Table.B Study Disposition of Phase 2/3 Randomized Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	**Placebo (N^a=22080) n^b (%)**	**Total (N^a=44165) n^b (%)**
Randomized	22085 (100.0)	22080 (100.0)	44165 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)	105 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 1	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 2	21675 (98.1)	21650 (98.1)	43325 (98.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	352 (1.6)	528 (2.4)	880 (2.0)
Reason for discontinuation			
Lost to follow-up	151 (0.7)	153 (0.7)	304 (0.7)
Withdrawal by subject	109 (0.5)	181 (0.8)	290 (0.7)
No longer meets eligibility criteria	26 (0.1)	120 (0.5)	146 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)
Physician decision	5 (0.0)	8 (0.0)	13 (0.0)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	3 (0.0)	2 (0.0)	5 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	18 (0.1)	20 (0.1)	38 (0.1)
Unblinded before 1-month post–Dose 2 visit	253 (1.1)	240 (1.1)	493 (1.1)

Table.B Study Disposition of Phase 2/3 Randomized Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	**Placebo (N^a=22080) n^b (%)**	**Total (N^a=44165) n^b (%)**
Completed 1-month post–Dose 2 visit	21382 (96.8)	21293 (96.4)	42675 (96.6)
Withdrawn from the study	343 (1.6)	484 (2.2)	827 (1.9)
Withdrawn after Dose 1 and before Dose 2	176 (0.8)	211 (1.0)	387 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	100 (0.5)	139 (0.6)	239 (0.5)
Withdrawn after 1-month post–Dose 2 visit	67 (0.3)	134 (0.6)	201 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	174 (0.8)	191 (0.9)	365 (0.8)
Withdrawal by subject	122 (0.6)	226 (1.0)	348 (0.8)
Protocol deviation	11 (0.0)	24 (0.1)	35 (0.1)
Death	16 (0.1)	15 (0.1)	31 (0.1)
Adverse event	9 (0.0)	8 (0.0)	17 (0.0)
Physician decision	3 (0.0)	6 (0.0)	9 (0.0)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (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	5 (0.0)	9 (0.0)	14 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	20404 (92.4)		
Received Dose 2/unplanned dose	87 (0.4)		
Completed 1-month post–Dose 2 visit	210 (1.0)		

Table.B Study Disposition of Phase 2/3 Randomized Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	**Placebo (N[a]=22080) n[b] (%)**	**Total (N[a]=44165) n[b] (%)**
Completed 6-month post–Dose 2 visit	6414 (29.0)		
Withdrawn from the study	105 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	103 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	56 (0.3)		
Protocol deviation	35 (0.2)		
Lost to follow-up	4 (0.0)		
Death	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		20948 (94.9)	
Completed 6-month post–Dose 2 visit		153 (0.7)	
Withdrawn from the study after unblinding and before Dose 3		497 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		15986 (72.4)	
Discontinued from open-label vaccination period[d]		24 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	

Table.B Study Disposition of Phase 2/3 Randomized Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
Adverse event		5 (0.0)	
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		7209 (32.6)	
Withdrawn from the study		14 (0.1)	
Withdrawn after Dose 3 and before Dose 4		11 (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		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
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.
Note: Because of a dosing error, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.

Table.B Study Disposition of Phase 2/3 Randomized Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	**Placebo (N^a=22080) n^b (%)**	**Total (N^a=44165) n^b (%)**

b. n = Number of subjects with the specified characteristic.
c. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1 month post–Dose 2.
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]).

Table.C Disposition of Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13 2021, Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=22026) n^b (%)	**Placebo (N^a=22021) n^b (%)**	**Total (N^a=44050) n^b (%)**
Randomized			44165
Not vaccinated			105
Vaccinated	22026 (100.0)	22021 (100.0)	44050 (100.0)
Completed 1 dose	22026 (100.0)	22021 (100.0)	44050 (100.0)
Completed 2 doses	21674 (98.4)	21645 (98.3)	43319 (98.3)
Safety population	22026 (100.0)	22021 (100.0)	44050 (100.0)
Reactogenicity subset	5033 (22.9)	5032 (22.9)	10068 (22.9)
HIV-positive	100 (0.5)	100 (0.5)	200 (0.5)
Indeterminate vaccine			3 (0.0)
Participants excluded from safety population			115 (0.3)
Reason for exclusion			
Participant did not receive study vaccine			105 (0.2)
Unreliable data due to lack of PI oversight			10 (0.0)
Completed at least 6 months follow-up after Dose 2 in blinded placebo-controlled follow-up period	1778 (8.1)	1304 (5.9)	3082 (7.0)
Completed at least 6 months follow-up after Dose 2 in blinded and open-label follow-up period	12006 (54.5)		
Completed 1-month post–Dose 2 visit (vaccination period)	21378 (97.1)	21291 (96.7)	42669 (96.9)
Discontinued from vaccination period but continued in the study up to 1-month post–Dose 2 visit	350 (1.6)	520 (2.4)	873 (2.0)

