

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Supplemental Statistical Methods

Statistical aspects of the vaccine efficacy analysis

Vaccine efficacy (VE) is defined as the percent reduction in the hazard, i.e. one minus the hazard ratio (HR, mRNA 1273 vs. placebo).

For the primary efficacy and secondary efficacy endpoints, a stratified Cox proportional hazard (PH) model with Efron's method of tie handling and with vaccine groups (mRNA-1273 or Placebo) as covariate is used to assess the vaccine efficacy (i.e. $1 - \text{HR}$) between mRNA-1273 vs. placebo. The model is adjusted for the same stratification factors used for randomization. The estimator of VE and its 95% CI is provided from the stratified Cox proportional model.

For the primary efficacy endpoint, Covid-19 cases based on adjudication committee assessments starting 14 days after the second injection in the Per-Protocol (PP) set, the one-sided p-value for testing the null hypothesis ($\text{VE} \leq 30\%$) derived from the stratified Cox model is provided. At IA1, based on a total of 95 cases, the one-sided p-value was <0.0001 , and was compared to a one-sided alpha of 0.0047 based on 62.9% information of the target total number (95/151) using the Lan-DeMets O'Brien-Fleming approximation. Therefore, the pre-specified statistical criterion for study success was demonstrated at IA1.

For the primary and secondary efficacy endpoints, incidence rate, defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) is calculated. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. *VE is defined as $1 - \text{ratio of incidence rate (mRNA-1273 vs. placebo)}$. The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years.

Stratified Cox regression model to derive estimates of vaccine efficacy as 1-HR.

The assumption of the cox proportional hazard model is that the hazard rate ratio is a constant, i.e. the vaccine efficacy is independent of the rate at which cases occur in the Placebo group in any short time interval. At the first interim analysis with a median follow-up time of 49 days after the second dose, based on 95 cases, the vaccine efficacy estimate from the stratified Cox model was 94.5%. At the primary analysis with a median follow-up time of approximately 9 weeks after the second dose, based on 196 cases, the vaccine efficacy estimate from the stratified Cox model was 94.1%. These results indicate the vaccine efficacy is independent of the rate on Placebo. Analyses based on the exact method conditional on the total number of cases have also been performed and the results are consistent with that from the stratified Cox model.

In addition, the pattern of cumulative incidence curves (based on $1 - \text{Kaplan-Meier estimate}$) for two treatment groups on Covid-19 counted starting 14 days after second dose in the PP set (primary analysis, Figure 3A) and Covid-19 counted starting from randomization in modified intent-to-treat (mITT) set (sensitivity analysis, Figure 3B) show that the proportional hazard assumption holds: two curves of the treatment groups start together with 0 events, separate around day 42 (14 days after second dose) in Figure 3A and Day 14 in Figure 3B, and then diverge over time without crossing.

The plot of log-log transformation of estimated survival probability was examined, based on November 25, 2020 data, of primary endpoint in the PP set. The curves for the two groups were approximately parallel, which supports that the proportional hazard assumption holds

Rationale for Assessment of Vaccine Efficacy in the Per-Protocol Population.

It is not uncommon to use the PP Set as the primary analysis population for efficacy for vaccine studies, as it usually includes participants who have received the intended vaccine regimen. In the PP set, participants are included in the vaccine group to which they were randomized. In our study, the PP Set excluded randomized participants who had positive or missing baseline SARS-CoV-2 status at baseline, who received the incorrect study vaccine, discontinued study before receiving dose 2, or received dose 2 outside of [day 22, 42] window, and other major protocol deviations that impacted critical data. The reasons for exclusions are summarized in Figures 1 and S1. Additionally, sensitivity analyses in the mITT set were performed to assess the consistency of vaccine efficacy.

Additional details supporting Figures 3A and 3B.

In Figures 3 and 4, the time axis started from randomization in days. Figure 3A presents the primary analysis of Covid-19 based on adjudication committee assessments starting 14 days after the second vaccination in the Per-Protocol Set. In this analysis, participants with an onset date of Covid-19 starting 14 days after second dose are events with date of onset; participants with an onset date for Covid-19 <14 days after the second dose (early case) were censored at the date of Covid-19. Participants who did not have Covid-19 were censored at the data cutoff date for efficacy. Participants who discontinued the study early or died due to cause unrelated to Covid-19 without documented Covid-19 are censored at the date of early discontinuation or death. Therefore, the cumulative incidence curves started to separate around 42 days after randomization as the date of Covid-19 in this analysis starts 14 days after second vaccination (with a target day of Day 29). The censoring started around day 29 as the earliest discontinuation in the Per-Protocol Set. Participants who discontinued before dose 2, received dose 2 outside of day [23, 42] window have been excluded from the Per-Protocol Set.

Figure 3B presents a sensitivity analysis of Covid-19 from randomization in the mITT Set. In this analysis, participants who had Covid-19 were events with date of onset. The other censoring rules are the same as above. The mITT Set only excludes randomized participants who did not receive any dose, or had positive or missing baseline SARS-CoV-2 status. Therefore, censoring starts early after randomization (early discontinuations), and the two curves started to separate early.

Baseline demographics and characteristics using the per-protocol set are provided as supportive data for Table 1 based on the randomized participants.

