
Hidradenitis	0	1 (0.2)	0	0
Hirsutism	0	0	1 (0.1)	0
Hyperhidrosis	1 (0.1)	2 (0.4)	3 (0.3)	1 (0.2)
Hyperkeratosis	1 (0.1)	0	0	0
Idiopathic urticaria	2 (0.2)	0	0	0
Ingrowing nail	1 (0.1)	0	1 (0.1)	0
Keloid scar	0	1 (0.2)	0	0
Keratosis pilaris	1 (0.1)	1 (0.2)	2 (0.2)	0
Mechanical urticaria	0	0	0	1 (0.2)
Miliaria	1 (0.1)	0	0	0
Nail psoriasis	1 (0.1)	0	0	0
Pityriasis	0	1 (0.2)	0	0
Pityriasis alba	0	0	1 (0.1)	0
Pityriasis rosea	0	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Psoriasis	6 (0.5)	1 (0.2)	7 (0.6)	3 (0.5)
Rash	0	1 (0.2)	2 (0.2)	0
Rosacea	1 (0.1)	0	1 (0.1)	0
Seborrhoea	1 (0.1)	0	0	0
Seborrhoeic dermatitis	0	2 (0.4)	0	0
Spider naevus	0	0	1 (0.1)	0
Urticaria	8 (0.7)	1 (0.2)	2 (0.2)	1 (0.2)
Vitiligo	0	0	2 (0.2)	0
Social circumstances	104 (9.2)	11 (2.0)	95 (8.4)	10 (1.8)
Alcohol use	0	1 (0.2)	0	0
Celibacy	0	0	0	1 (0.2)
Corrective lens user	8 (0.7)	5 (0.9)	10 (0.9)	6 (1.1)
Ex-tobacco user	0	1 (0.2)	0	0
Inadequate diet	0	0	0	1 (0.2)
Menarche	11 (1.0)	0	16 (1.4)	0
Premenarche	88 (7.8)	0	69 (6.1)	0
Substance use	0	2 (0.4)	0	0
Tobacco user	0	4 (0.7)	0	1 (0.2)
Vegan	1 (0.1)	0	0	1 (0.2)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Vegetarian	2 (0.2)	0	6 (0.5)	0
Woman of childbearing potential	0	0	1 (0.1)	0
Surgical and medical procedures	110 (9.7)	92 (17.1)	117 (10.4)	91 (16.2)
Abdominal hernia repair	1 (0.1)	1 (0.2)	0	0
Abscess drainage	0	0	2 (0.2)	0
Adenoidectomy	33 (2.9)	3 (0.6)	22 (1.9)	5 (0.9)
Adenotonsillectomy	1 (0.1)	1 (0.2)	2 (0.2)	0
Ankle arthroplasty	0	0	0	1 (0.2)
Ankle operation	0	1 (0.2)	1 (0.1)	1 (0.2)
Anorectal operation	0	0	1 (0.1)	0
Antibiotic therapy	0	1 (0.2)	0	0
Appendectomy	9 (0.8)	8 (1.5)	10 (0.9)	2 (0.4)
Arterial switch operation	0	0	1 (0.1)	0
Atrial septal defect repair	1 (0.1)	0	1 (0.1)	0
Benign breast lump removal	0	1 (0.2)	0	0
Bone lesion excision	0	1 (0.2)	0	0
Bone operation	1 (0.1)	2 (0.4)	1 (0.1)	2 (0.4)
Brain operation	0	1 (0.2)	0	0
Breast operation	0	0	0	1 (0.2)



<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Caesarean section	0	1 (0.2)	0	2 (0.4)
Cardiac ablation	0	0	1 (0.1)	1 (0.2)
Cardiac operation	0	1 (0.2)	1 (0.1)	0
Cataract operation	0	0	1 (0.1)	0
Cautery to nose	1 (0.1)	0	1 (0.1)	0
Central venous catheterisation	1 (0.1)	0	0	0
Cerebral cyst excision	1 (0.1)	0	0	0
Cholecystectomy	1 (0.1)	3 (0.6)	0	5 (0.9)
Cholesteatoma removal	0	0	0	1 (0.2)
Chondroplasty	1 (0.1)	1 (0.2)	0	0
Circumcision	2 (0.2)	2 (0.4)	4 (0.4)	1 (0.2)
Cochlea implant	0	0	0	1 (0.2)
Colectomy	0	1 (0.2)	0	0
Colon operation	0	0	1 (0.1)	0
Contraception	0	0	0	1 (0.2)
Contraceptive implant	0	1 (0.2)	0	2 (0.4)
Dacryocystorhinostomy	0	0	1 (0.1)	0
Diverticulectomy	0	0	0	1 (0.2)
Ear operation	0	0	1 (0.1)	1 (0.2)
Ear tube insertion	12 (1.1)	3 (0.6)	10 (0.9)	4 (0.7)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Ear tube removal	1 (0.1)	0	1 (0.1)	0
Elbow operation	0	1 (0.2)	1 (0.1)	1 (0.2)
Enterostomy	0	1 (0.2)	0	0
Epiphyseal surgery	1 (0.1)	0	0	0
Epiphysiodesis	1 (0.1)	0	0	0
Eye operation	2 (0.2)	0	4 (0.4)	0
Facial lesion excision	1 (0.1)	0	1 (0.1)	0
Finger amputation	1 (0.1)	0	1 (0.1)	0
Foot operation	0	3 (0.6)	1 (0.1)	1 (0.2)
Fracture treatment	3 (0.3)	2 (0.4)	5 (0.4)	2 (0.4)
Gastrectomy	0	1 (0.2)	0	1 (0.2)
Gastric bypass	0	0	0	1 (0.2)
Gingival operation	0	0	0	1 (0.2)
Heart valve replacement	0	1 (0.2)	0	0
Hernia diaphragmatic repair	1 (0.1)	1 (0.2)	1 (0.1)	0
Hernia repair	2 (0.2)	1 (0.2)	0	3 (0.5)
Hip surgery	0	0	1 (0.1)	1 (0.2)
Hydrocele operation	1 (0.1)	0	0	0
Hymenectomy	1 (0.1)	0	0	0
Inguinal hernia repair	1 (0.1)	0	1 (0.1)	2 (0.4)

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Intervertebral disc operation	0	1 (0.2)	0	0
Intestinal operation	1 (0.1)	0	0	0
Intestinal resection	0	1 (0.2)	0	0
Intra-uterine contraceptive device insertion	0	2 (0.4)	0	1 (0.2)
Intrauterine contraception	2 (0.2)	1 (0.2)	0	0
Jaw operation	1 (0.1)	0	0	0
Joint stabilisation	0	0	1 (0.1)	0
Knee operation	2 (0.2)	0	0	1 (0.2)
Lacrimal duct procedure	0	0	1 (0.1)	0
Ligament operation	1 (0.1)	4 (0.7)	0	1 (0.2)
Limb operation	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Limb reconstructive surgery	0	0	1 (0.1)	0
Lipoma excision	0	0	1 (0.1)	0
Liposuction	0	0	1 (0.1)	0
Lung assist device therapy	0	1 (0.2)	0	0
Lymphadenectomy	0	0	1 (0.1)	0
Mammoplasty	0	0	0	1 (0.2)
Mass excision	1 (0.1)	0	0	0
Mastoidectomy	1 (0.1)	0	0	1 (0.2)
Medical device change	0	0	1 (0.1)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Medical device removal	0	1 (0.2)	0	0
Medical diet	1 (0.1)	0	0	0
Meniscus operation	1 (0.1)	1 (0.2)	0	0
Metabolic surgery	0	1 (0.2)	0	0
Middle ear operation	1 (0.1)	0	0	0
Mole excision	0	0	1 (0.1)	0
Myringotomy	11 (1.0)	1 (0.2)	8 (0.7)	0
Nail operation	1 (0.1)	0	0	0
Nasal septal operation	0	0	0	1 (0.2)
Nephrectomy	0	0	1 (0.1)	0
Oesophagogastric fundoplasty	0	0	1 (0.1)	0
Open reduction of fracture	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
Oral surgery	0	1 (0.2)	0	0
Orchidectomy	0	1 (0.2)	0	2 (0.4)
Orchidopexy	1 (0.1)	0	0	0
Ostectomy	1 (0.1)	0	0	0
Otoplasty	0	0	0	1 (0.2)
Ovarian cystectomy	0	0	0	1 (0.2)
Papilloma excision	0	1 (0.2)	0	0
Penis frenulectomy	0	1 (0.2)	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Peripheral nerve operation	0	0	0	1 (0.2)
Pharyngeal reconstruction	0	0	1 (0.1)	0
Pilonidal sinus repair	0	1 (0.2)	1 (0.1)	0
Portal shunt procedure	0	0	1 (0.1)	0
Rectal prolapse repair	0	0	0	1 (0.2)
Removal of foreign body from external ear	0	0	1 (0.1)	0
Rhinoplasty	0	2 (0.4)	1 (0.1)	2 (0.4)
Salivary gland resection	0	0	0	1 (0.2)
Salpingectomy	0	0	0	1 (0.2)
Scar excision	0	0	0	1 (0.2)
Scleral buckling surgery	0	0	0	1 (0.2)
Scoliosis surgery	1 (0.1)	1 (0.2)	1 (0.1)	0
Scrotal cystectomy	0	0	1 (0.1)	0
Sinuplasty	0	0	1 (0.1)	0
Skin lesion removal	1 (0.1)	0	0	0
Spinal fusion surgery	2 (0.2)	1 (0.2)	1 (0.1)	0
Splenectomy	0	0	0	1 (0.2)
Splenorrhaphy	0	1 (0.2)	0	0
Stoma closure	0	1 (0.2)	0	0
Strabismus correction	2 (0.2)	2 (0.4)	2 (0.2)	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Suture insertion	1 (0.1)	0	0	0
Synovial cyst removal	0	1 (0.2)	0	0
Temporomandibular joint surgery	0	0	1 (0.1)	0
Tendon graft	0	1 (0.2)	0	0
Tenoplasty	0	1 (0.2)	0	0
Tenotomy	0	1 (0.2)	0	0
Testes exploration	1 (0.1)	0	0	0
Testicular operation	1 (0.1)	1 (0.2)	0	0
Tetralogy of Fallot repair	0	1 (0.2)	0	0
Thoracic operation	0	1 (0.2)	0	0
Thyroglossal cyst excision	1 (0.1)	0	0	0
Thyroidectomy	0	1 (0.2)	0	1 (0.2)
Toe operation	1 (0.1)	0	0	2 (0.4)
Tongue tie operation	0	0	0	1 (0.2)
Tonsillectomy	33 (2.9)	17 (3.2)	31 (2.7)	20 (3.6)
Tooth extraction	1 (0.1)	0	1 (0.1)	2 (0.4)
Transgender hormonal therapy	0	0	1 (0.1)	0
Turbinectomy	1 (0.1)	0	0	0
Turbinoplasty	1 (0.1)	0	0	0
Tympanoplasty	1 (0.1)	1 (0.2)	0	0

<b>Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
<b>System Organ Class Preferred Term</b>	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131)</b>	<b>16-25 Years (N<sup>a</sup>=537)</b>	<b>12-15 Years (N<sup>a</sup>=1129)</b>	<b>16-25 Years (N<sup>a</sup>=561)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Umbilical hernia repair	2 (0.2)	2 (0.4)	3 (0.3)	0
Urethral operation	0	1 (0.2)	0	0
Urethral repair	1 (0.1)	0	1 (0.1)	1 (0.2)
Urinary tract operation	0	0	1 (0.1)	0
Varicocele repair	0	0	0	1 (0.2)
Ventricular septal defect repair	0	1 (0.2)	0	0
Vitrectomy	0	0	1 (0.1)	0
Wisdom teeth removal	2 (0.2)	10 (1.9)	5 (0.4)	11 (2.0)
Wound closure	0	0	0	1 (0.2)
Vascular disorders	3 (0.3)	1 (0.2)	2 (0.2)	4 (0.7)
Hypertension	0	0	1 (0.1)	2 (0.4)
Hypotension	1 (0.1)	0	1 (0.1)	0
Orthostatic hypertension	0	1 (0.2)	0	0
Peripheral venous disease	1 (0.1)	0	0	0
Raynaud's phenomenon	1 (0.1)	0	0	2 (0.4)
Note: MedDRA (v23.1) coding dictionary applied. Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives. a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.				

**Medical History – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =1131)	16-25 Years (N <sup>a</sup> =537)	12-15 Years (N <sup>a</sup> =1129)	16-25 Years (N <sup>a</sup> =561)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)	n <sup>b</sup> (%)	n <sup>b</sup> (%)

b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences of the same preferred term are counted only once.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:42)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/admh\_s002\_ped\_saf



<b>Follow-up Time After Dose 2 – Subjects 12 Through 15 Years of Age – Safety Population</b>			
	<b>Vaccine Group (as Administered)</b>		
	<b>BNT162b2 (30 µg)</b>	<b>Placebo</b>	<b>Total</b>
	<b>(N<sup>a</sup>=1131)</b>	<b>(N<sup>a</sup>=1129)</b>	<b>(N<sup>a</sup>=2260)</b>
	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>	<b>n<sup>b</sup> (%)</b>
Subjects (%) with length of follow-up of:			
Total exposure from Dose 2 to cutoff date			
<1 Month	13 (1.1)	25 (2.2)	38 (1.7)
≥1 Month to <2 months	458 (40.5)	456 (40.4)	914 (40.4)
≥2 Months to <3 months	612 (54.1)	599 (53.1)	1211 (53.6)
≥3 Months	48 (4.2)	49 (4.3)	97 (4.3)
Note: Follow-up time was calculated to the cutoff date or the date of unblinding, whichever date was earlier.			
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.			
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (00:54)			
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_ped_saf			

Immunogenicity Blood Samples Drawn – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset)				
	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =280) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =280) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =50) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =50) n <sup>b</sup> (%)
Randomized	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Not vaccinated	0	0	0	0
Blood sample drawn	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Vaccinated at Dose 1	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Blood sample drawn before Dose 1 <sup>c</sup>	279 (99.6)	280 (100.0)	50 (100.0)	50 (100.0)
Not obtained	1 (0.4)	0	0	0
Vaccinated at Dose 2	279 (99.6)	280 (100.0)	50 (100.0)	50 (100.0)
Blood sample drawn 1 month after Dose 2 <sup>c</sup>				
<28 Days	2 (0.7)	5 (1.8)	0	0
28 to 35 Days	271 (96.8)	255 (91.1)	49 (98.0)	45 (90.0)
>35 Days	6 (2.1)	15 (5.4)	1 (2.0)	4 (8.0)
Not obtained	0	5 (1.8)	0	1 (2.0)
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations. b. n = Number of subjects with the specified characteristic. c. Protocol-specified time frame. PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (00:54) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s001_imm_bld_ped_rand				

<b>Vaccine as Administered, by Vaccine Group – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset)</b>				
<b>Vaccine (as Administered)</b>	<b>Vaccine Group (as Randomized)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=539) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=564) n<sup>b</sup> (%)</b>
Vaccinated	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Not vaccinated	0	0	0	0
Dose 1				
BNT162b2 (30 µg)	1131 (100.0)	539 (100.0)	0	0
Placebo	0	0	1129 (100.0)	564 (100.0)
Dose 2				
BNT162b2 (30 µg)	1124 (99.4)	526 (97.6)	0	0
Placebo	0	0	1117 (98.9)	537 (95.2)
<p>Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.</p> <p>a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.</p> <p>b. n = Number of subjects with the specified characteristic.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:54) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_adm_ped_rand</p>				