Table.C Disposition of Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13 2021, Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N^a=22026) n^b (%)	**Placebo (N^a=22021) n^b (%)**	**Total (N^a=44050) n^b (%)**
Discontinued after Dose 1 and before Dose 2	233 (1.1)	359 (1.6)	595 (1.4)
Discontinued after Dose 2 and before 1-month post–Dose 2 visit	117 (0.5)	161 (0.7)	278 (0.6)
Reason for discontinuation from vaccination period			
Lost to follow-up	151 (0.7)	149 (0.7)	300 (0.7)
Withdrawal by subject	108 (0.5)	181 (0.8)	289 (0.7)
No longer meets eligibility criteria	25 (0.1)	120 (0.5)	145 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)
Physician decision	5 (0.0)	7 (0.0)	12 (0.0)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	2 (0.0)	0	5 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	19 (0.1)	19 (0.1)	38 (0.1)
Withdrawn from study before 1-month post–Dose 2 visit	273 (1.2)	344 (1.6)	617 (1.4)
Withdrawn after Dose 1 and before Dose 2	173 (0.8)	205 (0.9)	378 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	100 (0.5)	139 (0.6)	239 (0.5)
Reason for withdrawal			
Lost to follow-up	151 (0.7)	153 (0.7)	304 (0.7)
Withdrawal by subject	101 (0.5)	168 (0.8)	269 (0.6)
Adverse event	9 (0.0)	7 (0.0)	16 (0.0)

Table.C Disposition of Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13 2021, Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	**Placebo (N[a]=22021) n[b] (%)**	**Total (N[a]=44050) n[b] (%)**
Physician decision	3 (0.0)	5 (0.0)	8 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Protocol deviation	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
No longer meets eligibility criteria	0	1 (0.0)	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	4 (0.0)	5 (0.0)	9 (0.0)

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.
Note: Because of a dosing error, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 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.
Note: "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were included in the number of subjects for "Total" column. These subjects were not included in the safety analysis but their safety data is listed separately.
a. N = number of randomized 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.

Table.E Demographics and Other Baseline Characteristics, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

Characteristic	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Sex: Female	10704 (48.6)	10923 (49.6)	21627 (49.1)
Sex: Male	11322 (51.4)	11098 (50.4)	22420 (50.9)
Age at Vaccination: Mean years (SD)	49.7 (15.99)	49.6 (16.05)	49.7 (16.02)
Age at Vaccination: Median (years)	51.0	51.0	51.0
Age at Vaccination: Min, max (years)	(16, 89)	(16, 91)	(16, 91)
Age Group: 16 to <18 years	378 (1.7)	376 (1.7)	754 (1.7)
Age Group: 18 to 55 years	12691 (57.6)	12719 (57.8)	25410 (57.7)
Age Group: >55 years	8957 (40.7)	8926 (40.5)	17883 (40.6)
Age Group: ≥65 years	4552 (20.7)	4545 (20.6)	9097 (20.7)
Race: American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Race: Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Race: Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
Race: Native Hawaiian or Other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Race: White	18056 (82.0)	18064 (82.0)	36120 (82.0)
Race: Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Race: Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Ethnicity: Hispanic or Latino	5704 (25.9)	5695 (25.9)	11399 (25.9)
Ethnicity: Not Hispanic or Latino	16211 (73.6)	16212 (73.6)	32423 (73.6)

Table.E Demographics and Other Baseline Characteristics, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

Characteristic	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Ethnicity: Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Obesity: Yes[c]	7543 (34.2)	7629 (34.6)	15172 (34.4)
Obesity: No	14483 (65.8)	14392 (65.4)	28875 (65.6)
Comorbidities: Yes[d]	10119 (45.9)	10071 (45.7)	20190 (45.8)
Comorbidities: No	11907 (54.1)	11950 (54.3)	23857 (54.2)
Baseline evidence of prior SARS-CoV-2 infection: Negative[f]	21185 (96.2)	21180 (96.2)	42365 (96.2)
Baseline evidence of prior SARS-CoV-2 infection: Positive[e]	689 (3.1)	716 (3.3)	1405 (3.2)
Baseline evidence of prior SARS-CoV-2 infection: Missing	152 (0.7)	125 (0.6)	277 (0.6)
Country: Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Country: Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Country: Germany	249 (1.1)	250 (1.1)	499 (1.1)
Country: South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Country: Turkey	249 (1.1)	249 (1.1)	498 (1.1)
Country: United States of America	16792 (76.2)	16794 (76.3)	33586 (76.3)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: 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, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Subjects who had BMI ≥30 kg/m^2.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.
e. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.

