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	2
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	4
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	6
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	7
Summary of Geometric Mean Ratio - NT50 - Comparison of Subjects 12 Through 15 Years of Age to Subjects 16 Through 25 Years of Age (Immunogenicity	r
Subset) – Subjects Without Evidence of Infection up to 1 Month After Dose 2 – Dose 2 Evaluable Immunogenicity Population	8
Number (%) of Subjects Achieving a ≥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	10
Number (%) of Subjects Achieving a ≥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	11

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

				BNT162b2 (30	Placebo						
	Dose/			12-15 Years		16-25 Years		12-15 Years		16-25 Years	
Assay	Sampling Time Point ^a	Baseline SARS-CoV-2 Status ^b	n ^c	GMT ^d (95% CI ^d)	n°	GMT ^d (95% CI ^d)	n ^c	GMT ^d (95% CI ^d)	n ^c	GMT ^d (95% CI ^d)	
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	155	44 <u>22</u> .2 (10.3, 12.3 <u>20.7, 23.8</u>)	136	10.5 (9.9, 11 <u>21.1</u> (20.2, 22.0)	29	11.2 (8.9, 14.0)22.3 (18.7, 26.7)	24	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	
		POS	8	54.1 (19.7, 148.7)61.0 (26.4, 140.8)	5	38.6 (6.4, 232 <u>45.3</u> (10.2, 201.9)	1	251.0 (NE, NE)	0	NE (NE, NE)	
		NEG	146	10.3 (9.7, 10.9)21.0 (20.0, 22.1)	131	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	27	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	24	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	
	2/1 Month	ALL	207	1283.0 (1139.6, 1444.5) 1296.4 <u>(1160.4, 1448.4)</u>	185	730.8 (646.7, 825 <u>733.6</u> (651.0, 826.8)	36	15.1 (10.7, 21.4)27.3 (20.9, 35.6)	32	10 <u>21.5</u> (19.5, 23.7 (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	10.020.5 (NE, NE)	
		NEG	192	1239 <u>1253</u> .2 (1096 <u>1118</u> .6, 1400.5 <u>1404.1</u>)	177	708 <u>711.6</u> (630.7 (626.4, 802.0 <u>9</u>)	33	13.1 (9.7, 17.7)24.4 (19.4, 30.8)	31	1021.5 (19.5, 23.8 (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.

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

					Vaccin	e Group (as Rar	domiz	zed)		
				BNT162b2	(30 μg)			Pla	acebo	
				12-15 Years		16-25 Years		12-15 Years		16-25 Years
	Dose/ Sampling Time	Baseline SARS-CoV-2		$\mathrm{GMT}^{\mathrm{d}}$		GMT ^d		GMT^{d}		GMT ^d
Assay	Point ^a	Status ^b	n ^c	(95% CI ^d)	n ^c	(95% CI ^d)	n ^c	(95% CI ^d)	n ^c	(95% CI ^d)

- 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 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 $0.5 \times LLOQ$.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:2509FEB2022 (12:16) Source Data: adva Table Generation: 27MAR2021 (04:5409FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2nda3 unblinded/C4591001 BLA_IMM/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 (a	as Randomized)
------------------	----------------

						1 (,		
				BNT162b2	ά (30 μ	Placebo				
			12-15 Years	16-25 Years			12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point ^a	Baseline SARS-CoV-2 Status ^b	n°	GMT ^d (95% CI ^d)	n ^c	GMT ^d (95% CI ^d)	n ^c	GMT ^d (95% CI ^d)	n ^c	GMT ^d (95% CI ^d)
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	ALL	156	11 <u>22</u> .2 (10.2, 12.3 <u>20.7, 23.8</u>)	140	10.5 (9.9, 11 <u>21</u> .1 (20.2, 22.0)	29	11.2 (8.9, 14.0)22.3 (18.7, 26.7)	25	10.0 (10.0, 10.0)20.5 (20.5, 20.5)
		POS	8	54.1 (19.7, 148.7)61.0 (26.4, 140.8)	5	38.6 (6.4, 23245.3 (10.2, 201.9)	1	251.0 (NE, NE)	0	NE (NE, NE)
		NEG	147	10.3 (9.7, 10.9)21.0 (20.0, 22.1)	135	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	27	10.0 (10.0, 10.0)20.5 (20.5, 20.5)	25	10.0 (10.0, 10.0)20.5 (20.5, 20.5)
	2/1 Month	ALL	208	1284.4 (1141.4, 1445 <u>1297.7</u> (1162.2, 1449.1)	190	726.3 (643.9, 819 <u>729.0</u> (648.0, 820.1)	36	15.1 (10.7, 21.4)27.3 (20.9, 35.6)	34	10.7 (9.3, 12.2)21.4 (19.6, 23.5)
		POS	10	2342.2 (1308.7, 4191.8)	8	1439.2 (727.1, 2848.7)	2	191.0 (1.2, 30873.6)	1	10.020.5 (NE, NE)
		NEG	193	1240.9 (1098.7, 1401.5)1254.8 (1120.6, 1405.1)	182	704.7 (624.1, 795.9)707.5 (628.2, 796.8)	33	13.1 (9.7, 17.7)24.4 (19.4, 30.8)	33	10.7 (9.3, 12.321.5 (19.5, 23.6)