<b>Vaccine Administration Timing – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset)</b>				
	<b>Vaccine Group (as Randomized)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years (N<sup>a</sup>=1131) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=539) n<sup>b</sup> (%)</b>	<b>12-15 Years (N<sup>a</sup>=1129) n<sup>b</sup> (%)</b>	<b>16-25 Years (N<sup>a</sup>=564) n<sup>b</sup> (%)</b>
Randomized	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Not vaccinated	0	0	0	0
Dose 1	1131 (100.0)	539 (100.0)	1129 (100.0)	564 (100.0)
Dose 2 <sup>c</sup>	1124 (99.4)	526 (97.6)	1117 (98.9)	537 (95.2)
<14 Days	0	0	0	0
14 to 20 Days	358 (31.7)	184 (34.1)	364 (32.2)	192 (34.0)
21 to 27 Days	737 (65.2)	325 (60.3)	729 (64.6)	328 (58.2)
28 to 34 Days	23 (2.0)	7 (1.3)	15 (1.3)	6 (1.1)
35 to 41 Days	4 (0.4)	5 (0.9)	4 (0.4)	4 (0.7)
42 to 48 Days	1 (0.1)	1 (0.2)	1 (0.1)	1 (0.2)
49 to 55 Days	1 (0.1)	0	3 (0.3)	2 (0.4)
>55 Days	0	4 (0.7)	1 (0.1)	4 (0.7)
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.				
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.				
b. n = Number of subjects with the specified characteristic.				
c. Days calculated since Dose 1.				
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:11)				
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_time_ped_rand				

**Concomitant Vaccines Received From After Dose 1 Through 1 Month After Dose 2 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

Vaccine <sup>b</sup>	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =1131)	16-25 Years (N <sup>a</sup> =536)	12-15 Years (N <sup>a</sup> =1129)	16-25 Years (N <sup>a</sup> =561)
	n <sup>c</sup> (%)	n <sup>c</sup> (%)	n <sup>c</sup> (%)	n <sup>c</sup> (%)
Any concomitant vaccine	15 (1.3)	17 (3.2)	8 (0.7)	18 (3.2)
ANTHRAX VACCINE	0	0	0	1 (0.2)
HPV VACCINE	2 (0.2)	2 (0.4)	4 (0.4)	1 (0.2)
HPV VACCINE VLP RL1 4V (YEAST)	1 (0.1)	0	0	0
INFLUENZA VACCINE	8 (0.7)	13 (2.4)	4 (0.4)	10 (1.8)
INFLUENZA VACCINE INACT SPLIT 3V	0	0	0	2 (0.4)
INFLUENZA VACCINE INACT SPLIT 4V	2 (0.2)	1 (0.2)	1 (0.1)	1 (0.2)
MENINGOCOCCAL VACCINE	1 (0.1)	1 (0.2)	0	1 (0.2)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197)	0	1 (0.2)	0	2 (0.4)
MENINGOCOCCAL VACCINE A/C/Y/W CONJ (DIP TOX)	1 (0.1)	1 (0.2)	0	1 (0.2)
MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV	0	1 (0.2)	0	1 (0.2)

Note: WHO DDE v202003 coding dictionary applied.

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

b. Subjects are counted only once for each preferred term.

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

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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adcm\_s001\_vax\_1m2\_ped\_saf

<b>E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years n<sup>a</sup> (%)</b>	<b>16-25 Years n<sup>a</sup> (%)</b>	<b>12-15 Years n<sup>a</sup> (%)</b>	<b>16-25 Years n<sup>a</sup> (%)</b>
Vaccinated at Dose 1 <sup>b</sup>	1131	537	1129	561
E-diary				
Not transmitted <sup>c</sup>	4 (0.4)	6 (1.1)	2 (0.2)	8 (1.4)
Transmitted <sup>d</sup>				
Day 1	1081 (95.6)	506 (94.2)	1066 (94.4)	514 (91.6)
Day 2	1089 (96.3)	509 (94.8)	1073 (95.0)	519 (92.5)
Day 3	1048 (92.7)	485 (90.3)	1056 (93.5)	515 (91.8)
Day 4	1025 (90.6)	478 (89.0)	1011 (89.5)	503 (89.7)
Day 5	1012 (89.5)	472 (87.9)	1002 (88.8)	492 (87.7)
Day 6	991 (87.6)	474 (88.3)	1002 (88.8)	484 (86.3)
Day 7	1006 (88.9)	476 (88.6)	989 (87.6)	476 (84.8)
All 7 days <sup>c</sup>	718 (63.5)	347 (64.6)	695 (61.6)	343 (61.1)
Vaccinated at Dose 2 <sup>b</sup>	1124	525	1117	535
E-diary				
Not transmitted <sup>c</sup>	27 (2.4)	35 (6.7)	39 (3.5)	39 (7.3)
Transmitted <sup>d</sup>				
Day 1	852 (75.8)	377 (71.8)	785 (70.3)	348 (65.0)
Day 2	984 (87.5)	437 (83.2)	879 (78.7)	406 (75.9)
Day 3	959 (85.3)	419 (79.8)	904 (80.9)	428 (80.0)
Day 4	913 (81.2)	418 (79.6)	907 (81.2)	431 (80.6)

<b>E-Diary Transmission – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>				
	<b>Vaccine Group (as Administered)</b>			
	<b>BNT162b2 (30 µg)</b>		<b>Placebo</b>	
	<b>12-15 Years n<sup>a</sup> (%)</b>	<b>16-25 Years n<sup>a</sup> (%)</b>	<b>12-15 Years n<sup>a</sup> (%)</b>	<b>16-25 Years n<sup>a</sup> (%)</b>
Day 5	917 (81.6)	421 (80.2)	909 (81.4)	433 (80.9)
Day 6	930 (82.7)	414 (78.9)	923 (82.6)	425 (79.4)
Day 7	925 (82.3)	412 (78.5)	912 (81.6)	426 (79.6)
All 7 days <sup>c</sup>	463 (41.2)	217 (41.3)	414 (37.1)	201 (37.6)
<p>Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.</p> <p>a. n = Number of subjects with the specified characteristic.</p> <p>b. These values are the denominators for the percentage calculations.</p> <p>c. If no data for temperature, local reactions, fever/pain medication, or systemic events are reported for the entire electronic diary (e-diary) collection period (Day 1 through Day 7), the e-diary is considered not transmitted.</p> <p>d. If any data for temperature, local reactions, fever/pain medication, or systemic events are reported for the specified day or set of days (ie, "all 7 days"), the e-diary is considered transmitted.</p> <p>e. "All 7 days" includes Day 1 through Day 7 after vaccination. Day 1 is the day of vaccination.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)            (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s200_trns_ped_saf</p>				

# Immunogenicity Populations – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset)

	Vaccine Group (as Randomized)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years n <sup>a</sup> (%)	16-25 Years n <sup>a</sup> (%)	12-15 Years n <sup>a</sup> (%)	16-25 Years n <sup>a</sup> (%)
Randomized <sup>b</sup>	280 (100.0)	280 (100.0)	50 (100.0)	50 (100.0)
Dose 2 all-available immunogenicity population	210 (75.0)	191 (68.2)	36 (72.0)	34 (68.0)
Subjects excluded from Dose 2 all-available immunogenicity population	70 (25.0)	89 (31.8)	14 (28.0)	16 (32.0)
Reason for exclusion				
Did not receive Dose 2	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)
Subjects excluded from Dose 2 evaluable immunogenicity population	71 (25.4)	94 (33.6)	14 (28.0)	18 (36.0)
Reason for exclusion <sup>c</sup>				
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 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.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (00:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s008\_imm\_pop\_ped



Safety Population – Subjects 12 Through 15 and 16 Through 25 Years of Age						
	Vaccine Group (as Administered)					
	12-15 Years			16-25 Years		
	BNT162b2 (30 µg) n <sup>a</sup>	Placebo n <sup>a</sup>	Total n <sup>a</sup>	BNT162b2 (30 µg) n <sup>a</sup>	Placebo n <sup>a</sup>	Total n <sup>a</sup>
Randomized <sup>b</sup>			2264			3788
Vaccinated	1131	1129	2260 (99.8)	1869	1906	3775 (99.7)
Safety population	1131	1129	2260 (99.8)	1867	1903	3770 (99.5)
Reactogenicity subset	1131	1129	2260 (99.8)	537	561	1098 (29.0)
HIV-positive	0	0	0	1	0	1 (0.0)
Excluded from safety population			4 (0.2)			18 (0.5)
Reason for exclusion						
Subject did not receive study vaccine			4 (0.2)			13 (0.3)
Unreliable data due to lack of PI oversight			0			5 (0.1)
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but not included in the analyses of the overall study objectives.						
a. n = Number of subjects with the specified characteristic, or the total sample.						
b. This value is the denominator for the percentage calculations.						
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (04:09)						
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_saf_pop_ped						

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Local Reaction	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
1	Redness <sup>d</sup>												
	Any	1127	65 (5.8)	(4.5, 7.3)	531	34 (6.4)	(4.5, 8.8)	1127	12 (1.1)	(0.6, 1.9)	553	5 (0.9)	(0.3, 2.1)
	Mild	1127	44 (3.9)	(2.9, 5.2)	531	25 (4.7)	(3.1, 6.9)	1127	11 (1.0)	(0.5, 1.7)	553	4 (0.7)	(0.2, 1.8)
	Moderate	1127	20 (1.8)	(1.1, 2.7)	531	7 (1.3)	(0.5, 2.7)	1127	1 (0.1)	(0.0, 0.5)	553	1 (0.2)	(0.0, 1.0)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	2 (0.4)	(0.0, 1.4)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Swelling <sup>d</sup>												
	Any	1127	78 (6.9)	(5.5, 8.6)	531	44 (8.3)	(6.1, 11.0)	1127	11 (1.0)	(0.5, 1.7)	553	6 (1.1)	(0.4, 2.3)
	Mild	1127	55 (4.9)	(3.7, 6.3)	531	31 (5.8)	(4.0, 8.2)	1127	9 (0.8)	(0.4, 1.5)	553	3 (0.5)	(0.1, 1.6)
	Moderate	1127	23 (2.0)	(1.3, 3.0)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	3 (0.5)	(0.1, 1.6)
	Severe	1127	0	(0.0, 0.3)	531	1 (0.2)	(0.0, 1.0)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Pain at the injection site <sup>e</sup>												
	Any	1127	971 (86.2)	(84.0, 88.1)	531	443 (83.4)	(80.0, 86.5)	1127	263 (23.3)	(20.9, 25.9)	553	88 (15.9)	(13.0, 19.2)
	Mild	1127	467 (41.4)	(38.5, 44.4)	531	204 (38.4)	(34.3, 42.7)	1127	227 (20.1)	(17.8, 22.6)	553	81 (14.6)	(11.8, 17.9)
	Moderate	1127	493 (43.7)	(40.8, 46.7)	531	227 (42.7)	(38.5, 47.1)	1127	36 (3.2)	(2.2, 4.4)	553	7 (1.3)	(0.5, 2.6)
	Severe	1127	11 (1.0)	(0.5, 1.7)	531	12 (2.3)	(1.2, 3.9)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Any local reaction <sup>f</sup>	1127	976 (86.6)	(84.5, 88.5)	531	445 (83.8)	(80.4, 86.8)	1127	271 (24.0)	(21.6, 26.7)	553	91 (16.5)	(13.5, 19.8)

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Local Reaction	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
2	Redness <sup>d</sup>												
	Any	1097	55 (5.0)	(3.8, 6.5)	488	28 (5.7)	(3.8, 8.2)	1078	10 (0.9)	(0.4, 1.7)	496	1 (0.2)	(0.0, 1.1)
	Mild	1097	29 (2.6)	(1.8, 3.8)	488	18 (3.7)	(2.2, 5.8)	1078	8 (0.7)	(0.3, 1.5)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1097	26 (2.4)	(1.6, 3.5)	488	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1097	0	(0.0, 0.3)	488	1 (0.2)	(0.0, 1.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Swelling <sup>d</sup>												
	Any	1097	54 (4.9)	(3.7, 6.4)	488	33 (6.8)	(4.7, 9.4)	1078	6 (0.6)	(0.2, 1.2)	496	1 (0.2)	(0.0, 1.1)
	Mild	1097	36 (3.3)	(2.3, 4.5)	488	23 (4.7)	(3.0, 7.0)	1078	4 (0.4)	(0.1, 0.9)	496	1 (0.2)	(0.0, 1.1)
	Moderate	1097	18 (1.6)	(1.0, 2.6)	488	10 (2.0)	(1.0, 3.7)	1078	2 (0.2)	(0.0, 0.7)	496	0	(0.0, 0.7)
	Severe	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Pain at the injection site <sup>e</sup>												
	Any	1097	866 (78.9)	(76.4, 81.3)	488	378 (77.5)	(73.5, 81.1)	1078	193 (17.9)	(15.7, 20.3)	496	60 (12.1)	(9.4, 15.3)
	Mild	1097	466 (42.5)	(39.5, 45.5)	488	202 (41.4)	(37.0, 45.9)	1078	164 (15.2)	(13.1, 17.5)	496	53 (10.7)	(8.1, 13.7)
	Moderate	1097	393 (35.8)	(33.0, 38.7)	488	169 (34.6)	(30.4, 39.0)	1078	29 (2.7)	(1.8, 3.8)	496	7 (1.4)	(0.6, 2.9)
	Severe	1097	7 (0.6)	(0.3, 1.3)	488	7 (1.4)	(0.6, 2.9)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any local reaction <sup>f</sup>	1097	872 (79.5)	(77.0, 81.8)	488	381 (78.1)	(74.1, 81.7)	1078	198 (18.4)	(16.1, 20.8)	496	62 (12.5)	(9.7, 15.7)
Any	Redness <sup>d</sup>												

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Local Reaction	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
dose													
	Any	1131	97 (8.6)	(7.0, 10.4)	535	55 (10.3)	(7.8, 13.2)	1129	18 (1.6)	(0.9, 2.5)	555	5 (0.9)	(0.3, 2.1)
	Mild	1131	55 (4.9)	(3.7, 6.3)	535	37 (6.9)	(4.9, 9.4)	1129	15 (1.3)	(0.7, 2.2)	555	4 (0.7)	(0.2, 1.8)
	Moderate	1131	41 (3.6)	(2.6, 4.9)	535	15 (2.8)	(1.6, 4.6)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	3 (0.6)	(0.1, 1.6)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Swelling <sup>d</sup>												
	Any	1131	104 (9.2)	(7.6, 11.0)	535	61 (11.4)	(8.8, 14.4)	1129	13 (1.2)	(0.6, 2.0)	555	7 (1.3)	(0.5, 2.6)
	Mild	1131	69 (6.1)	(4.8, 7.7)	535	44 (8.2)	(6.0, 10.9)	1129	10 (0.9)	(0.4, 1.6)	555	4 (0.7)	(0.2, 1.8)
	Moderate	1131	35 (3.1)	(2.2, 4.3)	535	16 (3.0)	(1.7, 4.8)	1129	3 (0.3)	(0.1, 0.8)	555	3 (0.5)	(0.1, 1.6)
	Severe	1131	0	(0.0, 0.3)	535	1 (0.2)	(0.0, 1.0)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Pain at the injection site <sup>e</sup>												
	Any	1131	1023 (90.5)	(88.6, 92.1)	535	468 (87.5)	(84.4, 90.2)	1129	341 (30.2)	(27.5, 33.0)	555	121 (21.8)	(18.4, 25.5)
	Mild	1131	394 (34.8)	(32.1, 37.7)	535	168 (31.4)	(27.5, 35.5)	1129	283 (25.1)	(22.6, 27.7)	555	108 (19.5)	(16.2, 23.0)
	Moderate	1131	612 (54.1)	(51.2, 57.0)	535	282 (52.7)	(48.4, 57.0)	1129	58 (5.1)	(3.9, 6.6)	555	13 (2.3)	(1.3, 4.0)
	Severe	1131	17 (1.5)	(0.9, 2.4)	535	18 (3.4)	(2.0, 5.3)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Any local reaction <sup>f</sup>	1131	1028 (90.9)	(89.1, 92.5)	535	471 (88.0)	(85.0, 90.7)	1129	349 (30.9)	(28.2, 33.7)	555	125 (22.5)	(19.1, 26.2)
Note: Reactions were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose.													

Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
		BNT162b2 (30 µg)						Placebo					
Dose	Local Reaction	12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Note: Grade 4 reactions were classified by the investigator or medically qualified person.													
a. N = number of subjects reporting at least 1 yes or no response for the specified reaction after the specified dose.													
b. n = Number of subjects with the specified characteristic.													
c. Exact 2-sided CI based on the Clopper and Pearson method.													
d. Mild: >2.0 to 5.0 cm; moderate: >5.0 to 10.0 cm; severe: >10.0 cm; Grade 4: necrosis (redness and swelling categories) or exfoliative dermatitis (redness category only).													
e. Mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe pain at the injection site.													
f. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.													
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s010_lr_sev_ped_saf													

Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Redness				
	n <sup>a</sup>	65	34	12	5
	Mean (SD)	2.4 (2.26)	1.8 (0.97)	1.3 (0.62)	1.2 (0.45)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 16)	(1, 5)	(1, 3)	(1, 2)
	Swelling				
	n <sup>a</sup>	78	44	11	6
	Mean (SD)	1.9 (1.10)	2.0 (1.50)	1.7 (1.35)	1.3 (0.82)
	Median	2.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 7)	(1, 5)	(1, 3)
	Pain at the injection site				
	n <sup>a</sup>	971	443	263	88
Mean (SD)	2.4 (1.35)	2.3 (1.37)	2.0 (1.75)	1.5 (1.27)	
Median	2.0	2.0	1.0	1.0	
Min, max	(1, 10)	(1, 9)	(1, 10)	(1, 11)	
2	Redness				
	n <sup>a</sup>	55	28	10	1
	Mean (SD)	1.8 (0.88)	1.9 (1.43)	1.7 (1.16)	1.0 (NE)
	Median	2.0	1.5	1.0	1.0
	Min, max	(1, 5)	(1, 8)	(1, 4)	(1, 1)
	Unknown <sup>b</sup>	1	0	0	0

Duration (Days) From First to Last Day of Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population				
		Vaccine Group (as Administered)		
Dose	Local Reaction	BNT162b2 (30 µg)		Placebo
		12-15 Years	16-25 Years	12-15 Years      16-25 Years
	Swelling			
	n <sup>a</sup>	54	33	6      1
	Mean (SD)	1.6 (0.93)	2.2 (1.69)	1.5 (0.55)      3.0 (NE)
	Median	1.0	2.0	1.5      3.0
	Min, max	(1, 5)	(1, 7)	(1, 2)      (3, 3)
	Pain at the injection site			
	n <sup>a</sup>	866	378	193      60
	Mean (SD)	2.5 (1.38)	2.8 (4.31)	1.8 (1.44)      2.2 (4.45)
	Median	2.0	2.0	1.0      1.0
	Min, max	(1, 11)	(1, 70)	(1, 8)      (1, 35)
	Unknown <sup>b</sup>	3	3	0      0
Abbreviation: NE = not estimable.				
Note: Duration was calculated in days as the difference from the start of the first reported reaction to the resolution of the last reported reaction, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.				
Note: Reactions were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for reactions lasting longer than 7 days was recorded on the subject's case report form.				
a. n = Number of subjects reporting the specified reaction on any of the 7 days, including subjects with reactions of unknown duration.				
b. Includes those reactions where the resolution date is partial or missing.				
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (01:29)				
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s030_lr_dur_ped_saf				

**Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

Dose	Local Reaction	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Redness				
	n <sup>a</sup>	65	34	12	5
	Mean (SD)	2.4 (0.82)	2.4 (1.05)	1.8 (1.11)	1.8 (1.30)
	Median	2.0	2.0	1.5	1.0
	Min, max	(1, 4)	(1, 5)	(1, 4)	(1, 4)
	Swelling				
	n <sup>a</sup>	78	44	11	6
	Mean (SD)	1.9 (0.85)	2.2 (1.02)	1.6 (1.21)	1.3 (0.82)
	Median	2.0	2.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 4)	(1, 3)
	Pain at the injection site				
	n <sup>a</sup>	971	443	263	88
	Mean (SD)	1.4 (0.55)	1.4 (0.51)	1.3 (0.84)	1.5 (1.05)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Any local reaction <sup>b</sup>				
	n <sup>a</sup>	976	445	271	91
	Mean (SD)	1.4 (0.56)	1.4 (0.51)	1.4 (0.87)	1.5 (1.06)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
2	Redness				



**Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

Dose	Local Reaction	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
	n <sup>a</sup>	55	28	10	1
	Mean (SD)	2.5 (0.84)	2.6 (0.79)	1.2 (0.42)	1.0 (NE)
	Median	2.0	3.0	1.0	1.0
	Min, max	(1, 5)	(1, 4)	(1, 2)	(1, 1)
	Swelling				
	n <sup>a</sup>	54	33	6	1
	Mean (SD)	2.1 (0.96)	2.0 (0.98)	2.8 (2.86)	3.0 (NE)
	Median	2.0	2.0	1.0	3.0
	Min, max	(1, 4)	(1, 4)	(1, 7)	(3, 3)
	Pain at the injection site				
	n <sup>a</sup>	866	378	193	60
	Mean (SD)	1.4 (0.61)	1.4 (0.62)	1.5 (1.14)	1.6 (1.06)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)
	Any local reaction <sup>b</sup>				
	n <sup>a</sup>	872	381	198	62
	Mean (SD)	1.4 (0.62)	1.4 (0.63)	1.5 (1.08)	1.6 (1.06)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 6)	(1, 7)	(1, 6)

Abbreviation: NE = not estimable.

Note: Day of onset is the first day the specified reaction was reported.

a. n = Number of subjects reporting the specified reaction, with each subject counted only once per reaction.

**Onset Days for Local Reactions – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Local Reaction	12-15 Years	16-25 Years	12-15 Years	16-25 Years

b. Any local reaction: any redness >2.0 cm, any swelling >2.0 cm, or any pain at the injection site.  
 PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)  
 (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adce\_s050\_lr\_onset\_ped\_saf

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
1	Fever												
	≥38.0°C	1127	114 (10.1)	(8.4, 12.0)	531	39 (7.3)	(5.3, 9.9)	1127	12 (1.1)	(0.6, 1.9)	553	8 (1.4)	(0.6, 2.8)
	≥38.0°C to 38.4°C	1127	74 (6.6)	(5.2, 8.2)	531	24 (4.5)	(2.9, 6.7)	1127	8 (0.7)	(0.3, 1.4)	553	5 (0.9)	(0.3, 2.1)
	>38.4°C to 38.9°C	1127	29 (2.6)	(1.7, 3.7)	531	12 (2.3)	(1.2, 3.9)	1127	2 (0.2)	(0.0, 0.6)	553	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1127	10 (0.9)	(0.4, 1.6)	531	3 (0.6)	(0.1, 1.6)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	>40.0°C	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Fatigue <sup>d</sup>												
	Any	1127	677 (60.1)	(57.1, 62.9)	531	318 (59.9)	(55.6, 64.1)	1127	457 (40.6)	(37.7, 43.5)	553	213 (38.5)	(34.4, 42.7)
	Mild	1127	278 (24.7)	(22.2, 27.3)	531	134 (25.2)	(21.6, 29.2)	1127	250 (22.2)	(19.8, 24.7)	553	118 (21.3)	(18.0, 25.0)
	Moderate	1127	384 (34.1)	(31.3, 36.9)	531	173 (32.6)	(28.6, 36.7)	1127	199 (17.7)	(15.5, 20.0)	553	89 (16.1)	(13.1, 19.4)
	Severe	1127	15 (1.3)	(0.7, 2.2)	531	11 (2.1)	(1.0, 3.7)	1127	8 (0.7)	(0.3, 1.4)	553	6 (1.1)	(0.4, 2.3)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Headache <sup>d</sup>												
	Any	1127	623 (55.3)	(52.3, 58.2)	531	286 (53.9)	(49.5, 58.2)	1127	396 (35.1)	(32.3, 38.0)	553	205 (37.1)	(33.0, 41.2)
	Mild	1127	361 (32.0)	(29.3, 34.8)	531	151 (28.4)	(24.6, 32.5)	1127	256 (22.7)	(20.3, 25.3)	553	138 (25.0)	(21.4, 28.8)
	Moderate	1127	251 (22.3)	(19.9, 24.8)	531	124 (23.4)	(19.8, 27.2)	1127	131 (11.6)	(9.8, 13.6)	553	63 (11.4)	(8.9, 14.3)
	Severe	1127	11 (1.0)	(0.5, 1.7)	531	11 (2.1)	(1.0, 3.7)	1127	9 (0.8)	(0.4, 1.5)	553	4 (0.7)	(0.2, 1.8)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Chills <sup>d</sup>												
	Any	1127	311 (27.6)	(25.0, 30.3)	531	133 (25.0)	(21.4, 29.0)	1127	109 (9.7)	(8.0, 11.5)	553	47 (8.5)	(6.3, 11.1)
	Mild	1127	195 (17.3)	(15.1, 19.6)	531	91 (17.1)	(14.0, 20.6)	1127	82 (7.3)	(5.8, 9.0)	553	31 (5.6)	(3.8, 7.9)
	Moderate	1127	111 (9.8)	(8.2, 11.7)	531	37 (7.0)	(5.0, 9.5)	1127	25 (2.2)	(1.4, 3.3)	553	15 (2.7)	(1.5, 4.4)
	Severe	1127	5 (0.4)	(0.1, 1.0)	531	5 (0.9)	(0.3, 2.2)	1127	2 (0.2)	(0.0, 0.6)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Vomiting <sup>e</sup>												
	Any	1127	31 (2.8)	(1.9, 3.9)	531	9 (1.7)	(0.8, 3.2)	1127	10 (0.9)	(0.4, 1.6)	553	9 (1.6)	(0.7, 3.1)
	Mild	1127	30 (2.7)	(1.8, 3.8)	531	9 (1.7)	(0.8, 3.2)	1127	8 (0.7)	(0.3, 1.4)	553	8 (1.4)	(0.6, 2.8)
	Moderate	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	2 (0.2)	(0.0, 0.6)	553	0	(0.0, 0.7)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	1 (0.2)	(0.0, 1.0)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Diarrhea <sup>f</sup>												
	Any	1127	90 (8.0)	(6.5, 9.7)	531	57 (10.7)	(8.2, 13.7)	1127	82 (7.3)	(5.8, 9.0)	553	62 (11.2)	(8.7, 14.1)
	Mild	1127	77 (6.8)	(5.4, 8.5)	531	50 (9.4)	(7.1, 12.2)	1127	72 (6.4)	(5.0, 8.0)	553	49 (8.9)	(6.6, 11.5)
	Moderate	1127	13 (1.2)	(0.6, 2.0)	531	7 (1.3)	(0.5, 2.7)	1127	10 (0.9)	(0.4, 1.6)	553	13 (2.4)	(1.3, 4.0)
	Severe	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0	(0.0, 0.7)
	New or worsened muscle pain <sup>d</sup>												

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population												
Vaccine Group (as Administered)												
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo				
		12-15 Years			16-25 Years			12-15 Years			16-25 Years	
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>
2	Any	1127	272 (24.1)	(21.7, 26.7)	531	143 (26.9)	(23.2, 30.9)	1127	148 (13.1)	(11.2, 15.2)	553	78 (14.1) (11.3, 17.3)
	Mild	1127	125 (11.1)	(9.3, 13.1)	531	67 (12.6)	(9.9, 15.7)	1127	88 (7.8)	(6.3, 9.5)	553	51 (9.2) (6.9, 11.9)
	Moderate	1127	145 (12.9)	(11.0, 15.0)	531	71 (13.4)	(10.6, 16.6)	1127	60 (5.3)	(4.1, 6.8)	553	27 (4.9) (3.2, 7.0)
	Severe	1127	2 (0.2)	(0.0, 0.6)	531	5 (0.9)	(0.3, 2.2)	1127	0	(0.0, 0.3)	553	0 (0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0 (0.0, 0.7)
	New or worsened joint pain <sup>d</sup>											
	Any	1127	109 (9.7)	(8.0, 11.5)	531	70 (13.2)	(10.4, 16.4)	1127	77 (6.8)	(5.4, 8.5)	553	28 (5.1) (3.4, 7.2)
	Mild	1127	66 (5.9)	(4.6, 7.4)	531	38 (7.2)	(5.1, 9.7)	1127	50 (4.4)	(3.3, 5.8)	553	17 (3.1) (1.8, 4.9)
	Moderate	1127	42 (3.7)	(2.7, 5.0)	531	29 (5.5)	(3.7, 7.7)	1127	27 (2.4)	(1.6, 3.5)	553	11 (2.0) (1.0, 3.5)
	Severe	1127	1 (0.1)	(0.0, 0.5)	531	3 (0.6)	(0.1, 1.6)	1127	0	(0.0, 0.3)	553	0 (0.0, 0.7)
	Grade 4	1127	0	(0.0, 0.3)	531	0	(0.0, 0.7)	1127	0	(0.0, 0.3)	553	0 (0.0, 0.7)
	Any systemic event <sup>g</sup>	1127	877 (77.8)	(75.3, 80.2)	531	403 (75.9)	(72.0, 79.5)	1127	636 (56.4)	(53.5, 59.4)	553	311 (56.2) (52.0, 60.4)
	Use of antipyretic or pain medication <sup>h</sup>	1127	413 (36.6)	(33.8, 39.5)	531	167 (31.5)	(27.5, 35.6)	1127	111 (9.8)	(8.2, 11.7)	553	62 (11.2) (8.7, 14.1)
	Fever											
	≥38.0°C	1097	215 (19.6)	(17.3, 22.1)	488	84 (17.2)	(14.0, 20.9)	1078	7 (0.6)	(0.3, 1.3)	496	2 (0.4) (0.0, 1.4)
	≥38.0°C to 38.4°C	1097	107 (9.8)	(8.1, 11.7)	488	45 (9.2)	(6.8, 12.1)	1078	5 (0.5)	(0.2, 1.1)	496	1 (0.2) (0.0, 1.1)
	>38.4°C to 38.9°C	1097	83 (7.6)	(6.1, 9.3)	488	32 (6.6)	(4.5, 9.1)	1078	1 (0.1)	(0.0, 0.5)	496	0 (0.0, 0.7)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population												
Vaccine Group (as Administered)												
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo				
		12-15 Years			16-25 Years			12-15 Years			16-25 Years	
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>
	>38.9°C to 40.0°C	1097	25 (2.3)	(1.5, 3.3)	488	7 (1.4)	(0.6, 2.9)	1078	1 (0.1)	(0.0, 0.5)	496	1 (0.2) (0.0, 1.1)
	>40.0°C	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0 (0.0, 0.7)
	Fatigue <sup>d</sup>											
	Any	1097	726 (66.2)	(63.3, 69.0)	488	320 (65.6)	(61.2, 69.8)	1078	264 (24.5)	(21.9, 27.2)	496	115 (23.2) (19.5, 27.2)
	Mild	1097	232 (21.1)	(18.8, 23.7)	488	98 (20.1)	(16.6, 23.9)	1078	133 (12.3)	(10.4, 14.5)	496	51 (10.3) (7.8, 13.3)
	Moderate	1097	468 (42.7)	(39.7, 45.7)	488	199 (40.8)	(36.4, 45.3)	1078	127 (11.8)	(9.9, 13.9)	496	62 (12.5) (9.7, 15.7)
	Severe	1097	26 (2.4)	(1.6, 3.5)	488	23 (4.7)	(3.0, 7.0)	1078	4 (0.4)	(0.1, 0.9)	496	2 (0.4) (0.0, 1.4)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0 (0.0, 0.7)
	Headache <sup>d</sup>											
	Any	1097	708 (64.5)	(61.6, 67.4)	488	297 (60.9)	(56.4, 65.2)	1078	263 (24.4)	(21.9, 27.1)	496	118 (23.8) (20.1, 27.8)
	Mild	1097	302 (27.5)	(24.9, 30.3)	488	119 (24.4)	(20.6, 28.4)	1078	169 (15.7)	(13.6, 18.0)	496	67 (13.5) (10.6, 16.8)
	Moderate	1097	384 (35.0)	(32.2, 37.9)	488	157 (32.2)	(28.0, 36.5)	1078	93 (8.6)	(7.0, 10.5)	496	46 (9.3) (6.9, 12.2)
	Severe	1097	22 (2.0)	(1.3, 3.0)	488	21 (4.3)	(2.7, 6.5)	1078	1 (0.1)	(0.0, 0.5)	496	5 (1.0) (0.3, 2.3)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0 (0.0, 0.7)
	Chills <sup>d</sup>											
	Any	1097	455 (41.5)	(38.5, 44.5)	488	195 (40.0)	(35.6, 44.5)	1078	73 (6.8)	(5.3, 8.4)	496	22 (4.4) (2.8, 6.6)
	Mild	1097	221 (20.1)	(17.8, 22.6)	488	82 (16.8)	(13.6, 20.4)	1078	52 (4.8)	(3.6, 6.3)	496	17 (3.4) (2.0, 5.4)
	Moderate	1097	214 (19.5)	(17.2, 22.0)	488	101 (20.7)	(17.2, 24.6)	1078	21 (1.9)	(1.2, 3.0)	496	5 (1.0) (0.3, 2.3)
	Severe	1097	20 (1.8)	(1.1, 2.8)	488	12 (2.5)	(1.3, 4.3)	1078	0	(0.0, 0.3)	496	0 (0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0 (0.0, 0.7)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
		Vaccine Group (as Administered)											
		BNT162b2 (30 µg)						Placebo					
Dose	Systemic Event	12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
	Vomiting <sup>e</sup>												
	Any	1097	29 (2.6)	(1.8, 3.8)	488	13 (2.7)	(1.4, 4.5)	1078	12 (1.1)	(0.6, 1.9)	496	9 (1.8)	(0.8, 3.4)
	Mild	1097	25 (2.3)	(1.5, 3.3)	488	10 (2.0)	(1.0, 3.7)	1078	11 (1.0)	(0.5, 1.8)	496	5 (1.0)	(0.3, 2.3)
	Moderate	1097	4 (0.4)	(0.1, 0.9)	488	3 (0.6)	(0.1, 1.8)	1078	1 (0.1)	(0.0, 0.5)	496	4 (0.8)	(0.2, 2.1)
	Severe	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Diarrhea <sup>f</sup>												
	Any	1097	65 (5.9)	(4.6, 7.5)	488	39 (8.0)	(5.7, 10.8)	1078	43 (4.0)	(2.9, 5.3)	496	26 (5.2)	(3.5, 7.6)
	Mild	1097	59 (5.4)	(4.1, 6.9)	488	32 (6.6)	(4.5, 9.1)	1078	38 (3.5)	(2.5, 4.8)	496	21 (4.2)	(2.6, 6.4)
	Moderate	1097	6 (0.5)	(0.2, 1.2)	488	5 (1.0)	(0.3, 2.4)	1078	5 (0.5)	(0.2, 1.1)	496	5 (1.0)	(0.3, 2.3)
	Severe	1097	0	(0.0, 0.3)	488	2 (0.4)	(0.0, 1.5)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	New or worsened muscle pain <sup>d</sup>												
	Any	1097	355 (32.4)	(29.6, 35.2)	488	199 (40.8)	(36.4, 45.3)	1078	90 (8.3)	(6.8, 10.2)	496	48 (9.7)	(7.2, 12.6)
	Mild	1097	152 (13.9)	(11.9, 16.0)	488	93 (19.1)	(15.7, 22.8)	1078	51 (4.7)	(3.5, 6.2)	496	29 (5.8)	(4.0, 8.3)
	Moderate	1097	197 (18.0)	(15.7, 20.4)	488	97 (19.9)	(16.4, 23.7)	1078	37 (3.4)	(2.4, 4.7)	496	18 (3.6)	(2.2, 5.7)
	Severe	1097	6 (0.5)	(0.2, 1.2)	488	9 (1.8)	(0.8, 3.5)	1078	2 (0.2)	(0.0, 0.7)	496	1 (0.2)	(0.0, 1.1)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	New or worsened joint pain <sup>d</sup>												