Table.E Demographics and Other Baseline Characteristics, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

Characteristic	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)

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

Table.P Safety Overview, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

	BNT162b2 (30 µg) n/N (%)	Placebo n/N (%)
Immediate unsolicited AE within 30 minutes after vaccination		
Dose1	105/21926 (0.5)	81/21921 (0.4)
Dose2	71/21571 (0.3)	54/21549 (0.3)
Solicited injection site reaction within 7 days		
Dose1	3877/4907 (79.0)	639/4897 (13.0)
Dose2	3351/4542 (73.8)	483/4517 (10.7)
Solicited systemic AE within 7 days		
Dose1	2963/4907 (60.4)	2308/4897 (47.1)
Dose2	3237/4542 (71.3)	1542/4517 (34.1)
From Dose 1 through 1 month after Dose 2		
Unsolicited non-serious AE	6557/21926 (29.9)	2996/21921 (13.7)
SAE	127/21926 (0.6)	116/21921 (0.5)
Dose 1 to Data Cutoff March 13 2021 /Participant Unblinding (whichever is Earlier)		
SAE	268/21926 (1.2)	268/21921 (1.2)
Withdrawal due to AEs	45/21926 (0.2)	51/21921 (0.2)
Deaths	15/21926 (<0.1)	14/21921 (<0.1)

Note: MedDRA (v23.1) coding dictionary applied.
Note: Immediate AE refers to an AE reported in the 30-minute observation period after vaccination.

Table.Q Characteristics of Solicited Local and Systemic Adverse Reactions, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

	Vaccine Group (as Administered)			
Event	**BNT162b2 (30 µg)/Dose 1 n/N**	**BNT162b2 (30 µg)/Dose 2 n/N**	**Placebo/Dose 1 n/N**	**Placebo/Dose 2 n/N**
Redness				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 6)	1.0 (1, 5)	2.0 (1, 6)
Duration: Median (range)	2.0 (1, 20)	2.0 (1, 34)	1.0 (1, 10)	1.0 (1, 7)
Persisted beyond 7 days	8/4907	8/4542	1/4897	0
Swelling				
Day of onset: Median (range)	2.0 (1, 5)	2.0 (1, 5)	1.0 (1, 5)	1.0 (1, 5)
Duration: Median (range)	1.0 (1, 12)	2.0 (1, 34)	1.0 (1, 11)	1.5 (1, 5)
Persisted beyond 7 days	1/4907	6/4542	2/4897	0
Pain at injection site				
Day of onset: Median (range)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: Median (range)	2.0 (1, 22)	2.0 (1, 70)	1.0 (1, 19)	1.0 (1, 35)
Persisted beyond 7 days	32/4907	35/4542	10/4897	4/4517
Any solicited local reaction				
Day of onset: Median (range)	2.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)	1.0 (1, 7)
Duration: Median (range)	2.0 (1, 22)	2.0 (1, 70)	1.0 (1, 19)	1.0 (1, 35)
Persisted beyond 7 days	41/4907	40/4542	11/4897	4/4517
Chills				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: Median (range)	1.0 (1, 11)	1.0 (1, 11)	1.0 (1, 31)	1.0 (1, 16)
Persisted beyond 7 days	7/4907	2/4542	6/4897	6/4517

Table.Q Characteristics of Solicited Local and Systemic Adverse Reactions, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

	Vaccine Group (as Administered)			
Event	**BNT162b2 (30 µg)/Dose 1 n/N**	**BNT162b2 (30 µg)/Dose 2 n/N**	**Placebo/Dose 1 n/N**	**Placebo/Dose 2 n/N**
Diarrhea				
Day of onset: Median (range)	3.0 (1, 7)	3.0 (1, 7)	3.0 (1, 7)	3.0 (1, 7)
Duration: Median (range)	1.0 (1, 39)	1.0 (1, 31)	1.0 (1, 23)	1.0 (1, 33)
Persisted beyond 7 days	7/4907	6/4542	12/4897	5/4517
Fatigue				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: Median (range)	1.0 (1, 34)	1.0 (1, 35)	1.0 (1, 23)	1.0 (1, 69)
Persisted beyond 7 days	84/4907	61/4542	93/4897	45/4517
Fever				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	4.0 (1, 7)	4.0 (1, 7)
Duration: Median (range)	1.0 (1, 7)	1.0 (1, 8)	1.0 (1, 8)	1.0 (1, 6)
Persisted beyond 7 days	0	1/4542	1/4897	0
Joint pain				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	3.0 (1, 7)	3.0 (1, 7)
Duration: Median (range)	1.0 (1, 36)	1.0 (1, 32)	1.0 (1, 17)	1.0 (1, 16)
Persisted beyond 7 days	7/4907	13/4542	8/4897	9/4517
Muscle pain				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	3.0 (1, 7)	2.0 (1, 7)
Duration: Median (range)	1.0 (1, 17)	1.0 (1, 23)	1.0 (1, 31)	1.0 (1, 27)
Persisted beyond 7 days	11/4907	7/4542	15/4897	12/4517
Vomiting				