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.

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

					Va	ccine Group (as R	andomi	ized)		
				BNT162	2b2 (30 μ ₂	g)		Pl	acebo	
				12-15 Years		16-25 Years		12-15 Years		16-25 Years
	Dose/ Sampling Time	Baseline SARS-CoV-2		GMT ^d		GMT^d		$\mathbf{GMT}^{\mathbf{d}}$		GMT ^d
Assay	Pointa	Status ^b	n ^c	(95% CI ^d)	n ^c	(95% CI ^d)	$\mathbf{n}^{\mathbf{c}}$	(95% CId)	n°	(95% CI ^d)

- 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 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 $0.5 \times LLOQ$.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:2509FEB2022 (12:16) Source Data: adva Table Generation: 27MAR2021 (04:5409FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2nda3 unblinded/C4591001 BLA IMM/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

				Vaccine Group (as Randomized)									
				BNT	162b2	(30 µg)		Place	ebo				
				12-15 Years		16-25 Years		12-15 Years	1	6-25 Years			
Assay	Dose/ Sampling Time Point ^a	Baseline SARS-CoV-2 Status ^b	n ^c	GMFR ^d (95% CI ^d)	n ^c	GMFR ^d (95% CI ^d)	n ^c	GMFR ^d (95% CI ^d)	n°	GMFR ^d (95% CI ^d)			
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	118.3 (101 <u>60</u> .4, 137.9 (52.5, 69.4)	135	71.2 (61.3, 82.7)35.5 (30.6, 41.0)	29	1.4 (<u>1.2</u> (0, <u>1</u> .9, <u>1.6</u>)	24	1.1 (0.9, 1. <u>32</u>)			
		POS	8	47.6 (26.4, 86 <u>42.2</u> (24.8, 72.0)	5	47.1 <u>40.2</u> (3. 1, 721.4 <u>7, 437.7</u>)	1	1.1 (NE, NE)	0	NE (NE, NE)			
		NEG	145	125.0 (10661.9, 146.2 (53.6, 71.5)	130	72 <u>35</u> .3 (62.9, 83.2<u>3</u>0.7, 40.6)	27	1.4 (<u>2</u> (<u>0.9,</u> 1. 0, 2.0 <u>6</u>)	24	1.1 (0.9, 1. <u>32</u>)			

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 (23:2509FEB2022 (12:16)) Source Data: adva Table Generation: 27MAR2021 (04:5409FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2nda3 unblinded/C4591001 BLA_IMM/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

			Vaccine Group (as Randomized)										
				BNT1621	o2 (30	μg)		Place	bo				
				12-15 Years		16-25 Years		12-15 Years	1	6-25 Years			
Assay	Dose/ Sampling Time Point ^a	Baseline SARS-CoV-2 Status ^b	n ^c	GMFR ^d (95% CI ^d)	n°	GMFR ^d (95% CI ^d)	n ^c	GMFR ^d (95% CI ^d)	n ^c	GMFR ^d (95% CI ^d)			
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	155	118 <u>60</u> .5 (101 <u>52</u> .7, 138.0 <u>69.4</u>)	139	7035.0 (30.3 (60.7, 81.5, 40.4)	29	1.4 (1.2 (0, 1.9, 1.6)	25	1.1 (0.9, 1. <u>32</u>)			
		POS	8	4 7.6 (26.4, 8642.2 (24.8, 72.0)	5	47.1 <u>40.2</u> (3. 1, 721.4 <u>7, 437.7</u>)	1	1.1 (NE, NE)	0	NE (NE, NE)			
		NEG	146	125.2 (107.2, 146.3)62.0 (53.7, 71.6)	134	7134.8 (30.4 (62.2, 81.9, 40.0)	27	1.4 (<u>2</u> (<u>0.9,</u> 1. 0, 2.0 <u>6</u>)	25	1.1 (0.9, 1. <u>32</u>)			