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population													
Vaccine Group (as Administered)													
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo					
		12-15 Years			16-25 Years			12-15 Years			16-25 Years		
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Any dose	Any	1097	173 (15.8)	(13.7, 18.1)	488	107 (21.9)	(18.3, 25.9)	1078	51 (4.7)	(3.5, 6.2)	496	20 (4.0)	(2.5, 6.2)
	Mild	1097	91 (8.3)	(6.7, 10.1)	488	49 (10.0)	(7.5, 13.1)	1078	30 (2.8)	(1.9, 3.9)	496	14 (2.8)	(1.6, 4.7)
	Moderate	1097	78 (7.1)	(5.7, 8.8)	488	54 (11.1)	(8.4, 14.2)	1078	21 (1.9)	(1.2, 3.0)	496	6 (1.2)	(0.4, 2.6)
	Severe	1097	4 (0.4)	(0.1, 0.9)	488	4 (0.8)	(0.2, 2.1)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Grade 4	1097	0	(0.0, 0.3)	488	0	(0.0, 0.8)	1078	0	(0.0, 0.3)	496	0	(0.0, 0.7)
	Any systemic event <sup>g</sup>	1097	904 (82.4)	(80.0, 84.6)	488	396 (81.1)	(77.4, 84.5)	1078	439 (40.7)	(37.8, 43.7)	496	183 (36.9)	(32.6, 41.3)
	Use of antipyretic or pain medication <sup>h</sup>	1097	557 (50.8)	(47.8, 53.8)	488	223 (45.7)	(41.2, 50.2)	1078	95 (8.8)	(7.2, 10.7)	496	59 (11.9)	(9.2, 15.1)
	Fever												
	≥38.0°C	1131	275 (24.3)	(21.8, 26.9)	535	113 (21.1)	(17.7, 24.8)	1129	17 (1.5)	(0.9, 2.4)	555	9 (1.6)	(0.7, 3.1)
	≥38.0°C to 38.4°C	1131	141 (12.5)	(10.6, 14.5)	535	63 (11.8)	(9.2, 14.8)	1129	11 (1.0)	(0.5, 1.7)	555	6 (1.1)	(0.4, 2.3)
	>38.4°C to 38.9°C	1131	100 (8.8)	(7.3, 10.6)	535	40 (7.5)	(5.4, 10.0)	1129	3 (0.3)	(0.1, 0.8)	555	2 (0.4)	(0.0, 1.3)
	>38.9°C to 40.0°C	1131	33 (2.9)	(2.0, 4.1)	535	10 (1.9)	(0.9, 3.4)	1129	3 (0.3)	(0.1, 0.8)	555	1 (0.2)	(0.0, 1.0)
	>40.0°C	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0	(0.0, 0.7)
	Fatigue <sup>d</sup>												
	Any	1131	876 (77.5)	(74.9, 79.9)	535	403 (75.3)	(71.4, 78.9)	1129	538 (47.7)	(44.7, 50.6)	555	240 (43.2)	(39.1, 47.5)
	Mild	1131	239 (21.1)	(18.8, 23.6)	535	104 (19.4)	(16.2, 23.1)	1129	266 (23.6)	(21.1, 26.1)	555	114 (20.5)	(17.3, 24.1)



Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population												
Vaccine Group (as Administered)												
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo				
		12-15 Years			16-25 Years			12-15 Years			16-25 Years	
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>
	Moderate	1131	597 (52.8)	(49.8, 55.7)	535	267 (49.9)	(45.6, 54.2)	1129	260 (23.0)	(20.6, 25.6)	555	119 (21.4) (18.1, 25.1)
	Severe	1131	40 (3.5)	(2.5, 4.8)	535	32 (6.0)	(4.1, 8.3)	1129	12 (1.1)	(0.6, 1.8)	555	7 (1.3) (0.5, 2.6)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Headache <sup>d</sup>											
	Any	1131	854 (75.5)	(72.9, 78.0)	535	386 (72.1)	(68.1, 75.9)	1129	506 (44.8)	(41.9, 47.8)	555	243 (43.8) (39.6, 48.0)
	Mild	1131	324 (28.6)	(26.0, 31.4)	535	140 (26.2)	(22.5, 30.1)	1129	303 (26.8)	(24.3, 29.5)	555	147 (26.5) (22.9, 30.4)
	Moderate	1131	499 (44.1)	(41.2, 47.1)	535	216 (40.4)	(36.2, 44.7)	1129	194 (17.2)	(15.0, 19.5)	555	87 (15.7) (12.8, 19.0)
	Severe	1131	31 (2.7)	(1.9, 3.9)	535	30 (5.6)	(3.8, 7.9)	1129	9 (0.8)	(0.4, 1.5)	555	9 (1.6) (0.7, 3.1)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Chills <sup>d</sup>											
	Any	1131	557 (49.2)	(46.3, 52.2)	535	256 (47.9)	(43.5, 52.2)	1129	159 (14.1)	(12.1, 16.3)	555	60 (10.8) (8.4, 13.7)
	Mild	1131	257 (22.7)	(20.3, 25.3)	535	117 (21.9)	(18.4, 25.6)	1129	114 (10.1)	(8.4, 12.0)	555	41 (7.4) (5.4, 9.9)
	Moderate	1131	276 (24.4)	(21.9, 27.0)	535	123 (23.0)	(19.5, 26.8)	1129	43 (3.8)	(2.8, 5.1)	555	18 (3.2) (1.9, 5.1)
	Severe	1131	24 (2.1)	(1.4, 3.1)	535	16 (3.0)	(1.7, 4.8)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2) (0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Vomiting <sup>e</sup>											
	Any	1131	59 (5.2)	(4.0, 6.7)	535	21 (3.9)	(2.4, 5.9)	1129	21 (1.9)	(1.2, 2.8)	555	16 (2.9) (1.7, 4.6)
	Mild	1131	54 (4.8)	(3.6, 6.2)	535	18 (3.4)	(2.0, 5.3)	1129	18 (1.6)	(0.9, 2.5)	555	11 (2.0) (1.0, 3.5)
	Moderate	1131	4 (0.4)	(0.1, 0.9)	535	3 (0.6)	(0.1, 1.6)	1129	3 (0.3)	(0.1, 0.8)	555	4 (0.7) (0.2, 1.8)
	Severe	1131	1 (0.1)	(0.0, 0.5)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	1 (0.2) (0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population												
Vaccine Group (as Administered)												
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo				
		12-15 Years			16-25 Years			12-15 Years			16-25 Years	
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>
	Diarrhea <sup>f</sup>											
	Any	1131	141 (12.5)	(10.6, 14.5)	535	81 (15.1)	(12.2, 18.5)	1129	106 (9.4)	(7.8, 11.2)	555	75 (13.5) (10.8, 16.6)
	Mild	1131	123 (10.9)	(9.1, 12.8)	535	67 (12.5)	(9.8, 15.6)	1129	91 (8.1)	(6.5, 9.8)	555	57 (10.3) (7.9, 13.1)
	Moderate	1131	18 (1.6)	(0.9, 2.5)	535	12 (2.2)	(1.2, 3.9)	1129	15 (1.3)	(0.7, 2.2)	555	18 (3.2) (1.9, 5.1)
	Severe	1131	0	(0.0, 0.3)	535	2 (0.4)	(0.0, 1.3)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	New or worsened muscle pain <sup>d</sup>											
	Any	1131	477 (42.2)	(39.3, 45.1)	535	261 (48.8)	(44.5, 53.1)	1129	196 (17.4)	(15.2, 19.7)	555	103 (18.6) (15.4, 22.0)
	Mild	1131	187 (16.5)	(14.4, 18.8)	535	108 (20.2)	(16.9, 23.8)	1129	110 (9.7)	(8.1, 11.6)	555	62 (11.2) (8.7, 14.1)
	Moderate	1131	282 (24.9)	(22.4, 27.6)	535	139 (26.0)	(22.3, 29.9)	1129	84 (7.4)	(6.0, 9.1)	555	40 (7.2) (5.2, 9.7)
	Severe	1131	8 (0.7)	(0.3, 1.4)	535	14 (2.6)	(1.4, 4.4)	1129	2 (0.2)	(0.0, 0.6)	555	1 (0.2) (0.0, 1.0)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	New or worsened joint pain <sup>d</sup>											
	Any	1131	229 (20.2)	(17.9, 22.7)	535	141 (26.4)	(22.7, 30.3)	1129	107 (9.5)	(7.8, 11.3)	555	42 (7.6) (5.5, 10.1)
	Mild	1131	122 (10.8)	(9.0, 12.7)	535	61 (11.4)	(8.8, 14.4)	1129	63 (5.6)	(4.3, 7.1)	555	26 (4.7) (3.1, 6.8)
	Moderate	1131	102 (9.0)	(7.4, 10.8)	535	73 (13.6)	(10.9, 16.8)	1129	44 (3.9)	(2.8, 5.2)	555	16 (2.9) (1.7, 4.6)
	Severe	1131	5 (0.4)	(0.1, 1.0)	535	7 (1.3)	(0.5, 2.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Grade 4	1131	0	(0.0, 0.3)	535	0	(0.0, 0.7)	1129	0	(0.0, 0.3)	555	0 (0.0, 0.7)
	Any systemic event <sup>g</sup>	1131	1026 (90.7)	(88.9, 92.3)	535	472 (88.2)	(85.2, 90.8)	1129	726 (64.3)	(61.4, 67.1)	555	343 (61.8) (57.6, 65.9)

Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population												
Vaccine Group (as Administered)												
Dose	Systemic Event	BNT162b2 (30 µg)						Placebo				
		12-15 Years			16-25 Years			12-15 Years			16-25 Years	
		N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	N <sup>a</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>
	Use of antipyretic or pain medication <sup>h</sup>	1131	664 (58.7)	(55.8, 61.6)	535	279 (52.1)	(47.8, 56.5)	1129	176 (15.6)	(13.5, 17.8)	555	95 (17.1) (14.1, 20.5)
<p>Note: Events and use of antipyretic or pain medication were collected in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. Grade 4 events were classified by the investigator or medically qualified person.</p> <p>Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.</p> <p>a. N = number of subjects reporting at least 1 yes or no response for the specified event after the specified dose.</p> <p>b. n = Number of subjects with the specified characteristic.</p> <p>c. Exact 2-sided CI based on the Clopper and Pearson method.</p> <p>d. Mild: does not interfere with activity; moderate: some interference with activity; severe: prevents daily activity; Grade 4: emergency room visit or hospitalization for severe fatigue, severe headache, severe chills, severe muscle pain, or severe joint pain.</p> <p>e. Mild: 1 to 2 times in 24 hours; moderate: &gt;2 times in 24 hours; severe: requires intravenous hydration; Grade 4: emergency room visit or hospitalization for severe vomiting.</p> <p>f. 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; Grade 4: emergency room visit or hospitalization for severe diarrhea.</p> <p>g. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.</p> <p>h. Severity was not collected for use of antipyretic or pain medication.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)</p> <p>(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s020_se_sev_ped_saf</p>												

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Fever (≥38.0°C)				
	n <sup>a</sup>	114	39	12	8
	Mean (SD)	1.1 (0.45)	1.1 (0.52)	1.7 (1.37)	1.9 (2.27)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 4)	(1, 4)	(1, 5)	(1, 7)
	Unknown <sup>b</sup>	0	0	0	1
	Fatigue				
	n <sup>a</sup>	677	318	457	213
	Mean (SD)	2.5 (3.20)	2.4 (2.08)	3.1 (2.92)	3.0 (2.67)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 45)	(1, 11)	(1, 22)	(1, 15)
	Unknown <sup>b</sup>	0	0	2	3
	Headache				
	n <sup>a</sup>	623	286	396	205
	Mean (SD)	2.4 (2.27)	2.5 (2.51)	2.7 (2.55)	2.9 (3.17)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 24)	(1, 25)	(1, 21)	(1, 22)
	Unknown <sup>b</sup>	0	0	1	2
	Chills				
	n <sup>a</sup>	311	133	109	47
	Mean (SD)	1.6 (1.48)	1.5 (1.28)	2.6 (2.87)	2.3 (1.82)

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 15)	(1, 8)	(1, 22)	(1, 7)
	Unknown <sup>b</sup>	1	1	2	1
	Vomiting				
	n <sup>a</sup>	31	9	10	9
	Mean (SD)	1.2 (0.88)	1.6 (1.33)	1.1 (0.32)	1.6 (1.13)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 5)	(1, 5)	(1, 2)	(1, 4)
	Diarrhea				
	n <sup>a</sup>	90	57	82	62
	Mean (SD)	1.6 (1.25)	1.7 (1.62)	1.7 (1.52)	1.7 (1.42)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 7)	(1, 9)	(1, 8)	(1, 7)
	New or worsened muscle pain				
	n <sup>a</sup>	272	143	148	78
	Mean (SD)	1.7 (1.28)	1.8 (1.65)	2.4 (3.02)	1.8 (1.95)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 9)	(1, 10)	(1, 22)	(1, 13)
	Unknown <sup>b</sup>	0	1	0	1
	New or worsened joint pain				
	n <sup>a</sup>	109	70	77	28