Table.Q Characteristics of Solicited Local and Systemic Adverse Reactions, Phase 2/3 Participants 16 Years of Age and Older, Through Data Cutoff March 13, 2021, Safety Population

	Vaccine Group (as Administered)			
Event	**BNT162b2 (30 µg)/Dose 1 n/N**	**BNT162b2 (30 µg)/Dose 2 n/N**	**Placebo/Dose 1 n/N**	**Placebo/Dose 2 n/N**
Day of onset: Median (range)	3.0 (1, 7)	2.0 (1, 7)	4.0 (1, 7)	4.0 (1, 7)
Duration: Median (range)	1.0 (1, 6)	1.0 (1, 37)	1.0 (1, 4)	1.0 (1, 6)
Persisted beyond 7 days	0	3/4542	0	0
Headache				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: Median (range)	1.0 (1, 25)	1.0 (1, 25)	1.0 (1, 22)	1.0 (1, 35)
Persisted beyond 7 days	50/4907	30/4542	61/4897	32/4517
Any solicited systemic reaction				
Day of onset: Median (range)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)	2.0 (1, 7)
Duration: Median (range)	1.0 (1, 39)	1.0 (1, 37)	1.0 (1, 31)	1.0 (1, 69)
Persisted beyond 7 days	138/4907	94/4542	139/4897	74/4517

Table.R Frequency of Unsolicited AEs with Occurrence in ≥1% of Phase 2/3 Participants in Any Treatment Group From Dose 1 to 1 Month After Dose 2, 16 Years of Age and Older, Safety Population

	BNT162b2 (30 µg) (N=21926)		Placebo (N=21921)	
SYSTEM ORGAN CLASS and Preferred Term	**Any n (%)**	**Severe n (%)**	**Any n (%)**	**Severe n (%)**
GASTROINTESTINAL DISORDERS				
Diarrhoea	248(1.1)	4 (0.0)	188(0.9)	5 (0.0)
Nausea	274(1.2)	1 (0.0)	87(0.4)	2 (0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Chills	1365(6.2)	18 (0.1)	120(0.5)	0 (0.0)
Fatigue	1463(6.7)	24 (0.1)	379(1.7)	2 (0.0)
Injection site pain	2915(13.3)	19 (0.1)	397(1.8)	0 (0.0)
Pain	628(2.9)	9 (0.0)	61(0.3)	0 (0.0)
Pyrexia	1517(6.9)	38 (0.2)	77(0.4)	1 (0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
Arthralgia	268(1.2)	4 (0.0)	102(0.5)	6 (0.0)
Myalgia	1239(5.7)	21 (0.1)	168(0.8)	3 (0.0)
NERVOUS SYSTEM DISORDERS				
Headache	1339(6.1)	25 (0.1)	424(1.9)	10 (0.0)

MedDRA v23.1 coding dictionary applied.

Table.R.1 Frequency of Unsolicited AEs with Occurrence in ≥1% of Phase 2/3 Participants in Any Treatment Group From Dose 1 to Data Cutoff March 13 2021 /Unblinding (whichever is Earlier), 16 Years of Age and Older, Safety Population

	BNT162b2 (30 µg) (N=21926)		Placebo (N=21921)	
SYSTEM ORGAN CLASS and Preferred Term	**Any n (%)**	**Severe n (%)**	**Any n (%)**	**Severe n (%)**
	n (%)		**n (%)**	
GASTROINTESTINAL DISORDERS				
Diarrhoea	255(1.2)	4 (0.0)	189(0.9)	5 (0.0)
Nausea	277(1.3)	1 (0.0)	88(0.4)	2 (0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS				
Chills	1368(6.2)	18 (0.1)	121(0.6)	0 (0.0)
Fatigue	1466(6.7)	24 (0.1)	379(1.7)	2 (0.0)
Injection site pain	2917(13.3)	19 (0.1)	399(1.8)	0 (0.0)
Pain	628(2.9)	9 (0.0)	62(0.3)	0 (0.0)
Pyrexia	1520(6.9)	38 (0.2)	78(0.4)	1 (0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS				
Arthralgia	281(1.3)	5 (0.0)	122(0.6)	7 (0.0)
Myalgia	1245(5.7)	21 (0.1)	170(0.8)	3 (0.0)
NERVOUS SYSTEM DISORDERS				
Headache	1348(6.1)	25 (0.1)	429(2.0)	12 (0.1)

MedDRA v23.1 coding dictionary applied.

