

Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population	2
Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age.....	4
Follow-up Time After Dose 2 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population	8
Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population.....	9
Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects 16-55 Years of Age – Safety Population.....	10

Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=13069) n^b (%)	Placebo (N^a=13095) n^b (%)	Total (N^a=26164) n^b (%)
Sex			
Male	6640 (50.8)	6412 (49.0)	13052 (49.9)
Female	6429 (49.2)	6683 (51.0)	13112 (50.1)
Race			
White	10221 (78.2)	10251 (78.3)	20472 (78.2)
Black or African American	1429 (10.9)	1436 (11.0)	2865 (11.0)
American Indian or Alaska Native	165 (1.3)	153 (1.2)	318 (1.2)
Asian	703 (5.4)	712 (5.4)	1415 (5.4)
Native Hawaiian or other Pacific Islander	43 (0.3)	21 (0.2)	64 (0.2)
Multiracial	437 (3.3)	438 (3.3)	875 (3.3)
Not reported	71 (0.5)	84 (0.6)	155 (0.6)
Racial designation			
Japanese	39 (0.3)	41 (0.3)	80 (0.3)
Ethnicity			
Hispanic/Latino	4047 (31.0)	4023 (30.7)	8070 (30.8)
Non-Hispanic/non-Latino	8967 (68.6)	9011 (68.8)	17978 (68.7)
Not reported	55 (0.4)	61 (0.5)	116 (0.4)
Country			
Argentina	1975 (15.1)	1973 (15.1)	3948 (15.1)
Brazil	1191 (9.1)	1189 (9.1)	2380 (9.1)
Germany	134 (1.0)	139 (1.1)	273 (1.0)
South Africa	328 (2.5)	330 (2.5)	658 (2.5)

Demographic Characteristics – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=13069) n^b (%)	Placebo (N^a=13095) n^b (%)	Total (N^a=26164) n^b (%)
Turkey	190 (1.5)	197 (1.5)	387 (1.5)
USA	9251 (70.8)	9267 (70.8)	18518 (70.8)
Age at vaccination (years)			
Mean (SD)	39.0 (10.76)	38.7 (10.75)	38.9 (10.76)
Median	40.0	40.0	40.0
Min, max	(16, 55)	(16, 55)	(16, 55)
Baseline SARS-CoV-2 status			
Positive ^c	517 (4.0)	541 (4.1)	1058 (4.0)
Negative ^d	12466 (95.4)	12485 (95.3)	24951 (95.4)
Missing	86 (0.7)	69 (0.5)	155 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m ²)	199 (1.5)	224 (1.7)	423 (1.6)
Normal weight (≥18.5 kg/m ² - 24.9 kg/m ²)	4208 (32.2)	4268 (32.6)	8476 (32.4)
Overweight (≥25.0 kg/m ² - 29.9 kg/m ²)	4258 (32.6)	4178 (31.9)	8436 (32.2)
Obese (≥30.0 kg/m ²)	4401 (33.7)	4421 (33.8)	8822 (33.7)
Missing	3 (0.0)	4 (0.0)	7 (0.0)
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.			
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.			
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Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age			
	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)	Total (N^a=26236) n^b (%)
Randomized	13104 (100.0)	13132 (100.0)	26236 (100.0)
Not vaccinated	31 (0.2)	32 (0.2)	63 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	13073 (99.8)	13100 (99.8)	26173 (99.8)
Dose 1	13073 (99.8)	13100 (99.8)	26173 (99.8)
Dose 2	12802 (97.7)	12825 (97.7)	25627 (97.7)
Discontinued from original blinded placebo-controlled vaccination period ^c	278 (2.1)	388 (3.0)	666 (2.5)
Reason for discontinuation			
Lost to follow-up	132 (1.0)	128 (1.0)	260 (1.0)
Withdrawal by subject	81 (0.6)	117 (0.9)	198 (0.8)
No longer meets eligibility criteria	23 (0.2)	94 (0.7)	117 (0.4)
Adverse event	15 (0.1)	12 (0.1)	27 (0.1)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	2 (0.0)	6 (0.0)	8 (0.0)
Physician decision	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	2 (0.0)	1 (0.0)	3 (0.0)
Death	0	2 (0.0)	2 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	13 (0.1)	18 (0.1)	31 (0.1)
Unblinded before 1-month post–Dose 2 visit	175 (1.3)	182 (1.4)	357 (1.4)
Completed 1-month post–Dose 2 visit	12586 (96.0)	12555 (95.6)	25141 (95.8)
Withdrawn from the study	259 (2.0)	349 (2.7)	608 (2.3)

Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age			
	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)	Total (N^a=26236) n^b (%)
Withdrawn after Dose 1 and before Dose 2	138 (1.1)	155 (1.2)	293 (1.1)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	85 (0.6)	104 (0.8)	189 (0.7)
Withdrawn after 1-month post–Dose 2 visit	36 (0.3)	90 (0.7)	126 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	150 (1.1)	160 (1.2)	310 (1.2)
Withdrawal by subject	88 (0.7)	147 (1.1)	235 (0.9)
Protocol deviation	3 (0.0)	20 (0.2)	23 (0.1)
Adverse event	6 (0.0)	3 (0.0)	9 (0.0)
Death	3 (0.0)	5 (0.0)	8 (0.0)
Physician decision	2 (0.0)	3 (0.0)	5 (0.0)
No longer meets eligibility criteria	1 (0.0)	2 (0.0)	3 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	4 (0.0)	8 (0.1)	12 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	11858 (90.5)		
Received Dose 2/unplanned dose	61 (0.5)		
Completed 1-month post–Dose 2 visit	141 (1.1)		
Completed 6-month post–Dose 2 visit	3341 (25.5)		
Withdrawn from the study	58 (0.4)		
Withdrawn before 6-month post–Dose 2 visit	56 (0.4)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			

Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age			
	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)	Total (N^a=26236) n^b (%)
Withdrawal by subject	32 (0.2)		
Protocol deviation	17 (0.1)		
Lost to follow-up	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	2 (0.0)		
Originally randomized to placebo		12299 (93.7)	
Withdrawn from the study after unblinding and before Dose 3		284 (2.2)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		11405 (86.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		8586 (65.4)	
Discontinued from open-label vaccination period ^d		16 (0.1)	
Reason for discontinuation from open-label vaccination period			
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Adverse event		3 (0.0)	
Protocol deviation		3 (0.0)	
Lost to follow-up		1 (0.0)	
Completed 1-month post–Dose 4 visit		3424 (26.1)	
Withdrawn from the study		8 (0.1)	
Withdrawn after Dose 3 and before Dose 4		6 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		0	

Disposition of All Randomized Subjects – Phase 2/3 Subjects 16-55 Years of Age			
	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=13104) n^b (%)	Placebo (N^a=13132) n^b (%)	Total (N^a=26236) n^b (%)
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.1)	
Protocol deviation		1 (0.0)	
<p>Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.</p> <p>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.</p> <p>Note: Because of a dosing error, Subject C4591001 1088 10881077 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo.</p> <p>a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.</p> <p>b. n = Number of subjects with the specified characteristic.</p> <p>c. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1 month post–Dose 2.</p> <p>d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).</p> <p>PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 31MAR2021 (18:10) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_EUA_1655/adds_s002_all_1655_rand</p>			

Follow-up Time After Dose 2 – Phase 2/3 Subjects 16-55 Years of Age – Safety Population			
	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=13069) n^b (%)	Placebo (N^a=13095) n^b (%)	Total (N^a=26164) n^b (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	917 (7.0)	962 (7.3)	1879 (7.2)
≥2 Months to <4 months	4448 (34.0)	4726 (36.1)	9174 (35.1)
≥4 Months to <6 months	6343 (48.5)	6327 (48.3)	12670 (48.4)
≥6 Months	1361 (10.4)	1080 (8.2)	2441 (9.3)
Total exposure from Dose 2 to cutoff date			
<2 Months	305 (2.3)		
≥2 Months to <4 months	552 (4.2)		
≥4 Months to <6 months	5546 (42.4)		
≥6 Months	6666 (51.0)		
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.			
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 31MAR2021 (17:26)			
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**Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 –
Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

Adverse Event	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N ^a =12995)	Placebo (N ^a =13026)
	n ^b (%)	n ^b (%)
Any event	4233 (32.6)	1871 (14.4)
Related ^c	3480 (26.8)	882 (6.8)
Severe	154 (1.2)	74 (0.6)
Life-threatening	8 (0.1)	11 (0.1)
Any serious adverse event	52 (0.4)	49 (0.4)
Related ^c	2 (0.0)	0
Severe	27 (0.2)	31 (0.2)
Life-threatening	8 (0.1)	11 (0.1)
Any adverse event leading to withdrawal	19 (0.1)	20 (0.2)
Related ^c	9 (0.1)	7 (0.1)
Severe	5 (0.0)	4 (0.0)
Life-threatening	0	3 (0.0)
Death	0	2 (0.0)

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

b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = 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: 31MAR2021 (17:46)

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**Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date –
Phase 2/3 Subjects 16-55 Years of Age – Safety Population**

Adverse Event	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N ^a =12995, TE ^b =49.7)			Placebo (N ^a =13026, TE ^b =49.1)		
	n ^c	IR (/100 PY) ^d	(95% CI) ^e	n ^c	IR (/100 PY) ^d	(95% CI) ^e
Any event	4396	88.4	(85.8, 91.0)	2136	43.5	(41.7, 45.4)
Related ^f	3484	70.0	(67.7, 72.4)	884	18.0	(16.8, 19.2)
Severe	193	3.9	(3.4, 4.5)	124	2.5	(2.1, 3.0)
Life-threatening	13	0.3	(0.1, 0.4)	20	0.4	(0.2, 0.6)
Any serious adverse event	103	2.1	(1.7, 2.5)	117	2.4	(2.0, 2.9)
Related ^f	3	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Severe	56	1.1	(0.9, 1.5)	75	1.5	(1.2, 1.9)
Life-threatening	13	0.3	(0.1, 0.4)	20	0.4	(0.2, 0.6)
Any adverse event leading to withdrawal	22	0.4	(0.3, 0.7)	28	0.6	(0.4, 0.8)
Related ^f	9	0.2	(0.1, 0.3)	8	0.2	(0.1, 0.3)
Severe	5	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.3)
Life-threatening	3	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.2)
Death	3	0.1	(0.0, 0.2)	4	0.1	(0.0, 0.2)

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

b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.

c. 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.

d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.

e. 2-sided CI based on Poisson distribution.

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

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