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
2	Mean (SD)	1.6 (1.33)	1.7 (2.83)	2.2 (2.88)	2.7 (2.60)
	Median	1.0	1.0	1.0	1.5
	Min, max	(1, 8)	(1, 24)	(1, 22)	(1, 12)
	Use of antipyretic or pain medication				
	n <sup>a</sup>	413	167	111	62
	Mean (SD)	1.6 (1.37)	1.7 (1.57)	2.1 (2.32)	3.2 (4.16)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 20)	(1, 10)	(1, 19)	(1, 23)
	Unknown <sup>b</sup>	0	0	1	2
	Fever (≥38.0°C)				
	n <sup>a</sup>	215	84	7	2
	Mean (SD)	1.0 (0.37)	1.1 (0.28)	3.0 (4.86)	1.0 (NE)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 6)	(1, 2)	(1, 14)	(1, 1)
	Unknown <sup>b</sup>	1	0	0	1
	Fatigue				
	n <sup>a</sup>	726	320	264	115
	Mean (SD)	2.1 (1.92)	2.2 (2.44)	2.8 (3.06)	3.3 (4.38)
	Median	1.0	1.0	2.0	2.0
	Min, max	(1, 23)	(1, 28)	(1, 37)	(1, 38)
	Unknown <sup>b</sup>	4	3	2	4

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Headache				
	n <sup>a</sup>	708	297	263	118
	Mean (SD)	2.1 (2.16)	2.1 (2.42)	2.5 (2.39)	3.5 (5.64)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 36)	(1, 24)	(1, 23)	(1, 35)
	Unknown <sup>b</sup>	6	1	3	3
	Chills				
	n <sup>a</sup>	455	195	73	22
	Mean (SD)	1.5 (1.07)	1.3 (0.91)	2.1 (1.90)	2.0 (1.41)
	Median	1.0	1.0	1.0	2.0
	Min, max	(1, 9)	(1, 11)	(1, 8)	(1, 6)
	Unknown <sup>b</sup>	1	1	1	1
	Vomiting				
	n <sup>a</sup>	29	13	12	9
	Mean (SD)	1.0 (0.19)	1.2 (0.38)	1.4 (0.90)	1.6 (1.67)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 2)	(1, 2)	(1, 4)	(1, 6)
	Diarrhea				
	n <sup>a</sup>	65	39	43	26
	Mean (SD)	2.1 (4.38)	1.4 (0.94)	1.5 (1.04)	4.4 (7.70)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 35)	(1, 5)	(1, 5)	(1, 33)

Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Unknown <sup>b</sup>	1	0	1	1
	New or worsened muscle pain				
	n <sup>a</sup>	355	199	90	48
	Mean (SD)	1.6 (1.49)	1.6 (1.82)	2.1 (1.84)	2.3 (2.04)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 17)	(1, 23)	(1, 9)	(1, 9)
	Unknown <sup>b</sup>	1	1	0	0
	New or worsened joint pain				
	n <sup>a</sup>	173	107	51	20
	Mean (SD)	1.5 (1.26)	1.6 (2.75)	2.7 (2.61)	2.2 (1.81)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 8)	(1, 28)	(1, 12)	(1, 8)
	Unknown <sup>b</sup>	2	2	0	0
	Use of antipyretic or pain medication				
	n <sup>a</sup>	557	223	95	59
	Mean (SD)	1.6 (1.37)	1.8 (2.64)	1.9 (2.61)	2.1 (2.28)
	Median	1.0	1.0	1.0	1.0
	Min, max	(1, 12)	(1, 28)	(1, 23)	(1, 15)
	Unknown <sup>b</sup>	3	0	2	2
Abbreviation: NE = not estimable.					
Note: Duration was calculated in days as the difference from the start of the first reported event to the resolution of the last reported event, inclusive. For symptoms that are ongoing at the time of the next dose, stop date is computed as the next dose date.					



Duration (Days) From First to Last Day of Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population				
		Vaccine Group (as Administered)		
		BNT162b2 (30 µg)		Placebo
		12-15 Years	16-25 Years	12-15 Years
Dose	Systemic Event			16-25 Years
<p>Note: Events and use of antipyretic or pain medication were recorded in the electronic diary (e-diary) from Day 1 through Day 7 after each dose. The resolution date for events lasting longer than 7 days was recorded on the subject's case report form.</p> <p>Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the e-diary, they do not appear in this table.</p> <p>a. n = Number of subjects reporting the specified event on any of the 7 days, including subjects with events of unknown duration.</p> <p>b. Includes those events where the resolution date is partial or missing.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adcevd Table Generation: 27MAR2021 (02:57) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s040_se_dur_ped_saf</p>				

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
Dose	Systemic Event	12-15 Years	16-25 Years	12-15 Years	16-25 Years
1	Fever (≥38.0°C)				
	n <sup>a</sup>	114	39	12	8
	Mean (SD)	2.1 (0.37)	2.4 (1.29)	3.6 (2.02)	3.0 (2.00)
	Median	2.0	2.0	3.0	2.5
	Min, max	(1, 5)	(1, 7)	(1, 7)	(1, 7)
	Fatigue				
	n <sup>a</sup>	677	318	457	213
	Mean (SD)	1.8 (0.99)	1.9 (1.15)	2.0 (1.49)	2.3 (1.63)
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n <sup>a</sup>	623	286	396	205
	Mean (SD)	2.1 (1.21)	2.2 (1.37)	2.4 (1.69)	2.4 (1.58)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n <sup>a</sup>	311	133	109	47
	Mean (SD)	2.1 (1.00)	2.2 (1.19)	2.9 (1.75)	2.9 (1.91)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Vomiting				

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
	n <sup>a</sup>	31	9	10	9
	Mean (SD)	3.0 (1.67)	3.4 (2.13)	3.0 (1.83)	3.2 (1.48)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 6)	(1, 5)
	Diarrhea				
	n <sup>a</sup>	90	57	82	62
	Mean (SD)	3.7 (1.79)	3.2 (1.48)	3.6 (1.85)	3.5 (1.81)
	Median	3.0	3.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n <sup>a</sup>	272	143	148	78
	Mean (SD)	2.1 (1.08)	2.2 (1.11)	2.5 (1.68)	3.0 (1.69)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n <sup>a</sup>	109	70	77	28
	Mean (SD)	2.5 (1.41)	2.5 (1.32)	3.0 (1.92)	3.4 (1.79)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event <sup>b</sup>				
	n <sup>a</sup>	877	403	636	311

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
2	Mean (SD)	1.8 (1.01)	1.8 (1.06)	1.9 (1.38)	2.1 (1.40)
	Median	2.0	2.0	1.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n <sup>a</sup>	413	167	111	62
	Mean (SD)	2.1 (0.91)	2.2 (1.03)	3.3 (1.93)	3.5 (1.90)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Fever (≥38.0°C)				
	n <sup>a</sup>	215	84	7	2
	Mean (SD)	2.0 (0.31)	2.0 (0.54)	3.0 (2.45)	1.5 (0.71)
	Median	2.0	2.0	2.0	1.5
	Min, max	(1, 4)	(1, 6)	(1, 7)	(1, 2)
	Fatigue				
	n <sup>a</sup>	726	320	264	115
	Mean (SD)	1.8 (0.67)	1.8 (0.79)	2.1 (1.59)	2.4 (1.48)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Headache				
	n <sup>a</sup>	708	297	263	118
	Mean (SD)	1.9 (0.66)	2.0 (0.92)	2.5 (1.68)	2.7 (1.83)

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Chills				
	n <sup>a</sup>	455	195	73	22
	Mean (SD)	2.0 (0.80)	1.9 (0.53)	2.8 (1.96)	3.0 (1.73)
	Median	2.0	2.0	2.0	3.0
	Min, max	(1, 7)	(1, 4)	(1, 7)	(1, 7)
	Vomiting				
	n <sup>a</sup>	29	13	12	9
	Mean (SD)	2.4 (1.12)	2.3 (0.85)	4.1 (1.62)	3.4 (2.35)
	Median	2.0	2.0	4.0	3.0
	Min, max	(1, 7)	(2, 5)	(2, 7)	(1, 7)
	Diarrhea				
	n <sup>a</sup>	65	39	43	26
	Mean (SD)	3.1 (1.55)	3.0 (1.48)	3.7 (2.06)	3.8 (1.97)
	Median	3.0	3.0	4.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened muscle pain				
	n <sup>a</sup>	355	199	90	48
	Mean (SD)	2.1 (0.83)	2.0 (0.72)	2.7 (1.90)	2.8 (1.66)
	Median	2.0	2.0	2.0	2.0

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose	Systemic Event	Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	New or worsened joint pain				
	n <sup>a</sup>	173	107	51	20
	Mean (SD)	2.1 (0.77)	2.0 (0.68)	2.9 (1.81)	3.8 (2.07)
	Median	2.0	2.0	2.0	4.0
	Min, max	(1, 6)	(1, 7)	(1, 7)	(1, 7)
	Any systemic event <sup>b</sup>				
	n <sup>a</sup>	904	396	439	183
	Mean (SD)	1.8 (0.77)	1.8 (0.88)	2.3 (1.70)	2.3 (1.46)
	Median	2.0	2.0	2.0	2.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
	Use of antipyretic or pain medication				
	n <sup>a</sup>	557	223	95	59
	Mean (SD)	2.0 (0.69)	2.0 (0.93)	3.2 (2.04)	3.0 (1.49)
	Median	2.0	2.0	3.0	3.0
	Min, max	(1, 7)	(1, 7)	(1, 7)	(1, 7)
Note: Day of onset is the first day the specified event was reported.					
Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this table.					
a. n = Number of subjects reporting the specified event, with each subject counted only once per event.					
b. Any systemic event: any fever ≥38.0°C, any fatigue, any vomiting, any chills, any diarrhea, any headache, any new or worsened muscle pain, or any new or worsened joint pain.					
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)					

Onset Days for Systemic Events – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population					
Dose      Systemic Event		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years	16-25 Years	12-15 Years	16-25 Years
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_s060_se_onset_ped_saf					

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population				
Adverse Event	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =1131) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =536) n <sup>b</sup> (%)	12-15 Years (N <sup>a</sup> =1129) n <sup>b</sup> (%)	16-25 Years (N <sup>a</sup> =561) n <sup>b</sup> (%)
Any event	68 (6.0)	58 (10.8)	67 (5.9)	45 (8.0)
Related <sup>c</sup>	33 (2.9)	33 (6.2)	21 (1.9)	12 (2.1)
Severe	7 (0.6)	9 (1.7)	2 (0.2)	3 (0.5)
Life-threatening	1 (0.1)	0	1 (0.1)	0
Any serious adverse event	4 (0.4)	2 (0.4)	1 (0.1)	2 (0.4)
Related <sup>c</sup>	0	0	0	0
Severe	2 (0.2)	2 (0.4)	0	1 (0.2)
Life-threatening	0	0	1 (0.1)	0
Any adverse event leading to withdrawal	2 (0.2)	1 (0.2)	0	2 (0.4)
Related <sup>c</sup>	1 (0.1)	1 (0.2)	0	0
Severe	1 (0.1)	1 (0.2)	0	0
Life-threatening	1 (0.1)	0	0	0
Death	0	0	0	0
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.				
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).				
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 = number of subjects reporting at least 1 occurrence of any event.				
c. Assessed by the investigator as related to investigational product.				



Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population				
Adverse Event	Vaccine Group (as Administered)			
	BNT162b2 (30 µg)		Placebo	
	12-15 Years (N <sup>a</sup> =1131)	16-25 Years (N <sup>a</sup> =536)	12-15 Years (N <sup>a</sup> =1129)	16-25 Years (N <sup>a</sup> =561)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)	n <sup>b</sup> (%)	n <sup>b</sup> (%)
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_pd2_ped_saf				

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), Subjects 12 Through 15 Years of Age – Safety Population**

Adverse Event	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131) n <sup>b</sup> (%)	Placebo (N <sup>a</sup> =1129) n <sup>b</sup> (%)
Any event	72 (6.4)	71 (6.3)
Related <sup>c</sup>	33 (2.9)	21 (1.9)
Severe	9 (0.8)	3 (0.3)
Life-threatening	1 (0.1)	1 (0.1)
Any serious adverse event	5 (0.4)	2 (0.2)
Related <sup>c</sup>	0	0
Severe	4 (0.4)	1 (0.1)
Life-threatening	0	1 (0.1)
Any adverse event leading to withdrawal	2 (0.2)	0
Related <sup>c</sup>	1 (0.1)	0
Severe	1 (0.1)	0
Life-threatening	1 (0.1)	0
Death	0	0

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

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 = number of subjects reporting at least 1 occurrence of any event.

c. Assessed by the investigator as related to investigational product.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_s091\_d1\_cut\_ped\_saf

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )
Any event		68 (6.0)	(4.7, 7.6)	58 (10.8)	(8.3, 13.8)	67 (5.9)	(4.6, 7.5)	45 (8.0)	(5.9, 10.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Lymphadenopathy		9 (0.8)	(0.4, 1.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
CARDIAC DISORDERS		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tachycardia		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
EAR AND LABYRINTH DISORDERS		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Ear pain		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Cerumen impaction		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
EYE DISORDERS		1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Eye pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Eyelid rash		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Ocular hyperaemia		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Retinal haemorrhage		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GASTROINTESTINAL DISORDERS		14 (1.2)	(0.7, 2.1)	5 (0.9)	(0.3, 2.2)	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.3)
Nausea		5 (0.4)	(0.1, 1.0)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
Diarrhoea		3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Abdominal pain	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Aphthous ulcer	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Lip swelling	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Gastritis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Inguinal hernia	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Rectal prolapse	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Toothache	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	(0.8, 2.3)	21 (3.9)	(2.4, 5.9)	11 (1.0)	(0.5, 1.7)	10 (1.8)	(0.9, 3.3)
Injection site pain	7 (0.6)	(0.2, 1.3)	10 (1.9)	(0.9, 3.4)	7 (0.6)	(0.2, 1.3)	2 (0.4)	(0.0, 1.3)
Fatigue	7 (0.6)	(0.2, 1.3)	7 (1.3)	(0.5, 2.7)	4 (0.4)	(0.1, 0.9)	3 (0.5)	(0.1, 1.6)
Pyrexia	5 (0.4)	(0.1, 1.0)	7 (1.3)	(0.5, 2.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Chills	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Injection site swelling	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Oedema peripheral	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Chest pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site bruising		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site discomfort		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site hyperaesthesia		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Nodule		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Peripheral swelling		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vessel puncture site pain		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
IMMUNE SYSTEM DISORDERS		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Food allergy		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS		7 (0.6)	(0.2, 1.3)	5 (0.9)	(0.3, 2.2)	7 (0.6)	(0.2, 1.3)	12 (2.1)	(1.1, 3.7)
Ear infection		3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Appendicitis		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Conjunctivitis		0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Otitis externa		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Otitis media		1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Sinusitis		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Tonsillitis		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Vulvovaginal mycotic infection	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Body tinea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Candida infection	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Cellulitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Cystitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Focal peritonitis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Folliculitis	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Genital herpes	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Genital herpes simplex	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Impetigo	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Infectious mononucleosis	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Oral fungal infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pharyngitis streptococcal	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pilonidal cyst	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Subcutaneous abscess	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Tinea capitis	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tinea infection	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Urinary tract infection	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Vulval abscess	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.7)	(0.3, 1.4)	3 (0.6)	(0.1, 1.6)	10 (0.9)	(0.4, 1.6)	6 (1.1)	(0.4, 2.3)
Ligament sprain	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)
Concussion	3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Accident	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Clavicle fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Contusion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Exposure during pregnancy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Fall	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Muscle strain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Procedural pain	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Tooth fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Fibula fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Flail chest	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Foot fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Hand fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Humerus fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Joint dislocation	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Lip injury	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Meniscus injury	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Patella fracture	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Radius fracture	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Road traffic accident	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INVESTIGATIONS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Electrocardiogram QT prolonged	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Decreased appetite	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.8)	(0.4, 1.5)	12 (2.2)	(1.2, 3.9)	8 (0.7)	(0.3, 1.4)	8 (1.4)	(0.6, 2.8)
Arthralgia	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	3 (0.3)	(0.1, 0.8)	4 (0.7)	(0.2, 1.8)
Myalgia	3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.4)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pain in extremity	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Arthropathy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Joint swelling	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Limb mass	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Mobility decreased	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)