| Baseline Demographics and Characteristics Based in the Per-Protocol Set | | | |
|--|------------------------------|--------------------------------|----------------------------|
| Characteristics n (%) | Placebo (N=14073) | mRNA-1273 (N=14134) | Total (N=28207) |
| Sex | | | |
| Male | 7462 (53.0) | 7366 (52.1) | 14828 (52.6) |
| Female | 6611 (47.0) | 6768 (47.9) | 13379 (47.4) |
| Age at Screening (yr) | | | |
| Mean (range) | 51.6 (18- 95) | 51.6 (18- 95) | 51.6 (18- 95) |
| Age (yr) and health risk for severe Covid-19* | | | |
| ≥18 and <65 and Not at Risk | 8200 (58.3) | 8189 (57.9) | 16389 (58.1) |
| ≥18 and <65 and at Risk | 2324 (16.5) | 2367 (16.7) | 4691 (16.6) |
| ≥65 | 3549 (25.2) | 3578 (25.3) | 7127 (25.3) |
| Ethnicity | | | |
| Hispanic or Latino | 2780 (19.8) | 2789 (19.7) | 5569 (19.7) |
| Not Hispanic or Latino | 11165 (79.3) | 11212 (79.3) | 22377 (79.3) |
| Not reported and unknown | 128 (0.9) | 133 (1.0) | 261 (0.9) |
| Race‡ | | | |
| White | 11174 (79.4) | 11253 (79.6) | 22427 (79.5) |
| Black or African American | 1349 (9.6) | 1385 (9.8) | 2734 (9.7) |
| Asian | 689 (4.9) | 620 (4.4) | 1309 (4.6) |
| American Indian or Alaska Native | 111 (0.8) | 108 (0.8) | 219 (0.8) |
| Native Hawaiian or Other Pacific Islander | 31 (0.2) | 35 (0.2) | 66 (0.2) |
| Multiracial | 307 (2.2) | 295 (2.1) | 602 (2.1) |
| Other | 295 (2.1) | 299 (2.1) | 594 (2.1) |
| Not reported and unknown | 117 (0.9) | 139 (1.0) | 256 (0.9) |
| Baseline SARS-CoV-2 Status† | | | |
| Negative | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 |
| Missing | 0 | 0 | 0 |
| Baseline RT-PCR | | | |
| Negative | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 |
| Missing | 0 | 0 | 0 |
| Baseline bAb Anti-SARS-CoV-2 | | | |
| Negative | 14073 (100) | 14134 (100) | 28207 (100) |
| Positive | 0 | 0 | 0 |
| Missing | 0 | 0 | 0 |
| Risk Factor for Severe Covid-19 at Screening‡ | | | |
| Chronic lung disease | 688(4.9) | 673 (4.8) | 1361 (4.8) |
| Significant cardiac disease | 694 (4.9) | 711 (5.0) | 1405 (5.0) |
| Severe obesity | 936 (6.7) | 956 (6.8) | 1892 (6.7) |
| Diabetes | 1345 (9.6) | 1364 (9.7) | 2709 (9.6) |
| Liver disease | 90 (0.6) | 95(0.7) | 185(0.7) |
| HIV | 77 (0.5) | 82 (0.6) | 159 (0.6) |
| Body Mass Index, (kg/m ²) | | | |
| Mean (SD) | 29.27 (6.650) | 29.28 (6.827) | 29.28 (6.739) |
| <p>bAb = binding antibody concentration; IRT = interactive response technology; RT-PCR = reverse transcription polymerase chain reaction. Internet-based randomization was used to randomize participants to treatment groups based on the information the Investigator entered regarding the age and potential comorbid conditions. *Based on stratification factor from IRT, participants who were <65 years old were categorized as at risk for severe Covid-19 illness if they had at least 1 of the risk factors specified in the study protocol at screening. †Baseline SARS-CoV-2 status was positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test, or bAb against SARS-CoV-2 nucleocapsid above limit of detection; or lower limit of quantification at Day 1. Negative was defined as negative RT-PCR test and negative bAb against SARS-CoV-2 assay result at Day 1. ‡Participants could be under one or more categories and were counted once at each category.</p> | | | |