Table.R.2 Frequency of Unsolicited AEs with Occurrence in ≥1% of Phase 2/3 Participants From Unblinding Date to Cutoff Date (13MAR2021)
– Open-Label Follow-up Period– Participants Who Originally Received BNT162b2 – 16 Years of Age and Older, Safety Population

Table not created

No subject meets the reporting criteria

MedDRA v23.1 coding dictionary applied.

Table.R.3 Frequency of Unsolicited AEs with Occurrence in ≥1% of Phase 2/3 Participants From Dose 3 to Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – 16 Years of Age and Older, Safety Population

	BNT162b2 (30 µg) (N=19525)	
SYSTEM ORGAN CLASS and Preferred Term	**Any n (%)**	**Severe n (%)**
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
Chills	994(5.1)	15 (0.1)
Fatigue	1379(7.1)	23 (0.1)
Injection site pain	2944(15.1)	19 (0.1)
Pain	394(2.0)	5 (0.0)
Pyrexia	906(4.6)	18 (0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
Myalgia	925(4.7)	15 (0.1)
NERVOUS SYSTEM DISORDERS		
Headache	1108(5.7)	18 (0.1)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
MedDRA v23.1 coding dictionary applied.

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Subjects with any unsolicited adverse events within SMQ	224 (1.02)	217 (0.99)
Angioedema (SMQ)	Any unsolicited adverse events within Angioedema (SMQ)	30 (0.14)	29 (0.13)
	Eye disorders	2 (0.01)	2 (0.01)
	Conjunctival oedema	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	4 (0.02)	7 (0.03)
	Face oedema	2 (0.01)	0
	Swelling face	2 (0.01)	7 (0.03)
	Respiratory, thoracic and mediastinal disorders	1 (0.00)	3 (0.01)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Skin and subcutaneous tissue disorders	21 (0.10)	18 (0.08)
	Angioedema	3 (0.01)	2 (0.01)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria papular	0	1 (0.00)
Arthritis (SMQ)	Any unsolicited adverse events within Arthritis (SMQ)	35 (0.16)	48 (0.22)
	Infections and infestations	1 (0.00)	0
	Arthritis bacterial	1 (0.00)	0
	Metabolism and nutrition disorders	5 (0.02)	3 (0.01)
	Gout	5 (0.02)	3 (0.01)
	Musculoskeletal and connective tissue disorders	29 (0.13)	45 (0.21)
	Arthritis	6 (0.03)	6 (0.03)
	Arthritis reactive	1 (0.00)	0
	Osteoarthritis	15 (0.07)	23 (0.10)
	Patellofemoral pain syndrome	0	1 (0.00)
	Periarthritis	4 (0.02)	1 (0.00)
	Polyarthritis	0	1 (0.00)
	Rheumatoid arthritis	0	2 (0.01)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Spinal osteoarthritis	2 (0.01)	4 (0.02)
	Spondylitis	1 (0.00)	1 (0.00)
	Synovitis	0	2 (0.01)
	Temporomandibular joint syndrome	1 (0.00)	4 (0.02)
Convulsions (SMQ)	Any unsolicited adverse events within Convulsions (SMQ)	2 (0.01)	2 (0.01)
	Nervous system disorders	2 (0.01)	2 (0.01)
	Generalised tonic-clonic seizure	0	1 (0.00)
	Seizure	2 (0.01)	1 (0.00)
Demyelination (SMQ)	Any unsolicited adverse events within Demyelination (SMQ)	2 (0.01)	1 (0.00)
	Nervous system disorders	2 (0.01)	1 (0.00)
	Guillain-Barre syndrome	0	1 (0.00)
	Optic neuritis	2 (0.01)	0
Hypersensitivity (SMQ)	Any unsolicited adverse events within Hypersensitivity (SMQ)	182 (0.83)	161 (0.73)
	Ear and labyrinth disorders	0	1 (0.00)
	Allergic otitis media	0	1 (0.00)
	Eye disorders	5 (0.02)	5 (0.02)
	Conjunctival oedema	0	1 (0.00)
	Conjunctivitis allergic	3 (0.01)	2 (0.01)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