**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Musculoskeletal chest pain		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Musculoskeletal discomfort		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Neck pain		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Osteochondrosis		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Plantar fasciitis		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Spinal disorder		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Torticollis		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Fibroadenoma of breast		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Skin papilloma		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS		12 (1.1)	(0.5, 1.8)	13 (2.4)	(1.3, 4.1)	7 (0.6)	(0.2, 1.3)	7 (1.2)	(0.5, 2.6)
Headache		5 (0.4)	(0.1, 1.0)	11 (2.1)	(1.0, 3.6)	4 (0.4)	(0.1, 0.9)	5 (0.9)	(0.3, 2.1)
Dizziness		2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
Migraine		2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Presyncope		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Burning sensation		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Neuralgia		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Paraesthesia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	7 (0.6)	(0.2, 1.3)	5 (0.9)	(0.3, 2.2)	5 (0.4)	(0.1, 1.0)	1 (0.2)	(0.0, 1.0)
Depression	3 (0.3)	(0.1, 0.8)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)
Attention deficit hyperactivity disorder	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Depressed mood	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Disorientation	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Generalised anxiety disorder	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Sleep terror	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tic	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Cervical dysplasia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	4 (0.4)	(0.1, 0.9)	4 (0.7)	(0.2, 1.8)
Rhinorrhoea	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Oropharyngeal pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	3 (0.5)	(0.1, 1.6)
Asthma	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Nasal congestion	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Reflux laryngitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	6 (0.5)	(0.2, 1.2)	5 (0.9)	(0.3, 2.2)	13 (1.2)	(0.6, 2.0)	2 (0.4)	(0.0, 1.3)
Rash	2 (0.2)	(0.0, 0.6)	3 (0.6)	(0.1, 1.6)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Urticaria	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Acne	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Dermatitis contact	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Macule	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Pityriasis rosea	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Rash erythematous	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Seborrhoeic dermatitis	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
SURGICAL AND MEDICAL PROCEDURES	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Sclerotherapy	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Tooth extraction	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Wisdom teeth removal	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).

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. For "any event," n = number of subjects reporting at least 1 occurrence of

**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term		Vaccine Group (as Administered)			
		BNT162b2 (30 µg)		Placebo	
		12-15 Years (N <sup>a</sup> =1131)	16-25 Years (N <sup>a</sup> =536)	12-15 Years (N <sup>a</sup> =1129)	16-25 Years (N <sup>a</sup> =561)
		n <sup>b</sup> (%) (95% CI) <sup>c</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>	n <sup>b</sup> (%) (95% CI) <sup>c</sup>

any event.  
c. Exact 2-sided CI based on the Clopper and Pearson method.  
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)  
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_s130\_1md2\_soc\_ped\_saf

<b>Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population</b>									
<b>System Organ Class Preferred Term</b>		<b>Vaccine Group (as Administered)</b>							
		<b>BNT162b2 (30 µg)</b>				<b>Placebo</b>			
		<b>12-15 Years (N<sup>a</sup>=1131)</b>		<b>16-25 Years (N<sup>a</sup>=536)</b>		<b>12-15 Years (N<sup>a</sup>=1129)</b>		<b>16-25 Years (N<sup>a</sup>=561)</b>	
		<b>n<sup>b</sup> (%)</b>	<b>(95% CI<sup>c</sup>)</b>	<b>n<sup>b</sup> (%)</b>	<b>(95% CI<sup>c</sup>)</b>	<b>n<sup>b</sup> (%)</b>	<b>(95% CI<sup>c</sup>)</b>	<b>n<sup>b</sup> (%)</b>	<b>(95% CI<sup>c</sup>)</b>
Any event		4 (0.4)	(0.1, 0.9)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)
GASTROINTESTINAL DISORDERS		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Abdominal pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Inguinal hernia		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INFECTIONS AND INFESTATIONS		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Appendicitis		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Focal peritonitis		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Flail chest		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
NERVOUS SYSTEM DISORDERS		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Neuralgia		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS		3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression		3 (0.3)	(0.1, 0.8)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Note: MedDRA (v23.1) coding dictionary applied.									

**Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through 1 Month After Dose 2, by  
System Organ Class and Preferred Term –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).

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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_s130\_1md2\_ser\_ped\_saf

Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
Vaccine Group (as Administered)									
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
System Organ Class Preferred Term		n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )
Any event		33 (2.9)	(2.0, 4.1)	33 (6.2)	(4.3, 8.5)	21 (1.9)	(1.2, 2.8)	12 (2.1)	(1.1, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		7 (0.6)	(0.2, 1.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
	Lymphadenopathy	7 (0.6)	(0.2, 1.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
EYE DISORDERS		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Eyelid rash	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
GASTROINTESTINAL DISORDERS		11 (1.0)	(0.5, 1.7)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
	Nausea	5 (0.4)	(0.1, 1.0)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Diarrhoea	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
	Abdominal pain	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Aphthous ulcer	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Lip swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Mouth swelling	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Oral mucosal blistering	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
	Vomiting	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		15 (1.3)	(0.7, 2.2)	19 (3.5)	(2.1, 5.5)	9 (0.8)	(0.4, 1.5)	9 (1.6)	(0.7, 3.0)
	Injection site pain	7 (0.6)	(0.2, 1.3)	10 (1.9)	(0.9, 3.4)	7 (0.6)	(0.2, 1.3)	2 (0.4)	(0.0, 1.3)

**Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by  
System Organ Class and Preferred Term –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Fatigue		7 (0.6)	(0.2, 1.3)	7 (1.3)	(0.5, 2.7)	3 (0.3)	(0.1, 0.8)	3 (0.5)	(0.1, 1.6)
Pyrexia		5 (0.4)	(0.1, 1.0)	7 (1.3)	(0.5, 2.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Chills		1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Injection site swelling		1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site bruising		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site discomfort		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site hyperaesthesia		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pain		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Peripheral swelling		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
METABOLISM AND NUTRITION DISORDERS		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Decreased appetite		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		3 (0.3)	(0.1, 0.8)	10 (1.9)	(0.9, 3.4)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Myalgia		3 (0.3)	(0.1, 0.8)	6 (1.1)	(0.4, 2.4)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Arthralgia		0	(0.0, 0.3)	3 (0.6)	(0.1, 1.6)	0	(0.0, 0.3)	0	(0.0, 0.7)
Back pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Musculoskeletal discomfort		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)



**Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by  
System Organ Class and Preferred Term –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
NERVOUS SYSTEM DISORDERS	5 (0.4)	(0.1, 1.0)	12 (2.2)	(1.2, 3.9)	5 (0.4)	(0.1, 1.0)	4 (0.7)	(0.2, 1.8)
Headache	3 (0.3)	(0.1, 0.8)	11 (2.1)	(1.0, 3.6)	3 (0.3)	(0.1, 0.8)	3 (0.5)	(0.1, 1.6)
Dizziness	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Migraine	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Presyncope	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Disorientation	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Oropharyngeal pain	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Rhinorrhoea	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	7 (0.6)	(0.2, 1.3)	0	(0.0, 0.7)
Urticaria	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	0	(0.0, 0.7)
Rash	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Rash maculo-papular	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years

**Number (%) of Subjects Reporting at Least 1 Related Adverse Event From Dose 1 Through 1 Month After Dose 2, by  
System Organ Class and Preferred Term –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>

of age who received an electronic diary (e-diary).

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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_s130\_1md2\_rel\_ped\_saf

Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
Vaccine Group (as Administered)									
System Organ Class Preferred Term		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Any event		7 (0.6)	(0.2, 1.3)	9 (1.7)	(0.8, 3.2)	2 (0.2)	(0.0, 0.6)	3 (0.5)	(0.1, 1.6)
GASTROINTESTINAL DISORDERS		0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
Abdominal pain		0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		2 (0.2)	(0.0, 0.6)	4 (0.7)	(0.2, 1.9)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Pyrexia		2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Fatigue		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site erythema		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site pain		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site swelling		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Appendicitis		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Otitis externa		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Flail chest		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Patella fracture		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)

**Number (%) of Subjects Reporting at Least 1 Severe Adverse Event From Dose 1 Through 1 Month After Dose 2,  
by System Organ Class and Preferred Term –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.1)	(0.0, 0.5)	2 (0.4)	(0.0, 1.3)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Arthralgia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Back pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Myalgia	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Headache	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Migraine	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).

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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.

c. Exact 2-sided CI based on the Clopper and Pearson method.

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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adae\_s130\_1md2\_sev\_ped\_saf

Number (%) of Subjects Reporting at Least 1 Life-Threatening Adverse Event From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Any event		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pyrexia		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
INFECTIONS AND INFESTATIONS		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Appendicitis		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Focal peritonitis		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Note: MedDRA (v23.1) coding dictionary applied.									
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.									
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).									
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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.									
c. Exact 2-sided CI based on the Clopper and Pearson method.									
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (01:37)									
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_life_ped_saf									

**Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term	Vaccine Group (as Administered)							
	BNT162b2 (30 µg)				Placebo			
	12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )
Any event	2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Injection site pain	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Pyrexia	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
Exposure during pregnancy	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	2 (0.4)	(0.0, 1.3)
NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
Headache	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)	0	(0.0, 0.3)	0	(0.0, 0.7)
PSYCHIATRIC DISORDERS	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Anxiety	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Depression	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)

Note: MedDRA (v23.1) coding dictionary applied.

Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.

Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).

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. For "any event," n = number of subjects reporting at least 1 occurrence of

**Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 Through 1 Month After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population**

System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>

any event.  
c. Exact 2-sided CI based on the Clopper and Pearson method.  
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Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 1, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
Vaccine Group (as Administered)									
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1131)		16-25 Years (N <sup>a</sup> =536)		12-15 Years (N <sup>a</sup> =1129)		16-25 Years (N <sup>a</sup> =561)	
System Organ Class	Preferred Term	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
	Any event	0	(0.0, 0.3)	0	(0.0, 0.7)	4 (0.4)	(0.1, 0.9)	2 (0.4)	(0.0, 1.3)
	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	0	(0.0, 0.3)	0	(0.0, 0.7)	3 (0.3)	(0.1, 0.8)	2 (0.4)	(0.0, 1.3)
	Injection site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	3 (0.3)	(0.1, 0.8)	1 (0.2)	(0.0, 1.0)
	Injection site erythema	0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
	Vessel puncture site pain	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
	NERVOUS SYSTEM DISORDERS	0	(0.0, 0.3)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
	Dizziness	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
	Headache	0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Note: MedDRA (v23.1) coding dictionary applied.									
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).									
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.									
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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.									
c. Exact 2-sided CI based on the Clopper and Pearson method.									
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Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population									
System Organ Class Preferred Term		Vaccine Group (as Administered)							
		BNT162b2 (30 µg)				Placebo			
		12-15 Years (N <sup>a</sup> =1124)		16-25 Years (N <sup>a</sup> =523)		12-15 Years (N <sup>a</sup> =1117)		16-25 Years (N <sup>a</sup> =535)	
		n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>	n <sup>b</sup> (%)	(95% CI) <sup>c</sup>
Any event		2 (0.2)	(0.0, 0.6)	1 (0.2)	(0.0, 1.1)	3 (0.3)	(0.1, 0.8)	2 (0.4)	(0.0, 1.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.1)	2 (0.2)	(0.0, 0.6)	2 (0.4)	(0.0, 1.3)
Injection site pain		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	2 (0.2)	(0.0, 0.6)	0	(0.0, 0.7)
Fatigue		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	1 (0.2)	(0.0, 1.0)
Chills		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Injection site bruising		0	(0.0, 0.3)	0	(0.0, 0.7)	0	(0.0, 0.3)	1 (0.2)	(0.0, 1.0)
Injection site hyperaesthesia		0	(0.0, 0.3)	1 (0.2)	(0.0, 1.1)	0	(0.0, 0.3)	0	(0.0, 0.7)
NERVOUS SYSTEM DISORDERS		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
Dizziness		1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)	0	(0.0, 0.3)	0	(0.0, 0.7)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Rash maculo-papular		0	(0.0, 0.3)	0	(0.0, 0.7)	1 (0.1)	(0.0, 0.5)	0	(0.0, 0.7)
Note: MedDRA (v23.1) coding dictionary applied.									
Note: This table includes all subjects 12 through 15 years of age (all of whom are in the reactogenicity subset) and the subset of subjects 16 through 25 years of age who received an electronic diary (e-diary).									
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.									
Note: Subjects who did not receive Dose 2 or who received a different vaccine at each dose were excluded from this table.									
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. For "any event," n = number of subjects reporting at least 1 occurrence of									

Number (%) of Subjects Reporting at Least 1 Immediate Adverse Event After Dose 2, by System Organ Class and Preferred Term – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population							
Vaccine Group (as Administered)							
BNT162b2 (30 µg)				Placebo			
12-15 Years (N <sup>a</sup> =1124)		16-25 Years (N <sup>a</sup> =523)		12-15 Years (N <sup>a</sup> =1117)		16-25 Years (N <sup>a</sup> =535)	
System Organ Class							
Preferred Term	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%)	(95% CI <sup>c</sup> )	n <sup>b</sup> (%) (95% CI <sup>c</sup> )
any event.							
c. Exact 2-sided CI based on the Clopper and Pearson method.							
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Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Any event	72 (6.4)	71 (6.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	9 (0.8)	2 (0.2)
Lymphadenopathy	9 (0.8)	2 (0.2)
EAR AND LABYRINTH DISORDERS	1 (0.1)	2 (0.2)
Ear pain	1 (0.1)	1 (0.1)
Cerumen impaction	0	1 (0.1)
EYE DISORDERS	1 (0.1)	1 (0.1)
Eyelid rash	1 (0.1)	0
Retinal haemorrhage	0	1 (0.1)
GASTROINTESTINAL DISORDERS	14 (1.2)	3 (0.3)
Nausea	5 (0.4)	1 (0.1)
Diarrhoea	3 (0.3)	1 (0.1)
Abdominal pain	2 (0.2)	0
Aphthous ulcer	1 (0.1)	0
Constipation	1 (0.1)	0
Gastritis	1 (0.1)	0
Lip swelling	1 (0.1)	0
Mouth swelling	1 (0.1)	0
Oral mucosal blistering	1 (0.1)	0

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Rectal prolapse	1 (0.1)	0
Toothache	0	1 (0.1)
Vomiting	1 (0.1)	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	16 (1.4)	11 (1.0)
Injection site pain	7 (0.6)	7 (0.6)
Fatigue	7 (0.6)	4 (0.4)
Pyrexia	5 (0.4)	0
Chills	1 (0.1)	1 (0.1)
Injection site swelling	1 (0.1)	0
Nodule	1 (0.1)	0
Oedema peripheral	0	1 (0.1)
Peripheral swelling	1 (0.1)	0
Vessel puncture site pain	0	1 (0.1)
IMMUNE SYSTEM DISORDERS	0	1 (0.1)
Food allergy	0	1 (0.1)
INFECTIONS AND INFESTATIONS	7 (0.6)	8 (0.7)
Ear infection	3 (0.3)	0
Appendicitis	0	2 (0.2)
Conjunctivitis	0	2 (0.2)
Body tinea	1 (0.1)	0
Candida infection	0	1 (0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Focal peritonitis	0	1 (0.1)
Infectious mononucleosis	0	1 (0.1)
Otitis externa	1 (0.1)	0
Otitis media	1 (0.1)	0
Pilonidal cyst	0	1 (0.1)
Subcutaneous abscess	0	1 (0.1)
Tinea capitis	1 (0.1)	0
Vulval abscess	1 (0.1)	0
Vulvovaginal mycotic infection	1 (0.1)	0
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	9 (0.8)	13 (1.2)
Concussion	3 (0.3)	2 (0.2)
Ligament sprain	1 (0.1)	2 (0.2)
Accident	1 (0.1)	1 (0.1)
Clavicle fracture	1 (0.1)	1 (0.1)
Contusion	1 (0.1)	1 (0.1)
Fall	1 (0.1)	1 (0.1)
Muscle strain	1 (0.1)	1 (0.1)
Procedural pain	0	2 (0.2)
Tooth fracture	0	2 (0.2)
Foot fracture	0	1 (0.1)
Hand fracture	1 (0.1)	0