Fig. S1. Study Disposition in Overall Randomized Set

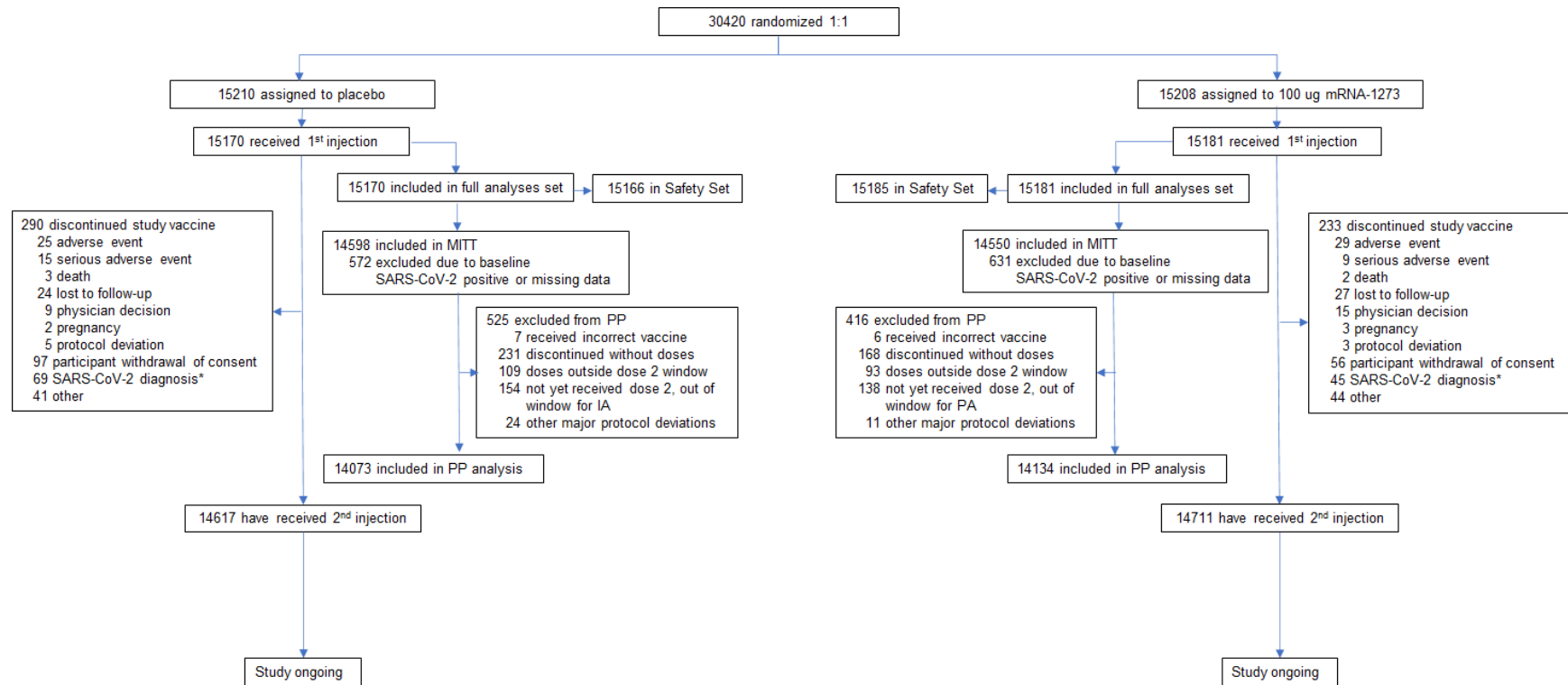


Table S1. Primary and Secondary Objectives of the Trial

| Objectives and Endpoints | |
|--|--|
| Primary Objective | Primary Endpoints |
| <p>Efficacy Objective (Primary): To demonstrate the efficacy of mRNA-1273 to prevent Covid-19.</p> | <p>Efficacy Endpoints (Primary): Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the second dose of investigational product (IP), where Covid-19 is defined as symptomatic disease based on the following criteria:</p> <ul style="list-style-type: none"> • The participant must have experienced at least TWO of the following systemic symptoms: Fever ($\geq 38^{\circ}\text{C}$), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR • The participant must have experienced at least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND • The participant must have at least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR. |
| <p>Safety Objective (Primary): To evaluate the safety and reactogenicity of 2 injections of the mRNA-1273 vaccine given 28 days apart.</p> | <p>Safety Endpoint (Primary):</p> <ul style="list-style-type: none"> • Solicited local and systemic ARs through 7 days after each dose of IP. • Unsolicited AEs through 28 days after each dose of IP. • Medically attended adverse events (MAAEs) or AEs leading to withdrawal through the entire study period. • SAEs throughout the entire study period. |
| Efficacy Objectives (Secondary) | Efficacy Endpoints (Secondary) |
| <p>To evaluate the efficacy of mRNA-1273 to prevent severe Covid-19.</p> | <ul style="list-style-type: none"> • Vaccine efficacy of mRNA-1273 to prevent severe Covid-19, defined as first occurrence of Covid-19 starting 14 days after the second dose of IP, (as per the primary endpoint) AND any of the following: <ul style="list-style-type: none"> ○ Clinical signs indicative of severe systemic illness, Respiratory Rate ≥ 30 per minute, Heart Rate ≥ 125 beats per minute, $\text{SpO}_2 \leq 93\%$ on room air at sea level or $\text{PaO}_2/\text{FIO}_2 < 300$ mm Hg, OR ○ Respiratory failure or Acute Respiratory Distress Syndrome (ARDS), (defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO), evidence of shock (systolic blood pressure < 90 mmHg, diastolic BP < 60 mmHg or requiring vasopressors), OR ○ Significant acute renal, hepatic or neurologic dysfunction, OR ○ Admission to an intensive care unit or death. |
| <p>To evaluate the efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or Covid-19 regardless of symptomatology or severity.</p> | <p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of either Covid-19 or SARS-CoV-2 infection starting 14 days after the second IP dose. This endpoint is a combination of Covid-19, defined as for the primary endpoint, and asymptomatic SARS-CoV-2 infection, determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative nasopharyngeal (NP) swab sample for SARS-CoV-2 at Day 1.</p> |
| <p>To evaluate VE against a secondary definition of Covid-19.</p> | <p>Vaccine efficacy of mRNA-1273 to prevent the secondary case definition of Covid-19 starting 14 days after the second IP dose. The secondary case definition of Covid-19 is defined as the following systemic symptoms: fever (temperature $\geq 38^{\circ}\text{C}$), or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting, or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR.</p> |
| <p>To evaluate VE to prevent death caused by Covid-19.</p> | <p>Vaccine efficacy of mRNA-1273 to prevent death due to a cause directly attributed to a complication of Covid-19, starting 14 days after the second IP dose.</p> |
| <p>To evaluate the efficacy of mRNA-1273 to prevent Covid-19 after the first dose of IP.</p> | <p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the first dose of IP.</p> |

| | |
|---|---|
| <p>To evaluate the efficacy of mRNA-1273 to prevent Covid-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection.</p> | <p>Vaccine efficacy of mRNA-1273 to prevent the first occurrence of Covid-19 starting 14 days after the second dose of IP regardless of evidence of prior SARS-CoV-2 infection determined by serologic titer against SARS-CoV-2 nucleocapsid (FAS analysis population).</p> |
| <p>To evaluate the efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection.</p> | <p>Vaccine efficacy to prevent the first occurrence of SARS-CoV-2 infection in the absence of symptoms defining Covid-19 starting 14 days after the second IP dose. SARS-CoV-2 infection determined by seroconversion assessed by bAb levels against SARS-CoV-2 as measured by a ligand-binding assay specific to the SARS-CoV-2 nucleocapsid protein and with a negative NP swab sample for SARS-CoV-2 at Day 1.</p> |

Table S2. Baseline Demographics and Characteristics by Randomized Strata Groups, Full Analysis Set