SMQ	Overall SMQ System Organ Class Preferred Term	Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=21926) n[b] (%)	Vaccine Group (as Administered) Placebo (N[a]=21921) n[b] (%)
	Eye allergy	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	8 (0.04)	9 (0.04)
	Application site rash	0	1 (0.00)
	Face oedema	2 (0.01)	0
	Injection site dermatitis	1 (0.00)	0
	Injection site rash	2 (0.01)	1 (0.00)
	Injection site urticaria	1 (0.00)	0
	Swelling face	2 (0.01)	7 (0.03)
	Immune system disorders	10 (0.05)	13 (0.06)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Anaphylactic reaction	1 (0.00)	0
	Anaphylactic shock	0	1 (0.00)
	Drug hypersensitivity	7 (0.03)	7 (0.03)
	Hypersensitivity	2 (0.01)	5 (0.02)
	Infections and infestations	5 (0.02)	1 (0.00)
	Dermatitis infected	0	1 (0.00)
	Pustule	3 (0.01)	0
	Rash pustular	2 (0.01)	0
	Injury, poisoning and procedural complications	3 (0.01)	0
	Administration related reaction	2 (0.01)	0
	Stoma site rash	1 (0.00)	0
	Investigations	1 (0.00)	0
	Blood immunoglobulin E increased	1 (0.00)	0
	Respiratory, thoracic and mediastinal disorders	19 (0.09)	21 (0.10)
	Allergic respiratory disease	0	1 (0.00)
	Allergic sinusitis	2 (0.01)	0
	Bronchospasm	3 (0.01)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Rhinitis allergic	13 (0.06)	14 (0.06)
	Skin and subcutaneous tissue disorders	134 (0.61)	119 (0.54)
	Angioedema	3 (0.01)	2 (0.01)
	Dermatitis	5 (0.02)	4 (0.02)
	Dermatitis acneiform	1 (0.00)	0
	Dermatitis allergic	3 (0.01)	5 (0.02)
	Dermatitis atopic	0	1 (0.00)
	Dermatitis bullous	0	1 (0.00)
	Dermatitis contact	14 (0.06)	21 (0.10)
	Dermatitis exfoliative	1 (0.00)	0
	Drug eruption	0	2 (0.01)
	Eczema	7 (0.03)	3 (0.01)
	Erythema nodosum	1 (0.00)	0
	Fixed eruption	1 (0.00)	0
	Hand dermatitis	2 (0.01)	2 (0.01)
	Perioral dermatitis	0	1 (0.00)
	Pruritus allergic	0	2 (0.01)
	Rash	62 (0.28)	52 (0.24)

Table.S Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Participants ≥16 Years of Age – Safety Population (Data Cutoff March 13, 2021)

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Rash erythematous	2 (0.01)	3 (0.01)
	Rash maculo-papular	7 (0.03)	4 (0.02)
	Rash papular	1 (0.00)	0
	Rash pruritic	8 (0.04)	6 (0.03)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria contact	0	1 (0.00)
	Urticaria papular	0	1 (0.00)
Peripheral neuropathy (SMQ)	Any unsolicited adverse events within Peripheral neuropathy (SMQ)	3 (0.01)	6 (0.03)
	Nervous system disorders	3 (0.01)	6 (0.03)
	Guillain-Barre syndrome	0	1 (0.00)
	Neuralgia	1 (0.00)	1 (0.00)
	Neuritis	0	1 (0.00)
	Neuropathy peripheral	1 (0.00)	3 (0.01)
	Peripheral sensory neuropathy	1 (0.00)	0

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

Table.T SAEs considered related by Investigator – Phase 2/3 Participants 16 Years of Age and Older, Safety Population (Data Cutoff March 13, 2021)

Product (Vaccine or Placebo)	SAE	Dose/Rel Day[a]	Demographics: Age/Sex/Risk Factors from Charlson Index	Resolution	Related per Investigator
BNT162b2	Shoulder injury related to vaccine administration	2/1	30 F; no relevant medical history	Resolved	Yes
BNT162b2	Paraesthesia	2/47	53 F; no relevant medical history	Resolving	Yes
BNT162b2	Ventricular arrhythmia	2/1	71 F; Any malignancy	Resolved	Yes
BNT162b2	Lymphadenopathy	1/13	48 F; no relevant medical history	Resolved	Yes
BNT162b2	Myocardial infarction	2/71#	41 M; no relevant medical history	Resolved	Yes
Placebo	Psoriatic arthropathy	2/38	25 M; no relevant medical history	Not Resolved	Yes
Placebo crossover to BNT162b2	Anaphylactoid reaction	3/3#	17 F; Chronic pulmonary disease	Resolved	Yes

Note: MedDRA (v23.1) coding dictionary applied.
Note: # = SAE occurring on or after unblinding.
a. Relative day (Rel Day) = date of SAE - date of last vaccination + 1.