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Humerus fracture	0	1 (0.1)
Lip injury	0	1 (0.1)
Patella fracture	0	1 (0.1)
Radius fracture	1 (0.1)	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.8)	8 (0.7)
Arthralgia	2 (0.2)	3 (0.3)
Myalgia	3 (0.3)	2 (0.2)
Joint swelling	0	1 (0.1)
Limb mass	1 (0.1)	0
Mobility decreased	1 (0.1)	0
Musculoskeletal chest pain	0	1 (0.1)
Neck pain	0	1 (0.1)
Osteochondrosis	1 (0.1)	0
Pain in extremity	1 (0.1)	0
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	0	2 (0.2)
Fibroadenoma of breast	0	1 (0.1)
Skin papilloma	0	1 (0.1)
NERVOUS SYSTEM DISORDERS	13 (1.1)	7 (0.6)
Headache	5 (0.4)	4 (0.4)
Dizziness	2 (0.2)	1 (0.1)
Presyncope	1 (0.1)	2 (0.2)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Migraine	2 (0.2)	0
Neuralgia	1 (0.1)	0
Paraesthesia	1 (0.1)	0
Syncope	1 (0.1)	0
PSYCHIATRIC DISORDERS	8 (0.7)	5 (0.4)
Depression	3 (0.3)	2 (0.2)
Anxiety	1 (0.1)	2 (0.2)
Attention deficit hyperactivity disorder	0	1 (0.1)
Disorientation	1 (0.1)	0
Generalised anxiety disorder	1 (0.1)	0
Sleep terror	1 (0.1)	0
Suicidal ideation	1 (0.1)	0
Tic	1 (0.1)	0
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	2 (0.2)	4 (0.4)
Rhinorrhoea	1 (0.1)	4 (0.4)
Nasal congestion	1 (0.1)	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	7 (0.6)	13 (1.2)
Rash	3 (0.3)	4 (0.4)
Urticaria	2 (0.2)	4 (0.4)
Acne	1 (0.1)	2 (0.2)
Dermatitis contact	1 (0.1)	1 (0.1)

Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
Pityriasis rosea	0	1 (0.1)
Rash maculo-papular	0	1 (0.1)
<p>Note: MedDRA (v23.1) coding dictionary applied.</p> <p>Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.</p> <p>a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.</p> <p>b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (04:09)</p> <p>(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d1_cut_soc_ped_saf</p>		



Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 Through Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Subjects 12 Through 15 Years of Age – Safety Population		
System Organ Class Preferred Term	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)	Placebo (N <sup>a</sup> =1129)
	n <sup>b</sup> (%)	n <sup>b</sup> (%)
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
Note: MedDRA (v23.1) coding dictionary applied.		
Note: Adverse events that occurred on the day of or after subjects were unblinded are excluded from this summary.		
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. For "any event," n = number of subjects reporting at least 1 occurrence of any event.		
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (04:09)		
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_d1_cut_ser_ped_saf		

**Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) –  
Dose 2 Evaluable Immunogenicity Population**

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	155	11.2 (10.3, 12.3)	136	10.5 (9.9, 11.2)	29	11.2 (8.9, 14.0)	24	10.0 (10.0, 10.0)
		POS	8	54.1 (19.7, 148.7)	5	38.6 (6.4, 232.9)	1	251.0 (NE, NE)	0	NE (NE, NE)
		NEG	146	10.3 (9.7, 10.9)	131	10.0 (10.0, 10.0)	27	10.0 (10.0, 10.0)	24	10.0 (10.0, 10.0)
	2/1 Month	ALL	207	1283.0 (1139.6, 1444.5)	185	730.8 (646.7, 825.8)	36	15.1 (10.7, 21.4)	32	10.7 (9.3, 12.4)
		POS	10	2342.2 (1308.7, 4191.8)	8	1439.2 (727.1, 2848.7)	2	191.0 (1.2, 30873.6)	1	10.0 (NE, NE)
		NEG	192	1239.2 (1096.6, 1400.5)	177	708.7 (626.4, 802.0)	33	13.1 (9.7, 17.7)	31	10.8 (9.3, 12.5)

Abbreviations: COVID-19 = coronavirus disease 2019; GMT = geometric mean titer; LLOQ = lower limit of quantitation;  
NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; NE = not estimable; NEG = negative;  
NT50 = 50% neutralizing titer; POS = positive; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.

**Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) –  
Dose 2 Evaluable Immunogenicity Population**

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )	
Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	n <sup>c</sup>		n <sup>c</sup>		n <sup>c</sup>		n <sup>c</sup>	

c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.

d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$ .

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s001\_gm\_ped\_eval

**Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) –  
Dose 2 All-Available Immunogenicity Population**

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMT <sup>d</sup> (95% CI <sup>d</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	156	11.2 (10.2, 12.3)	140	10.5 (9.9, 11.1)	29	11.2 (8.9, 14.0)	25	10.0 (10.0, 10.0)
		POS	8	54.1 (19.7, 148.7)	5	38.6 (6.4, 232.9)	1	251.0 (NE, NE)	0	NE (NE, NE)
		NEG	147	10.3 (9.7, 10.9)	135	10.0 (10.0, 10.0)	27	10.0 (10.0, 10.0)	25	10.0 (10.0, 10.0)
	2/1 Month	ALL	208	1284.4 (1141.4, 1445.2)	190	726.3 (643.9, 819.1)	36	15.1 (10.7, 21.4)	34	10.7 (9.3, 12.2)
		POS	10	2342.2 (1308.7, 4191.8)	8	1439.2 (727.1, 2848.7)	2	191.0 (1.2, 30873.6)	1	10.0 (NE, NE)
		NEG	193	1240.9 (1098.7, 1401.5)	182	704.7 (624.1, 795.9)	33	13.1 (9.7, 17.7)	33	10.7 (9.3, 12.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMT = geometric mean titer; LLOQ = lower limit of quantitation;  
NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; NE = not estimable; NEG = negative;  
NT50 = 50% neutralizing titer; POS = positive; Prevax = before vaccination; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.

**Summary of Geometric Mean Titers, by Baseline SARS-CoV-2 Status – NT50 –  
Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) –  
Dose 2 All-Available Immunogenicity Population**

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )		GMT <sup>d</sup> (95% CI <sup>d</sup> )	
Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	n <sup>c</sup>		n <sup>c</sup>		n <sup>c</sup>		n <sup>c</sup>	

c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.

d. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$ .

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s001\_gm\_ped\_aai

**Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population**

Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	118.3 (101.4, 137.9)	135	71.2 (61.3, 82.7)	29	1.4 (1.0, 1.9)	24	1.1 (0.9, 1.3)
		POS	8	47.6 (26.4, 86.0)	5	47.1 (3.1, 721.4)	1	1.1 (NE, NE)	0	NE (NE, NE)
		NEG	145	125.0 (106.9, 146.2)	130	72.3 (62.9, 83.2)	27	1.4 (1.0, 2.0)	24	1.1 (0.9, 1.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.

c. n = Number of subjects with valid and determinate assay results for the specified assay both prevaccination time points and at the given dose/sampling time point.

d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s002\_gmfr\_ped\_eval

**Summary of Geometric Mean Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 All-Available Immunogenicity Population**

Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
			n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )	n <sup>c</sup>	GMFR <sup>d</sup> (95% CI <sup>d</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	155	118.5 (101.7, 138.0)	139	70.3 (60.7, 81.5)	29	1.4 (1.0, 1.9)	25	1.1 (0.9, 1.3)
		POS	8	47.6 (26.4, 86.0)	5	47.1 (3.1, 721.4)	1	1.1 (NE, NE)	0	NE (NE, NE)
		NEG	146	125.2 (107.2, 146.3)	134	71.4 (62.2, 81.9)	27	1.4 (1.0, 2.0)	25	1.1 (0.9, 1.3)

Abbreviations: COVID-19 = coronavirus disease 2019; GMFR = geometric mean fold rise; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; N-binding = SARS-CoV-2 nucleoprotein-binding; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status.

c. n = Number of subjects with valid and determinate assay results for the specified assay both prevaccination time points and at the given dose/sampling time point.

d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (06:15)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s002\_gmfr\_ped\_aai

**Summary of Geometric Mean Ratio – NT50 –  
Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity Subset) –  
Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population**

Vaccine Group (as Randomized)							
BNT162b2 (30 µg)							
Assay	Dose/ Sampling Time Point <sup>a</sup>	12-15 Years		16-25 Years		12-15 Years/16-25 Years	
		n <sup>b</sup>	GMT <sup>c</sup> (95% CI <sup>c</sup> )	n <sup>b</sup>	GMT <sup>c</sup> (95% CI <sup>c</sup> )	GMR <sup>d</sup> (95% CI <sup>d</sup> )	Met Noninferiority Objective <sup>e</sup> (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	190	1239.5 (1095.5, 1402.5)	170	705.1 (621.4, 800.2)	1.76 (1.47, 2.10)	Y

Abbreviations: GMR = geometric mean ratio; GMT = geometric mean titer; LLOQ = lower limit of quantitation;

NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Subjects who had no serological or virological evidence (up to 1 month 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 up to 1 month after Dose 2 were included in the analysis.

a. Protocol-specified timing for blood sample collection.

b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.

c. GMTs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$ .

d. GMRs and 2-sided 95% CIs were calculated by exponentiating the mean difference of the logarithms of the titers (Group 1 [12-15 years] – Group 2 [16-25 years]) and the corresponding CI (based on the Student t distribution).

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s001\_gmr\_ped\_ev\_eval



**Number (%) of Subjects Achieving a  $\geq 4$ -Fold Rise From Before Vaccination to Each Subsequent Time Point, by Baseline SARS-CoV-2 Status – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population**

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)				Placebo			
			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point <sup>a</sup>	Baseline SARS-CoV-2 Status <sup>b</sup>	N <sup>c</sup>	n <sup>d</sup> (%) (95% CI <sup>e</sup> )	N <sup>c</sup>	n <sup>d</sup> (%) (95% CI <sup>e</sup> )	N <sup>c</sup>	n <sup>d</sup> (%) (95% CI <sup>e</sup> )	N <sup>c</sup>	n <sup>d</sup> (%) (95% CI <sup>e</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	151 (98.1) (94.4, 99.6)	135	134 (99.3) (95.9, 100.0)	29	1 (3.4) (0.1, 17.8)	24	1 (4.2) (0.1, 21.1)
		POS	8	8 (100.0) (63.1, 100.0)	5	4 (80.0) (28.4, 99.5)	1	0 (0.0) (0.0, 97.5)	0	0 (NE) (NE, NE)
		NEG	145	142 (97.9) (94.1, 99.6)	130	130 (100.0) (97.2, 100.0)	27	1 (3.7) (0.1, 19.0)	24	1 (4.2) (0.1, 21.1)

Abbreviations: LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Baseline assay results below the LLOQ were set to LLOQ in the analysis.

a. Protocol-specified timing for blood sample collection.

b. POS = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. NEG = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. ALL = irrespective of baseline SARS-CoV-2 status, including missing baseline status

c. N = number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point. These values are the denominators for the percentage calculations.

d. n = Number of subjects with  $\geq 4$ -fold rise from before vaccination for the given assay at the given dose/sampling time point.

e. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (06:29)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s001\_4fold\_ped\_eval

**Number (%) of Subjects Achieving a  $\geq 4$ -Fold Rise From Before Vaccination to Each Subsequent Time Point  
1 Month After Dose 2 – NT50 – Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25  
Years of Age (Immunogenicity Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 –  
Dose 2 Evaluable Immunogenicity Population**

		Vaccine Group (as Randomized)					
		BNT162b2 (30 µg)					
		12-15 Years		16-25 Years		Difference	
Assay	Dose/ Sampling Time Point <sup>a</sup>	N <sup>b</sup>	n <sup>c</sup> (%) (95% CI <sup>d</sup> )	N <sup>b</sup>	n <sup>c</sup> (%) (95% CI <sup>d</sup> )	% <sup>e</sup>	(95% CI <sup>f</sup> )
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	143	140 (97.9) (94.0, 99.6)	124	124 (100.0) (97.1, 100.0)	-2.1	(-6.0, 0.9)

Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Subjects who had no serological or virological evidence (up to 1 month 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 up to 1 month after Dose 2 were included in the analysis.

Note: Baseline assay results below the LLOQ were set to LLOQ in the analysis.

a. Protocol-specified timing for blood sample collection.

b. N = number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point. These values are the denominators for the percentage calculations.

c. n = Number of subjects with  $\geq 4$ -fold rise from before vaccination for the given assay at the given dose/sampling time point.

d. Exact 2-sided CI based on the Clopper and Pearson method.

e. Difference in proportions, expressed as a percentage (12-15 years – 16-25 years).

f. 2-Sided CI, based on the Miettinen and Nurminen method for the difference in proportions, expressed as a percentage.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (05:56)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adva\_s003\_4fold\_ped\_eval

**Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2**  
**– Blinded Placebo-Controlled Follow-up Period**  
**– Subjects 12 Through 15 Years of Age and Without Evidence of Infection Prior to 7 Days After Dose 2**  
**– Evaluable Efficacy (7 Days) Population**

Efficacy Endpoint	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N <sup>a</sup> =1005)			Placebo (N <sup>a</sup> =978)		
	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	VE (%)	(95% CI <sup>e</sup> )
First COVID-19 occurrence from 7 days after Dose 2	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.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 30MAR2021 (22:23)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adc19ef\_ve\_cov\_7pd2\_peds\_wo\_eval

**Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2**  
**– Blinded Placebo-Controlled Follow-up Period**  
**– Subjects 12 Through 15 Years of Age and With or Without Evidence of Infection Prior to 7 Days After Dose 2**  
**– Evaluable Efficacy (7 Days) Population**

Efficacy Endpoint	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N <sup>a</sup> =1119)			Placebo (N <sup>a</sup> =1110)		
	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	VE (%)	(95% CI <sup>e</sup> )
First COVID-19 occurrence from 7 days after Dose 2	0	0.170 (1109)	18	0.163 (1094)	100.0	(78.1, 100.0)

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 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.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 30MAR2021 (22:24)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adc19ef\_ve\_cov\_7pd2\_peds\_eval

**Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period  
– Subjects 12 Through 15 Years of Age – Dose 1 All-Available Efficacy Population**

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized)				VE (%)	(95% CI <sup>e</sup> )
	BNT162b2 (30 µg) (N <sup>a</sup> =1131)		Placebo (N <sup>a</sup> =1129)			
	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )	n1 <sup>b</sup>	Surveillance Time <sup>c</sup> (n2 <sup>d</sup> )		
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)
After Dose 1 to <11 days after Dose 1	3		4		25.0	(-343.3, 89.0)
≥11 Days after Dose 1 to before Dose 2	0		8		100.0	(41.4, 100.0)
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)
≥7 days after Dose 2 to <2 Months after Dose 2	0		16		100.0	(74.1, 100.0)
≥2 Months after Dose 2 to <4 Months after Dose 2	0		2		100.0	(-432.5, 100.0)

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.