| Characteristic n (%) | ≥18-<65 yr and not at risk | | | ≥18-<65 yr and at risk | | | ≥65 yr | | | Overall | | |
|--|----------------------------|--------------|--------------|------------------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|--------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | N=8886 | N=8888 | N=17774 | N=2535 | N=2530 | N=5065 | N=3749 | N=3763 | N=7512 | N=15170 | N=15181 | N=30351 |
| Age at screening, yr mean (range) | 43.8 (18-72) | 44.0 (18-64) | 43.9 (18-72) | 49.2 (18-79) | 48.9 (18-76) | 49.0 (18-79) | 70.7 (40-95) | 70.4 (64-95) | 70.6 (40-95) | 51.3 (18-95) | 51.4 (18-95) | 51.4 (18-95) |
| Sex | | | | | | | | | | | | |
| Male | 4632 (52.1) | 4544 (51.1) | 9176 (51.6) | 1329 (52.4) | 1305 (51.6) | 2634 (52.0) | 2101 (56.0) | 2074 (55.1) | 4175 (55.6) | 8062 (53.1) | 7923 (52.2) | 15985 (52.7) |
| Female | 4254 (47.9) | 4344 (48.9) | 8598 (48.4) | 1206 (47.6) | 1225 (48.4) | 2431 (48.0) | 1648 (44.0) | 1689 (44.9) | 3337 (44.4) | 7108 (46.9) | 7258 (47.8) | 14366 (47.3) |
| Race | | | | | | | | | | | | |
| White | 6789 (76.4) | 6756 (76.0) | 13545 (76.2) | 1870 (73.8) | 1900 (75.1) | 3770 (74.4) | 3336 (89.0) | 3373 (89.6) | 6709 (89.3) | 11995 (79.1) | 12029 (79.2) | 24024 (79.2) |
| Black or African American | 899 (10.1) | 968 (10.9) | 1867 (10.5) | 413 (16.3) | 374 (14.8) | 787 (15.5) | 215 (5.7) | 221 (5.9) | 436 (5.8) | 1527 (10.1) | 1563 (10.3) | 3090 (10.2) |
| Asian | 570 (6.4) | 501 (5.6) | 1071 (6.0) | 84 (3.3) | 85 (3.4) | 169 (3.3) | 77 (2.1) | 65 (1.7) | 142 (1.9) | 731 (4.8) | 651 (4.3) | 1382 (4.6) |
| American Indian or Alaska Native | 72 (0.8) | 65 (0.7) | 137 (0.8) | 23 (0.9) | 26 (1.0) | 49 (1.0) | 26 (0.7) | 21 (0.6) | 47 (0.6) | 121 (0.8) | 112 (0.7) | 233 (0.8) |
| Native Hawaiian or Pacific Islander | 20 (0.2) | 25 (0.3) | 45 (0.3) | 9 (0.4) | 7 (0.3) | 16 (0.3) | 3 (<0.1) | 3 (<0.1) | 6 (<0.1) | 32 (0.2) | 35 (0.2) | 67 (0.2) |
| Multiracial | 232 (2.6) | 231 (2.6) | 463 (2.6) | 51 (2.0) | 50 (2.0) | 101 (2.0) | 38 (1.0) | 34 (0.9) | 72 (1.0) | 321 (2.1) | 315 (2.1) | 636 (2.1) |
| Other | 229 (2.6) | 233 (2.6) | 462 (2.6) | 54 (2.1) | 61 (2.4) | 115 (2.3) | 33 (0.9) | 27 (0.7) | 60 (0.8) | 316 (2.1) | 321 (2.1) | 637 (2.1) |
| Not reported | 42 (0.5) | 67 (0.8) | 109 (0.6) | 1 (0.7) | 16 (0.6) | 34 (0.7) | 13 (0.3) | 13 (0.3) | 26 (0.3) | 73 (0.5) | 96 (0.6) | 169 (0.6) |
| Unknown | 33 (0.4) | 42 (0.5) | 75 (0.4) | 13 (0.5) | 11 (0.4) | 24 (0.5) | 8 (0.2) | 6 (0.2) | 14 (0.2) | 54 (0.4) | 59 (0.4) | 113 (0.4) |
| Race and Ethnicity Group* | | | | | | | | | | | | |
| White | 4975 (56.0) | 5005 (56.3) | 9980 (56.1) | 1426 (56.3) | 1456 (57.5) | 2882 (56.9) | 3060 (81.6) | 3068 (81.5) | 6128 (81.6) | 9461 (62.4) | 9529 (62.8) | 18990 (62.6) |
| Communities of color | 3903 (43.9) | 3869 (43.5) | 7772 (43.7) | 1104 (43.6) | 1068 (42.2) | 2172 (42.9) | 676 (18.0) | 689 (18.3) | 1365 (18.2) | 5683 (37.5) | 5626 (37.1) | 11309 (37.3) |
| Missing | 8 (<0.1) | 14 (0.2) | 22 (0.1) | 5 (0.2) | 6 (0.2) | 11 (0.2) | 13 (0.3) | 6 (0.2) | 19 (0.3) | 26 (0.2) | 26 (0.2) | 52 (0.2) |
| Ethnicity | | | | | | | | | | | | |
| Hispanic or Latino | 2228 (25.1) | 2209 (24.9) | 4437 (25.0) | 552 (21.8) | 558 (22.1) | 1110 (21.9) | 334 (8.9) | 354 (9.4) | 688 (9.2) | 3114 (20.5) | 3121 (20.6) | 6235 (20.5) |
| Not Hispanic or Latino | 6585 (74.1) | 6599 (74.2) | 13184 (74.2) | 1960 (77.3) | 1953 (77.2) | 3913 (77.3) | 3372 (89.9) | 3366 (89.4) | 6738 (89.7) | 11917 (78.6) | 11918 (78.5) | 23835 (78.5) |
| Not Reported | 43 (0.5) | 58 (0.7) | 101 (0.6) | 15 (0.6) | 14 (0.6) | 29 (0.6) | 27 (0.7) | 32 (0.9) | 59 (0.8) | 85 (0.6) | 104 (0.7) | 189 (0.6) |
| Unknown | 30 (0.3) | 22 (0.2) | 52 (0.3) | 8 (0.3) | 5 (0.2) | 13 (0.3) | 16 (0.4) | 11 (0.3) | 27 (0.4) | 54 (0.4) | 38 (0.3) | 92 (0.3) |
| BMI kg/m2, mean (SD) | 28.0 (5.2) | 28.0 (5.3) | 28.0 (5.2) | 35.0 (9.2) | 35.2 (9.6) | 35.1 (9.4) | 28.7 (5.9) | 28.7 (5.9) | 28.7 (5.9) | 29.3 (6.7) | 29.3 (6.9) | 29.3 (6.8) |
| At risk for severe Covid-19 at screening | | | | | | | | | | | | |
| Yes | 141 (1.6) | 127 (1.4) | 268 (1.5) | 2163 (85.3) | 2171 (85.8) | 4334 (85.6) | 1114 (29.7) | 1101 (29.3) | 2215 (29.5) | 3418 (22.5) | 3399 (22.4) | 6817 (22.5) |
| No | 8745 (98.4) | 8761 (98.6) | 17506 (98.5) | 372 (14.7) | 359 (14.2) | 731 (14.4) | 2635 (70.3) | 2662 (70.7) | 5297 (70.5) | 11752 (77.5) | 11782 (77.6) | 23534 (77.5) |