Table.U Deaths, Phase 2/3 Participants 16 Years of Age and Older, Safety Population, (Data Cutoff March 13, 2021)

Product - Number of doses received	Subject Number	Dose/Rel Day[a]	Primary Cause of Death	Positive COVID-19 test (Y/N)	Age/Sex/ Race/Ethnicity	Demographics: Risk Factors from Charlson Index
BNT162b2 - 2	C4591001 1007 10071101∞	2/63	Cardiac arrest	N	56/F/White/Not Hispanic or Latino	Chronic pulmonary disease
BNT162b2 - 2	C4591001 1021 10211127∞	2/88	Cardiac failure congestive	Y	54/M/Black or African American/Not Hispanic or Latino	Chronic pulmonary disease, Congestive heart failure
BNT162b2 - 2	C4591001 1036 10361140∞#	2/91	Road traffic accident	N	64/M/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1039 10391010∞	2/71	Arteriosclerosis	N	84/M/White/Not Hispanic or Latino	Cerebrovascular disease
BNT162b2 - 2	C4591001 1084 10841266∞	2/121	Sepsis	N	77/M/White/Hispanic or Latino	Congestive heart failure, Diabetes without chronic complication, Peripheral vascular disease
BNT162b2 - 2	C4591001 1088 10881139∞#	2/143	Metastases to lung	N	82/M/White/Not Hispanic or Latino	Chronic pulmonary disease
BNT162b2 - 2	C4591001 1089 10891073∞	2/70	Chronic obstructive pulmonary disease	N	63/F/White/Not Hispanic or Latino	Any malignancy, Chronic pulmonary disease, Diabetes with chronic complication, Diabetes without chronic complication, Myocardial infarction
BNT162b2 - 2	C4591001 1097 10971023∞	2/98	Septic shock	N	86/F/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1114 11141050∞	2/42	Unevaluable event	N	63/F/White/Not Hispanic or Latino	Rheumatic disease
BNT162b2	C4591001 1120	2/73	Cardiac arrest	N	58/F/White/Not Hispanic or	Diabetes without chronic complication

Table.U Deaths, Phase 2/3 Participants 16 Years of Age and Older, Safety Population, (Data Cutoff March 13, 2021)

Product - Number of doses received	Subject Number	Dose/Rel Day[a]	Primary Cause of Death	Positive COVID-19 test (Y/N)	Age/Sex/ Race/Ethnicity	Demographics: Risk Factors from Charlson Index
- 2	11201050∞				Latino	
BNT162b2 - 2	C4591001 1120 11201266∞	2/113	Lung cancer metastatic	N	51/M/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1127 11271112∞	2/86	Cardio-respiratory arrest	N	53/M/Multiple/Not Hispanic or Latino	Chronic pulmonary disease, Myocardial infarction
BNT162b2 - 2	C4591001 1129 11291166∞#	2/129	Myocardial infarction	N	78/F/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1136 11361102∞	2/31	Cardiac arrest	N	76/M/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1140 11401117∞	2/117	Cardiac arrest	N	58/M/White/Not Hispanic or Latino	
BNT162b2 - 1	C4591001 1152 11521497∞	1/36	Shigella sepsis	N	72/M/White/Hispanic or Latino	Diabetes without chronic complication
BNT162b2 - 2	C4591001 1156 11561160∞†	2/74	Road traffic accident	N	62/F/Black or African American/Not Hispanic or Latino	AIDS/HIV, Chronic pulmonary disease
BNT162b2 - 1	C4591001 1162 11621327∞	1/4	Arteriosclerosis	Y	60/M/White/Not Hispanic or Latino	
BNT162b2 - 2	C4591001 1252 12521010∞	2/110	COVID-19 pneumonia	N	80/M/White/Not Hispanic or Latino	
Placebo - 2	C4591001 1019 10191146	2/87	Metastases to liver	N	67/M/White/Not Hispanic or Latino	Chronic pulmonary disease
Placebo - 2	C4591001 1027 10271191#	2/135	Respiratory failure	Y	68/F/Black or African American/Not Hispanic or	Any malignancy, Chronic pulmonary disease

Table.U Deaths, Phase 2/3 Participants 16 Years of Age and Older, Safety Population, (Data Cutoff March 13, 2021)