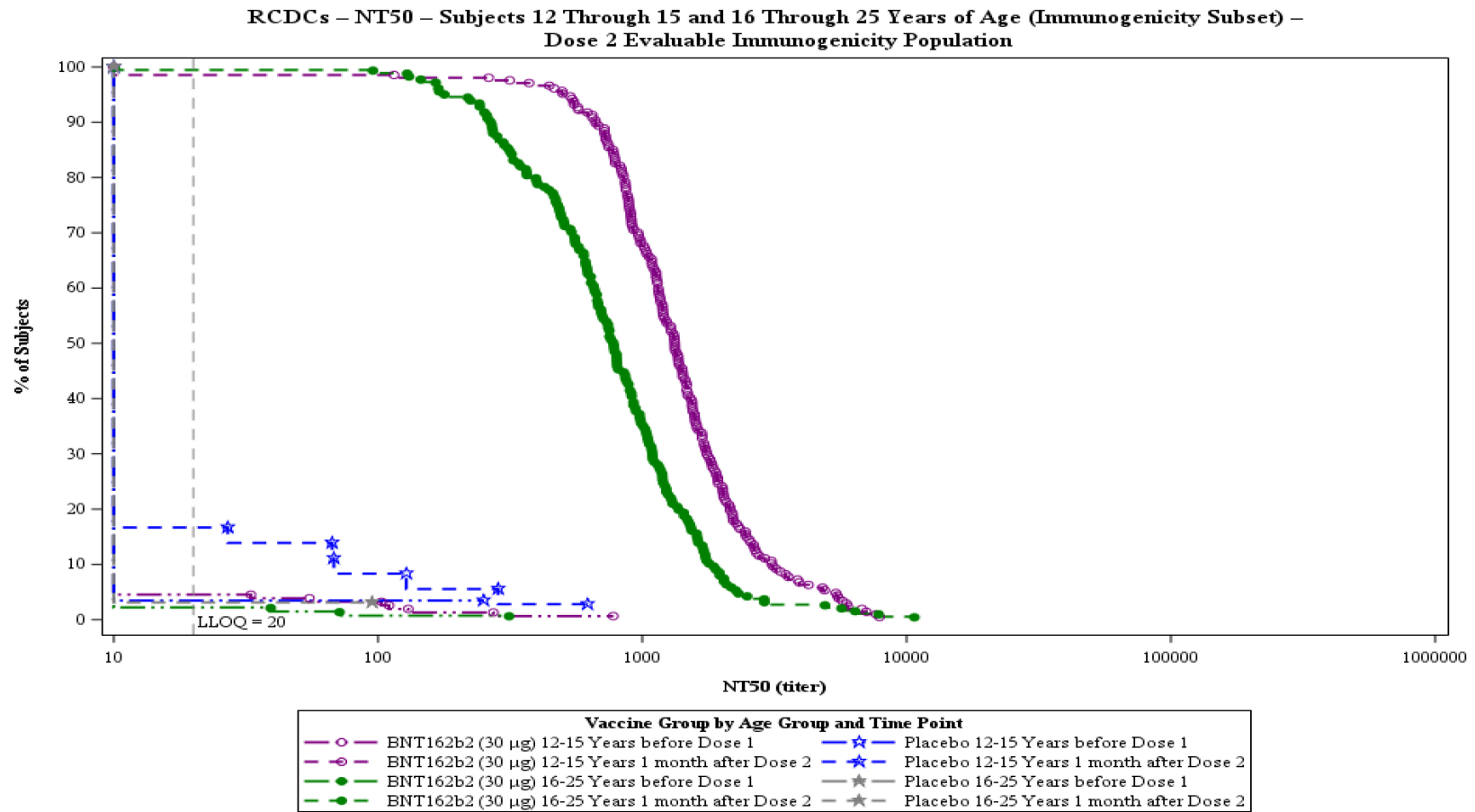
d. n2 = Number of subjects at risk for the endpoint.

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 30MAR2021 (22:24)

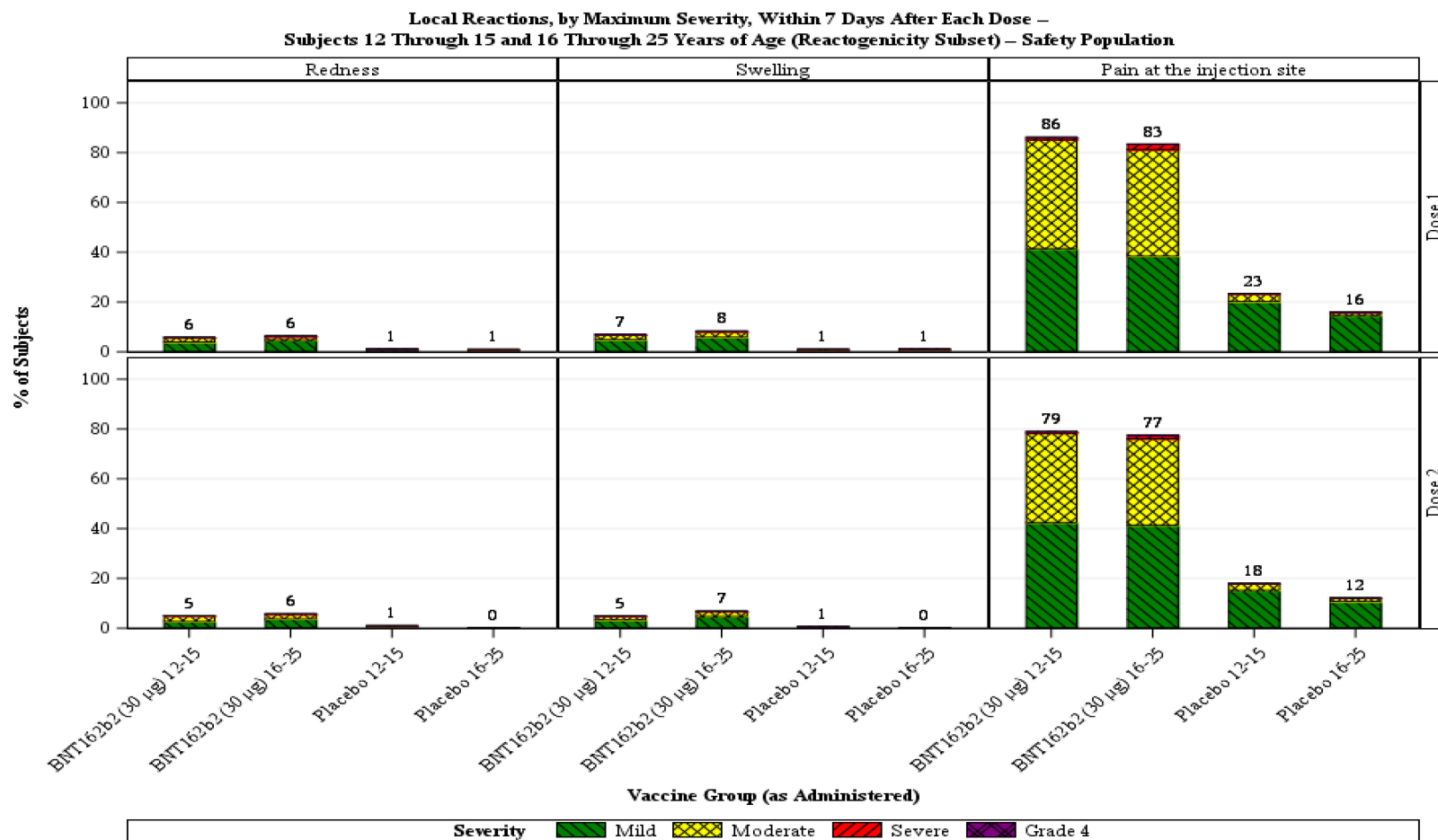
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2\_unblinded/C4591001\_BLA/adc19ef\_ve\_cov\_pd1\_peds\_aai

Reverse Cumulative Distribution Curves, SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population



Abbreviations: LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; RCDC = reverse cumulative distribution curve; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.  
 Note: LLOQ value is represented using a vertical line. Assay results below the LLOQ were set to  $0.5 \times \text{LLOQ}$  in the analysis.  
 PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)  
 (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2\_unblinded/C4591001\_BLA/adva\_f003\_sars\_50\_ped

Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population

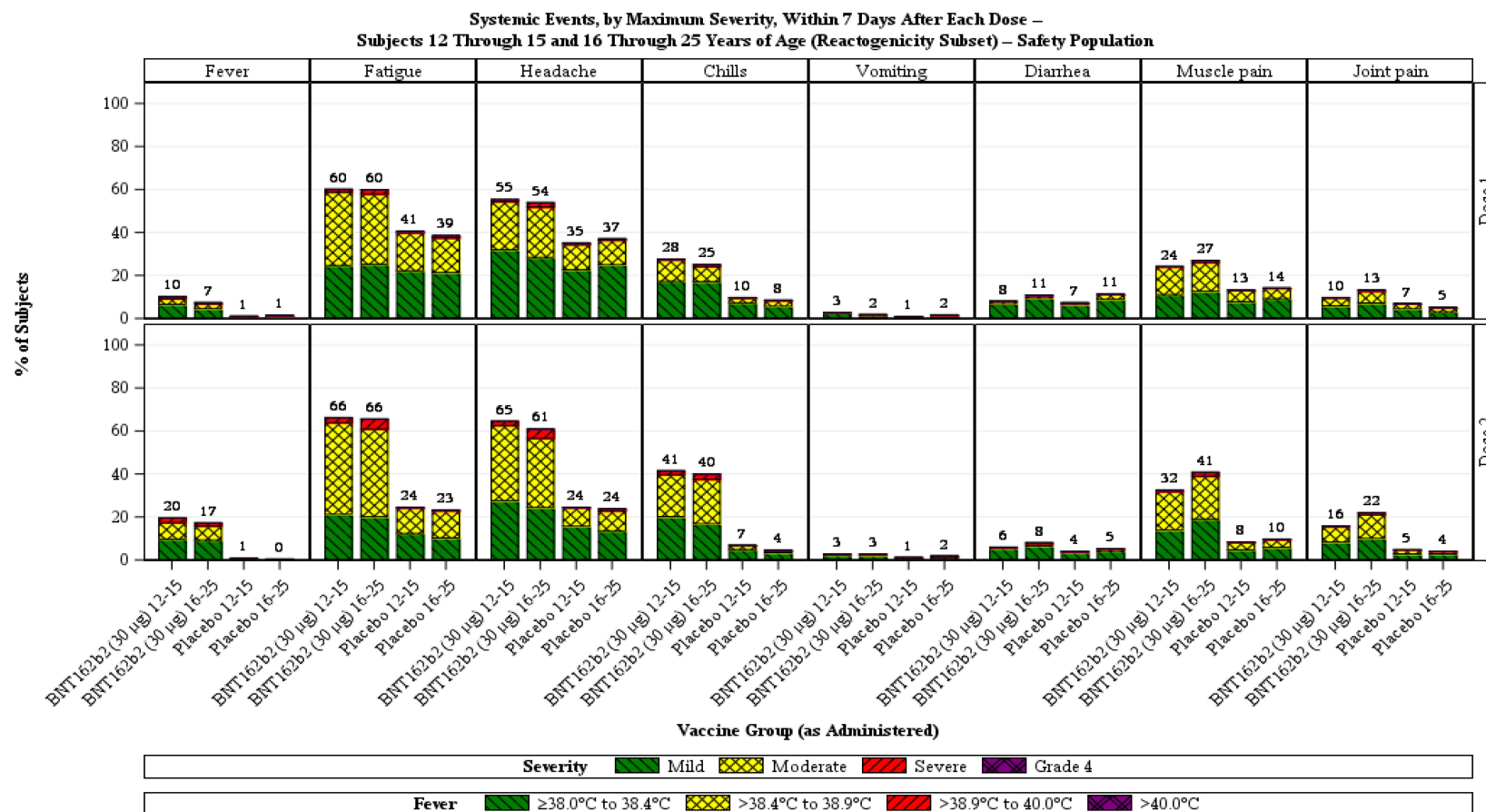


Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2\_unblinded/C4591001\_BLA/adce\_f001\_lr\_max\_ped

Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Subjects 12 Through 15 and 16 Through 25 Years of Age (Reactogenicity Subset) – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.

Note: Subject C4591001 1077 10771278 (13 years of age) experienced systemic events, including a temperature of 40.4°C, on the day of Dose 2. Since these events were recorded as adverse events and not in the electronic diary (e-diary), they do not appear in this output.

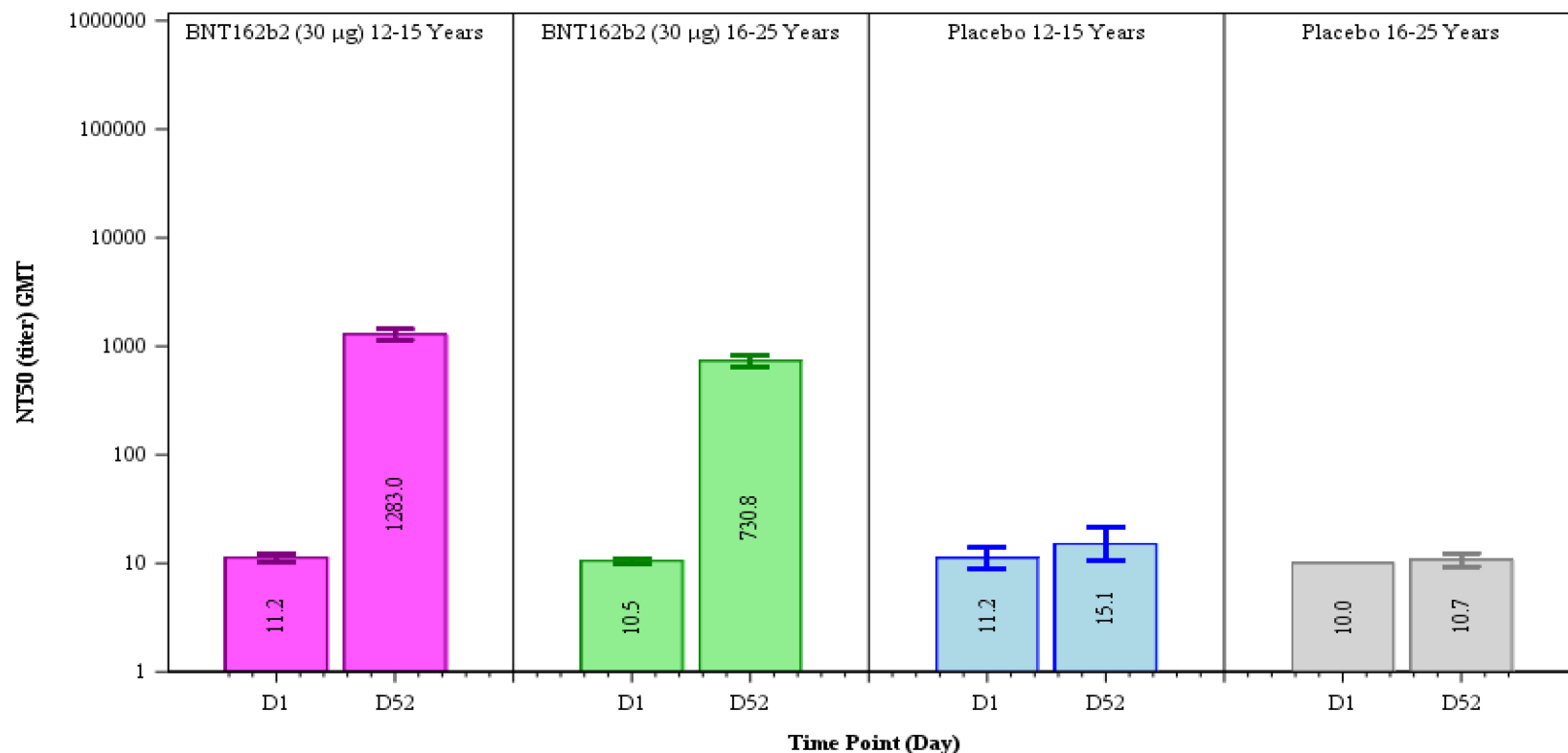
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2\_unblinded/C4591001\_BLA/adce\_f001\_se\_max\_ped



Geometric Mean Titers and 95% CIs: SARS-CoV-2 Neutralization Assay – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population

**GMTs and 95% CIs – NT50 – Subjects 12 Through 15 and 16 Through 25 Years of Age (Immunogenicity Subset) – Dose 2 Evaluable Immunogenicity Population**



Abbreviations: D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:54)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2\_unblinded/C4591001\_BLA/adva\_f002\_sars\_50\_ped