| | | | | | | | | | | | | |
|--|--------------|-------------|---------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|--------------|--------------|
| Baseline RT-PCR | | | | | | | | | | | | |
| Negative | 8755 (98.5) | 8728 (98.2) | 17483 (98.4) | 2474 (97.6) | 2478 (97.9) | 4952 (97.8) | 3694 (98.5) | 3711 (98.6) | 7405 (98.6) | 14923 (98.4) | 14917 (98.3) | 29840 (98.3) |
| Positive | 65 (0.7) | 64 (0.7) | 129 (0.7) | 20 (0.8) | 16 (0.6) | 36 (0.7) | 10 (0.3) | 7 (0.2) | 17 (0.2) | 95 (0.6) | 87 (0.6) | 182 (0.6) |
| Missing | 66 (0.7) | 96 (1.1) | 162 (0.9) | 41 (1.6) | 36 (1.4) | 77 (1.5) | 45 (1.2) | 45 (1.2) | 90 (1.2) | 152 (1.0) | 177 (1.2) | 329 (1.1) |
| Baseline bAb Anti-SARS-CoV-2 | | | | | | | | | | | | |
| Negative | 8595 (96.7) | 8555 (96.3) | 17150 (96.5) | 2449 (96.6) | 2451 (96.9) | 4900 (96.7) | 3682 (98.2) | 3684 (97.9) | 7366 (98.1) | 14726 (97.1) | 14690 (96.8) | 29416 (96.9) |
| Positive | 216 (2.4) | 230 (2.6) | 44 (2.5) | 59 (2.3) | 42 (1.7) | 101 (2.0) | 28 (0.7) | 33 (0.9) | 61 (0.8) | 303 (2.0) | 305 (2.0) | 608 (2.0) |
| Missing | 75 (0.8) | 103 (1.2) | 178 (1.0) | 27 (1.1) | 37 (1.5) | 64 (1.3) | 39 (1.0) | 46 (1.2) | 85 (1.1) | 141 (0.9) | 186 (1.2) | 327 (1.1) |
| Baseline SARS-CoV-2 Status† | | | | | | | | | | | | |
| Negative | 8532 (96.0) | 8468 (95.3) | 17000 (95.6) | 2415 (95.3) | 2427 (95.9) | 4842 (95.6) | 3651 (97.4) | 3655 (97.1) | 7306 (97.3) | 14598 (96.2) | 14550 (95.8) | 29148 (96.0) |
| Positive | 239 (2.7) | 260 (2.9) | 499 (2.8) | 65 (2.6) | 47 (1.9) | 112 (2.2) | 33 (0.9) | 36 (1.0) | 69 (0.9) | 337 (2.2) | 343 (2.3) | 680 (2.2) |
| Missing | 115 (1.3) | 160 (1.8) | 275 (1.5) | 55 (2.2) | 56 (2.2) | 111 (2.2) | 65 (1.7) | 72 (1.9) | 137 (1.8) | 235 (1.5) | 288 (1.9) | 523 (1.7) |
| Age Subgroup at Screening (yr) | | | | | | | | | | | | |
| ≥18 and <65 | 8885 (>99.9) | 8888 (100) | 17773 (>99.9) | 2532 (99.9) | 2524 (99.8) | 5056 (99.8) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 11418 (75.3) | 11413 (75.2) | 22831 (75.2) |
| ≥65 and <75 | 1 (<0.1) | 0 | 1 (<0.1) | 2 (<0.1) | 5 (0.2) | 7 (0.1) | 3008 (80.2) | 3105 (82.5) | 6113 (81.4) | 3011 (19.8) | 3110 (20.5) | 6121 (20.2) |
| ≥75 and <85 | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 691 (18.4) | 616 (16.4) | 1307 (17.4) | 692 (4.6) | 617 (4.1) | 1309 (4.3) |
| ≥85 Years | 0 | 0 | 0 | 0 | 0 | 0 | 49 (1.3) | 41 (1.1) | 90 (1.2) | 49 (0.3) | 41 (0.3) | 90 (0.3) |
| Risk Factor for Severe Covid-19 at Screening | | | | | | | | | | | | |
| Chronic lung disease | 17 (0.2) | 19 (0.2) | 36 (0.2) | 485 (19.1) | 455 (18.0) | 940 (18.6) | 242 (6.5) | 236 (6.3) | 478 (6.4) | 744 (4.9) | 710 (4.7) | 1454 (4.8) |
| Significant cardiac disease | 11 (0.1) | 12 (0.1) | 23 (0.1) | 285 (11.2) | 306 (12.1) | 591 (11.7) | 448 (11.9) | 434 (11.5) | 882 (11.7) | 744 (4.9) | 752 (5.0) | 1496 (4.9) |
| Severe obesity | 69 (0.8) | 59 (0.7) | 128 (0.7) | 809 (31.9) | 807 (31.9) | 1616 (31.9) | 143 (3.8) | 159 (4.2) | 302 (4.0) | 1021 (6.7) | 1025 (6.8) | 2046 (6.7) |
| Diabetes | 33 (0.4) | 32 (0.4) | 65 (0.4) | 871 (34.4) | 876 (34.6) | 1747 (34.5) | 536 (14.3) | 527 (14.0) | 1063 (14.2) | 1440 (9.5) | 1435 (9.5) | 2875 (9.5) |
| Liver disease | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) | 62 (2.4) | 76 (3.0) | 138 (2.7) | 26 (0.7) | 18 (0.5) | 44 (0.6) | 96 (0.6) | 100 (0.7) | 196 (0.6) |
| HIV | 13 (0.1) | 14 (0.2) | 27 (0.2) | 59 (2.3) | 62 (2.5) | 121 (2.4) | 15 (0.4) | 16 (0.4) | 31 (0.4) | 87 (0.6) | 92 (0.6) | 179 (0.6) |
| Occupational Risk | 7962 (89.6) | 7929 (89.2) | 15891 (89.4) | 2165 (85.4) | 2144 (84.7) | 4309 (85.1) | 2378 (63.4) | 2356 (62.6) | 4734 (63.0) | 12505 (82.4) | 12429 (81.9) | 24934 (82.2) |
| Healthcare Workers | 2734 (30.8) | 2735 (30.8) | 5469 (30.8) | 593 (23.4) | 595 (23.5) | 1188 (23.5) | 504 (13.4) | 460 (12.2) | 964 (12.8) | 3831 (25.3) | 3790 (25.0) | 7621 (25.1) |
| Emergency Response | 220 (2.5) | 233 (2.6) | 453 (2.5) | 58 (2.3) | 49 (1.9) | 107 (2.1) | 19 (0.5) | 20 (0.5) | 39 (0.5) | 297 (2.0) | 302 (2.0) | 599 (2.0) |
| Retail/Restaurant | 689 (7.8) | 683 (7.7) | 1372 (7.7) | 186 (7.3) | 171 (6.8) | 357 (7.0) | 99 (2.6) | 100 (2.7) | 199 (2.6) | 974 (6.4) | 954 (6.3) | 1928 (6.4) |
| Manufacturing and Production | 306 (3.4) | 289 (3.3) | 595 (3.3) | 85 (3.4) | 102 (4.0) | 187 (3.7) | 30 (0.8) | 34 (0.9) | 64 (0.9) | 421 (2.8) | 425 (2.8) | 846 (2.8) |
| Warehouse Shipping and Fulfillment | 121 (1.4) | 138 (1.6) | 259 (1.5) | 42 (1.7) | 44 (1.7) | 86 (1.7) | 12 (0.3) | 9 (0.2) | 21 (0.3) | 175 (1.2) | 19 (1.3) | 366 (1.2) |