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 $0.5 \times LLOQ$ in the analysis.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:2509FEB2022 (12:16) Source Data: adva Table Generation: 27MAR2021 (06:1509FEB2022

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

				Vaco	ine Group (as Ran	domize	d)	
			BNT16	2b2 (30 μ	ıg)		Place	ebo
			12-15 Years		16-25 Years		12-15 Years	16-25 Years
Assay	 Baseline SARS-CoV-2 Status ^b	n ^c	GMFR ^d (95% CI ^d)	n°	GMFR ^d (95% CI ^d)	n ^c	GMFR ^d (95% CI ^d)	GMFR ^d n ^c (95% CI ^d)

(18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2nda3 unblinded/C4591001 BLA_IMM/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)

			DIVII	0202 (3	υ μg)		
			12-15 Years		16-25 Years	12-15 Y	ears/16-25 Years
Assay	Dose/ Sampling Time Point ^a	n ^b	GMT ^c (95% CI ^c)	n ^b	GMT ^c (95% CI ^c)	GMR ^d (95% CI ^d)	Met Noninferiority Objective ^e (Y/N)
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	190	1239.5 (1095.5, 1402.5)1253.6 (1117.7, 1406.1)	170	705708.1 (621.4, 800.2625.9, 801.1)	1. 76 <u>77</u> (1.47 <u>50,</u> 2. 10 <u>09</u>)	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

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 Ran	domized)		
		В	NT162b2 (30 μ	g)		
		12-15 Years		16-25 Years	12-15 Y	ears/16-25 Years
Assay	Dose/ Sampling Time Point ^a n ^b	GMT ^c (95% CI ^c)	$\mathbf{n}^{\mathbf{b}}$	GMT° (95% CI°)	GMR ^d (95% CI ^d)	Met Noninferiority Objective ^e (Y/N)

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 $0.5 \times LLOQ$.
- 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 (23:2509FEB2022 (12:16) Source Data: adva Table Generation: 27MAR2021 (04:5409FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2nda3 unblinded/C4591001 BLA IMM/adva s001 gmr ped ev eval

Number (%) of Subjects Achieving a ≥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			
			1	12-15 Years		16-25 Years	12-15 Years		16-25 Years	
Assay	Dose/ Sampling Time Point ^a	Baseline SARS-CoV-2 Status ^b	N°	n ^d (%) (95% CI ^e)	$\mathbf{N}^{\mathbf{c}}$	n ^d (%) (95% CI°)	N°	n ^d (%) (95% CI ^e)	N°	n ^d (%) (95% CI ^e)
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	ALL	154	151 (98.1) (94150 (97.4) (93.5, 99.63)	135	134 (99 <u>130 (96</u> .3) (95.9, 100.091.6, 98.8)	29	1 (3.4) (0.1, 17.8)	24	1 (40 (0.0) (0.0, 14.2) (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	142141 (97. 9) (942) (93.1, 99.62)	130	130 (100.0) (97126 (96.9) (92.3, 99.2, 100.0)	27	1 (3.7) (0.1, 19.0)	24	1 (40 (0.0) (0.0, 14.2) (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. $n = Number of subjects with \ge 4-fold rise from before vaccination for the given assay at the given dose/sampling time point.$
- e. Exact 2-sided CI based on the Clopper and Pearson method.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:2509FEB2022 (12:16)) Source Data: adva Table Generation: 27MAR2021 (06:2909FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2nda3 unblinded/C4591001 BLA IMM/adva s001 4fold ped eval

Number (%) of Subjects Achieving a ≥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 ^a	N^{b}	n ^c (%) (95% CI ^d)	$\mathbf{N^b}$	n° (%) (95% CI ^d)	0/0 ^e	(95% CI ^f)			
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	143	140 <u>139</u> (97. 9) (94 <u>2)</u> (<u>93</u> .0, 99.6 <u>2</u>)	124	124 (100.0) (97 <u>120 (96.8)</u> (91.9, 99.1 , 100.0)	2.1 0.4	(- 6.0, 0.9 <u>4.2, 5.5</u>)			

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

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:2509FEB2022 (12:16)) Source Data: adva Table Generation: 27MAR2021 (05:5609FEB2022 (18:59)

(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2nda3 unblinded/C4591001 BLA IMM/adva s003 4fold ped eval