| **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) (Na=22085) nb (%)** | **Placebo (Na=22080) nb (%)** | **Total (Na=44165) nb (%)** |
|  | | | |
|  | | | |
| 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 periodc | 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) |
| 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| Withdrawn from the study | 343 (1.6) | 484 (2.2) | 827 (1.9) |
| Withdrawn after Dose 1 and before Dose 2 | 176 (0.8) | 211 (1.0) | 387 (0.9) |
| Withdrawn after Dose 2 and before 1-month post–Dose 2 visit | 100 (0.5) | 139 (0.6) | 239 (0.5) |
| Withdrawn after 1-month post–Dose 2 visit | 67 (0.3) | 134 (0.6) | 201 (0.5) |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) |  |  |
| 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 periodd |  | 24 (0.1) |  |
| Reason for discontinuation from open-label vaccination period |  |  |  |
| Protocol deviation |  | 6 (0.0) |  |
| 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.  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) (Na=22026) nb (%)** | **Placebo (Na=22021) nb (%)** | **Total (Na=44050) nb (%)** |
|  | | | |
|  | | | |
| 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) |
| 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) |
| 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** | | | |
| --- | --- | --- | --- |
|  | **Vaccine Group (as Administered)** | |  |
| **Characteristic** | **BNT162b2 (30 μg) (Na=22026) nb (%)** | **Placebo (Na=22021) nb (%)** | **Total (Na=44047) nb (%)** |
|  | | | |
|  | | | |
| 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) |
| Ethnicity: Not reported | 111 (0.5) | 114 (0.5) | 225 (0.5) |
|  | | | |
| Obesity: Yesc | 7543 (34.2) | 7629 (34.6) | 15172 (34.4) |
| Obesity: No | 14483 (65.8) | 14392 (65.4) | 28875 (65.6) |
|  | | | |
| Comorbidities: Yesd | 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: Negativef | 21185 (96.2) | 21180 (96.2) | 42365 (96.2) |
| Baseline evidence of prior SARS-CoV-2 infection: Positivee | 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/m2.  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/m2.  e.     Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.  f.     Negative N-binding antibody result and negative NAAT result at Visit 1 and no medical history of COVID-19. | | | |

| **Table.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 |
|  | | | | |
| 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 |  |  |  |  |
| 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 (%) n (%)** | **Any n (%) Severe 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 (%) 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) (Na=21926)** | **Placebo (Na=21921)** |
| **SMQ** | **Overall SMQ System Organ Class Preferred Term** | **nb (%)** | **nb (%)** |
|  | | | |
|  | 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) |
|  | 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) |
|  | 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) |
|  | 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) |
|  | 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) |
|  | 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) |
|  | 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 Daya** | **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 Daya** | **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 - 2 | C4591001 1120 11201050∞ | 2/73 | Cardiac arrest | N | 58/F/White/Not Hispanic or Latino | Diabetes without chronic complication |
| 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 Latino | Any malignancy, Chronic pulmonary disease |
| 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 |  |
| 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.