| | | | | | | | | | | | | |
|---|-------------|-------------|--------------|-------------|-------------|-------------|-------------|-------------|-------------|--------------|--------------|--------------|
| Transportation and Delivery | 313 (3.5) | 335 (3.8) | 648 (3.6) | 9 (3.9) | 97 (3.8) | 195 (3.8) | 62 (1.7) | 50 (1.3) | 112 (1.5) | 473 (3.1) | 482 (3.2) | 955 (3.1) |
| Border Protection and Military Personnel | 51 (0.6) | 53 (0.6) | 104 (0.6) | 11 (0.4) | 13 (0.5) | 24 (0.5) | 6 (0.2) | 3 (<0.1) | 9 (0.1) | 6 (0.4) | 69 (0.5) | 137 (0.5) |
| Personal Care and In-Home Services | 330 (3.7) | 299 (3.4) | 629 (3.5) | 78 (3.1) | 103 (4.1) | 181 (3.6) | 61 (1.6) | 67 (1.8) | 128 (1.7) | 469 (3.1) | 469 (3.1) | 938 (3.1) |
| Hospitality and Tourism Workers | 149 (1.7) | 163 (1.8) | 312 (1.8) | 40 (1.6) | 38 (1.5) | 78 (1.5) | 43 (1.1) | 36 (1.0) | 79 (1.1) | 232 (1.5) | 237 (1.6) | 469 (1.5) |
| Pastoral, Social or Public Health Workers | 264 (3.0) | 296 (3.3) | 560 (3.2) | 101 (4.0) | 90 (3.6) | 19 (3.8) | 138 (3.7) | 147 (3.9) | 285 (3.8) | 503 (3.3) | 533 (3.5) | 1036 (3.4) |
| Educators and Students | 1113 (12.5) | 1083 (12.2) | 2196 (12.4) | 270 (10.7) | 276 (10.9) | 546 (10.8) | 169 (4.5) | 184 (4.9) | 353 (4.7) | 1552 (10.2) | 1543 (10.2) | 3095 (10.2) |
| Other | 2591 (29.2) | 2582 (29.1) | 5173 (29.1) | 789 (31.1) | 810 (32.0) | 1599 (31.6) | 1423 (38.0) | 1426 (37.9) | 2849 (37.9) | 4803 (31.7) | 4818 (31.7) | 9621 (31.7) |
| Location and Living Circumstances Risk | 7444 (83.8) | 7481 (84.2) | 14925 (84.0) | 2080 (82.1) | 2046 (80.9) | 4126 (81.5) | 3089 (82.4) | 3119 (82.9) | 6208 (82.6) | 12613 (83.1) | 12646 (83.3) | 25259 (83.2) |
| Nursing Home or Assisted Living Facility | 6 (<0.1) | 11 (0.1) | 17 (<0.1) | 3 (0.1) | 11 (0.4) | 14 (0.3) | 20 (0.5) | 11 (0.3) | 31 (0.4) | 29 (0.2) | 33 (0.2) | 62 (0.2) |
| Multi-Family Dwelling | 266 (3.0) | 304 (3.4) | 570 (3.2) | 80 (3.2) | 92 (3.6) | 172 (3.4) | 63 (1.7) | 66 (1.8) | 129 (1.7) | 409 (2.7) | 462 (3.0) | 871 (2.9) |
| High Density Housing | 873 (9.8) | 839 (9.4) | 1712 (9.6) | 195 (7.7) | 195 (7.7) | 390 (7.7) | 239 (6.4) | 251 (6.7) | 490 (6.5) | 1307 (8.6) | 1285 (8.5) | 2592 (8.5) |
| Low Density, Multi-Family Setting | 952 (10.7) | 934 (10.5) | 1886 (10.6) | 275 (10.8) | 301 (11.9) | 576 (11.4) | 255 (6.8) | 244 (6.5) | 499 (6.6) | 1482 (9.8) | 1479 (9.7) | 2961 (9.8) |
| Single Family Home | 4739 (53.3) | 4771 (53.7) | 9510 (53.5) | 1366 (53.9) | 1288 (50.9) | 2654 (52.4) | 2245 (59.9) | 2270 (60.3) | 4515 (60.1) | 8350 (55.0) | 8329 (54.9) | 16679 (55.0) |
| Other | 1306 (14.7) | 1329 (15.0) | 2635 (14.8) | 331 (13.1) | 315 (12.5) | 646 (12.8) | 528 (14.1) | 545 (14.5) | 1073 (14.3) | 2165 (14.3) | 2189 (14.4) | 4354 (14.3) |

Percentages are based on the number of participants in full analysis set (FAS), presented for overall and 3 age stratification groups. Baseline SARS-CoV-2 status was positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or positive bAb result at day 1; negative was defined as negative RT-PCR test and negative bAb result at day 1. *White was defined as white and non-Hispanic, and communities of color includes all the others whose race or ethnicity is not unknown, unreported or missing. †Baseline SARS-CoV-2 Status was considered positive if there was immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or bAb result at day 1; negative was defined as negative RT-PCR test and bAb results at day 1. Age and health risk for severe Covid-19 are derived from age and risk factors collected on case report form. Note that some participants were incorrectly stratified on the basis of Covid-19 risk.