Product - Number of doses received	Subject Number	Dose/Rel Day[a]	Primary Cause of Death	Positive COVID-19 test (Y/N)	Age/Sex/ Race/Ethnicity	Demographics: Risk Factors from Charlson Index
					Latino	
Placebo - 1	C4591001 1066 10661350	1/16	Myocardial infarction	N	58/M/White/Not Hispanic or Latino	Congestive heart failure, Myocardial infarction
Placebo - 2	C4591001 1081 10811194	2/37	Myocardial infarction	N	51/F/White/Not Hispanic or Latino	Chronic pulmonary disease
Placebo - 2	C4591001 1084 10841470	2/83	Multiple organ dysfunction syndrome	N	65/M/White/Hispanic or Latino	Chronic pulmonary disease
Placebo - 2	C4591001 1088 10881126	2/70	Cardiac arrest	Y	65/M/White/Not Hispanic or Latino	
Placebo - 2	C4591001 1089 10891088	2/125	Dementia	N	82/F/White/Not Hispanic or Latino	Dementia
Placebo - 2	C4591001 1094 10941112	2/81	Acute respiratory failure	N	57/F/White/Hispanic or Latino	Chronic pulmonary disease, Diabetes without chronic complication
Placebo - 2	C4591001 1128 11281009	2/102	Pneumonia	N	66/M/White/Not Hispanic or Latino	Diabetes without chronic complication, Myocardial infarction
Placebo - 2	C4591001 1131 11311204*#	3/26	Cardio-respiratory arrest	N	84/M/White/Not Hispanic or Latino	Cerebrovascular disease, Peripheral vascular disease
Placebo - 2	C4591001 1135 11351033*#	3/5		N	67/M/White/Not Hispanic or Latino	
Placebo - 1	C4591001 1152 11521085	1/8	Death	N	42/F/White/Not Hispanic or Latino	Any malignancy
Placebo - 2	C4591001 1156 11561124	2/32	Overdose	N	53/M/White/Not Hispanic or Latino	

Table.U Deaths, Phase 2/3 Participants 16 Years of Age and Older, Safety Population, (Data Cutoff March 13, 2021)

Product - Number of doses received	Subject Number	Dose/Rel Day[a]	Primary Cause of Death	Positive COVID-19 test (Y/N)	Age/Sex/ Race/Ethnicity	Demographics: Risk Factors from Charlson Index
Placebo - 2	C4591001 1168 11681083	2/65	Aortic rupture	N	64/M/White/Not Hispanic or Latino	
Placebo - 2	C4591001 1207 12071055#	2/76	Pneumonia bacterial	N	65/M/White/Not Hispanic or Latino	Diabetes without chronic complication, Mild liver disease
Placebo - 2	C4591001 1229 12291083†	2/76	COVID-19 pneumonia	N	55/F/Black or African American/Not Hispanic or Latino	AIDS/HIV, Chronic pulmonary disease
Placebo - 2	C4591001 1231 12313972	2/16	Haemorrhagic stroke	N	61/F/White/Hispanic or Latino	
Placebo - 2	C4591001 1231 12314987	2/82	Cardio-respiratory arrest	N	47/M/White/Hispanic or Latino	
Placebo - 2	C4591001 1231 12315324	2/136	Multiple organ dysfunction syndrome	Y	58/F/White/Hispanic or Latino	

Note: MedDRA (v23.1) coding dictionary applied.
Note: † = Human immunodeficiency virus (HIV)-positive subject, # = death occurring on or after unblinding, * = subjects who originally received placebo and then received BNT162b2 after unblinding, ∞ = subjects who originally received BNT162b2.
a. Relative day (Rel Day)= date of death - date of last vaccination + 1.

Table V. Clinical Trials Submitted in Support of Safety and Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine

Study Number/ Country	Study Description	Number of BNT162b2 (30 µg) subjects (N)	Number of placebo subjects (N)	Study Status
C4591001 Phase 1	A Phase 1/2/3 Study to Evaluate the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals	24	6	Ongoing
C4591001 Phase 2/3		22085	22080	Ongoing
Argentina		2887	2889	
Brazil		1452	1448	
Germany		250	250	
South Africa		401	399	
Turkey		251	249	
USA		16844	16845	
BNT162-01 Phase 1/2 Germany (BNT162b2 30 µg)	A multi-site, Phase I/II, 2-part, dose escalation trial investigating the safety and immunogenicity of four prophylactic SARS-CoV-2 RNA vaccines against COVID-19 using different dosing regimens in healthy adults	24	0	Ongoing

N= total number of randomized participants 16 years of age and older, as of March 13, 2021.