Table S3. Solicited Adverse Reactions Within 7 Days After First Vaccination by Grade, Solicited Safety Set

| Adverse reaction Vaccination 1 n (%) | Overall Safety Set | | | ≥18-<65 years | | | ≥65 years | | |
|--|--------------------|--------------|--------------|---------------|--------------|--------------|-------------|-------------|-------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=15155) | (N=15168) | (N=30323) | (N=11407) | (N=11406) | (N=22813) | N=3748 | N=3762 | N=7510 |
| Any solicited AR | 7284 (48) | 13319 (87.8) | 20603 (67.9) | 5738 (50.3) | 10261 (90.0) | 15999 (70.1) | 1546 (41.2) | 3058 (81.3) | 4604 (61.3) |
| Grade 1 | 5147 (34.0) | 9342 (61.6) | 14489 (47.8) | 4003 (35.1) | 6959 (61.0) | 10962 (48.1) | 1144 (30.5) | 2383 (63.3) | 3527 (47.0) |
| Grade 2 | 1770 (11.7) | 3124 (20.6) | 4894 (16.1) | 1459 (12.8) | 2593 (22.7) | 4052 (17.8) | 311 (8.3) | 531 (14.1) | 842 (11.2) |
| Grade 3 | 361(2.4) | 848 (5.6) | 1209 (4.0) | 272 (2.4) | 704 (6.2) | 976 (4.3) | 89 (2.4) | 144 (3.8) | 233 (3.1) |
| Grade 4 | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) | 2 (<0.1) | 0 | 2 (<0.1) |
| Any Local AR | 2997 (19.8) | 12765 (84.2) | 15762 (52.0) | 2430 (21.3) | 9960 (87.4) | 12390 (54.3) | 567 (15.1) | 2805 (74.6) | 3372 (44.9) |
| Grade 1 | 2837 (18.7) | 10731 (70.8) | 13568 (44.8) | 2333 (20.5) | 8154 (71.5) | 10487 (46.0) | 504 (13.5) | 2577 (68.5) | 3081 (41.0) |
| Grade 2 | 82 (0.5) | 1505 (9.9) | 1587 (5.2) | 58 (0.5) | 1354 (11.9) | 1412 (6.2) | 24 (0.6) | 151 (4.0) | 175 (2.3) |
| Grade 3 | 78 (0.5) | 529 (3.5) | 607 (2.0) | 39 (0.3) | 452 (4.0) | 491 (2.2) | 39 (1.0) | 77 (2.0) | 116 (1.5) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Local AR | | | | | | | | | |
| Pain | 2658 (17.5) | 12690 (83.7) | 15348 (50.6) | 2177 (19.1) | 9908 (86.9) | 12085 (53.0) | 481 (12.8) | 2782 (74.0) | 3263 (43.5) |
| Grade 1 | 2549 (16.8) | 10990 (72.5) | 13539 (44.7) | 2114 (18.5) | 8362 (73.3) | 10476 (45.9) | 435 (11.6) | 2628 (69.9) | 3063 (40.8) |
| Grade 2 | 54 (0.4) | 1284 (8.5) | 1338 (4.4) | 40 (0.4) | 1180 (10.3) | 1220 (5.3) | 14 (0.4) | 104 (2.8) | 118 (1.6) |
| Grade 3 | 55 (0.4) | 416 (2.7) | 471 (1.6) | 23 (0.2) | 366 (3.2) | 389 (1.7) | 32 (0.9) | 50 (1.3) | 82 (1.1) |
| Erythema | 67 (0.4) | 430 (2.8) | 497 (1.6) | 47 (0.4) | 344 (3.0) | 391 (1.7) | 20 (0.5) | 86 (2.3) | 106 (1.4) |
| Grade 1 | 47 (0.3) | 267 (1.8) | 314 (1.0) | 32 (0.3) | 212 (1.9) | 244 (1.1) | 15 (0.4) | 55 (1.5) | 70 (0.9) |
| Grade 2 | 7 (<0.1) | 121 (0.8) | 128 (0.4) | 4 (<0.1) | 98 (0.9) | 102 (0.4) | 3 (<0.1) | 23 (0.6) | 26 (0.3) |
| Grade 3 | 13 (<0.1) | 42 (0.3) | 55 (0.2) | 11 (<0.1) | 34 (0.3) | 45 (0.2) | 2 (<0.1) | 8 (0.2) | 10 (0.1) |
| Swelling | 52 (0.3) | 932 (6.1) | 984 (3.2) | 34 (0.3) | 767 (6.7) | 801 (3.5) | 18 (0.5) | 165 (4.4) | 183 (2.4) |
| Grade 1 | 39 (0.3) | 605 (4.0) | 644 (2.1) | 28 (0.2) | 500 (4.4) | 528 (2.3) | 11 (0.3) | 105 (2.8) | 116 (1.5) |
| Grade 2 | 7 (<0.1) | 245 (1.6) | 252 (0.8) | 3 (<0.1) | 205 (1.8) | 208 (0.9) | 4 (0.1) | 40 (1.1) | 44 (0.6) |
| Grade 3 | 6 (<0.1) | 82 (0.5) | 88 (0.3) | 3 (<0.1) | 62 (0.5) | 65 (0.3) | 3 (<0.1) | 20 (0.5) | 23 (0.3) |
| Axillary swelling/tenderness* | 722 (4.8) | 1553 (10.2) | 2275 (7.5) | 567 (5.0) | 1322 (11.6) | 1889 (8.3) | 155 (4.1) | 231 (6.1) | 386 (5.1) |
| Grade 1 | 668 (4.4) | 1395 (9.2) | 2063 (6.8) | 534 (4.7) | 1181 (10.4) | 1715 (7.5) | 134 (3.6) | 214 (5.7) | 348 (4.6) |
| Grade 2 | 27 (0.2) | 109 (0.7) | 136 (0.4) | 20 (0.2) | 104 (0.9) | 124 (0.5) | 7 (0.2) | 5 (0.1) | 12 (0.2) |
| Grade 3 | 27 (0.2) | 49 (0.3) | 76 (0.3) | 13 (0.1) | 37 (0.3) | 50 (0.2) | 14 (0.4) | 12 (0.3) | 26 (0.3) |
| Any Systemic AR | 6399 (42.2) | 8320 (54.9) | 14719 (48.5) | 5065 (44.4) | 6503 (57.0) | 11568 (50.7) | 1334 (35.6) | 1817 (48.3) | 3151 (42.0) |
| Grade 1 | 4346 (28.7) | 5372 (35.4) | 9718 (32.0) | 3375 (29.6) | 4092 (35.9) | 7467 (32.7) | 971 (25.9) | 1280 (34.0) | 2251 (30.0) |
| Grade 2 | 1739 (11.5) | 2496 (16.5) | 4235 (14.0) | 1438 (12.6) | 2043 (17.9) | 3481 (15.3) | 301 (8.0) | 453 (12.0) | 754 (10.0) |
| Grade 3 | 308 (2.0) | 447 (2.9) | 755 (2.5) | 248 (2.2) | 363 (3.2) | 611 (2.7) | 60 (1.6) | 84 (2.2) | 144 (1.9) |
| Grade 4 | 6 (<0.1) | 5 (<0.1) | 11 (<0.1) | 4 (<0.1) | 5 (<0.1) | 9 (<0.1) | 2 (<0.1) | 0 | 2 (<0.1) |
| Systemic AR | | | | | | | | | |
| Fever | 44 (0.3) | 115 (0.8) | 159 (0.5) | 37 (0.3) | 105 (0.9) | 142 (0.6) | 7 (0.2) | 10 (0.3) | 17 (0.2) |
| Grade 1 | 29 (0.2) | 74 (0.5) | 103 (0.3) | 26 (0.2) | 67 (0.6) | 93 (0.4) | 3 (<0.1) | 7 (0.2) | 10 (0.1) |
| Grade 2 | 7 (<0.1) | 26 (0.2) | 33 (0.1) | 6 (<0.1) | 24 (0.2) | 30 (0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Grade 3 | 2 (<0.1) | 11 (<0.1) | 13 (<0.1) | 1 (<0.1) | 10 (<0.1) | 11 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |

| | | | | | | | | | |
|-----------------|-------------|-------------|-------------|-------------|-------------|-------------|------------|-------------|-------------|
| Grade 4 | 6 (<0.1) | 4 (<0.1) | 10 (<0.1) | 4 (<0.1) | 4 (<0.1) | 8 (<0.1) | 2 (<0.1) | 0 | 2 (<0.1) |
| Headache | 4027 (26.6) | 4951 (32.7) | 8978 (29.6) | 3304 (29.0) | 4030 (35.3) | 7334 (32.2) | 723 (19.3) | 921 (24.5) | 1644 (21.9) |
| Grade 1 | 3306 (21.8) | 3953 (26.1) | 7259 (23.9) | 2676 (23.5) | 3174 (27.8) | 5850 (25.7) | 630 (16.8) | 779 (20.7) | 1409 (18.8) |
| Grade 2 | 525 (3.5) | 727 (4.8) | 1252 (4.1) | 466 (4.1) | 637 (5.6) | 1103 (4.8) | 59 (1.6) | 90 (2.4) | 149 (2.0) |
| Grade 3 | 196 (1.3) | 271 (1.8) | 467 (1.5) | 162 (1.4) | 219 (1.9) | 381 (1.7) | 34 (0.9) | 52 (1.4) | 86 (1.1) |
| Fatigue | 4133 (27.3) | 5635 (37.2) | 9768 (32.2) | 3282 (28.8) | 4384 (38.4) | 7666 (33.6) | 851 (22.7) | 1251 (33.3) | 2102 (28.0) |
| Grade 1 | 2709 (17.9) | 3599 (23.7) | 6308 (20.8) | 2104 (18.4) | 2744 (24.1) | 4848 (21.3) | 605 (16.2) | 855 (22.7) | 1460 (19.5) |
| Grade 2 | 1319 (8.7) | 1885 (12.4) | 3204 (10.6) | 1095 (9.6) | 1519 (13.3) | 2614 (11.5) | 224 (6.0) | 366 (9.7) | 590 (7.9) |
| Grade 3 | 105 (0.7) | 150 (1.0) | 255 (0.8) | 83 (0.7) | 120 (1.1) | 203 (0.9) | 22 (0.6) | 30 (0.8) | 52 (0.7) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 |
| Myalgia | 2071 (13.7) | 3441 (22.7) | 5512 (18.2) | 1628 (14.3) | 2699 (23.7) | 4327 (19.0) | 443 (11.8) | 742 (19.7) | 1185 (15.8) |
| Grade 1 | 1567 (10.3) | 2445 (16.1) | 4012 (13.2) | 1205 (10.6) | 1876 (16.5) | 3081 (13.5) | 362 (9.7) | 569 (15.1) | 931 (12.4) |
| Grade 2 | 457 (3.0) | 906 (6.0) | 1363 (4.5) | 385 (3.4) | 750 (6.6) | 1135 (5.0) | 72 (1.9) | 156 (4.1) | 228 (3.0) |
| Grade 3 | 47 (0.3) | 90 (0.6) | 137 (0.5) | 38 (0.3) | 73 (0.6) | 111 (0.5) | 9 (0.2) | 17 (0.5) | 26 (0.3) |
| Arthralgia | 1783 (11.8) | 2511 (16.6) | 4294 (14.2) | 1327 (11.6) | 1893 (16.6) | 3220 (14.1) | 456 (12.2) | 618 (16.4) | 1074 (14.3) |
| Grade 1 | 1341 (8.9) | 1846 (12.2) | 3187 (10.5) | 970 (8.5) | 1371 (12.0) | 2341 (10.3) | 371 (9.9) | 475 (12.6) | 846 (11.3) |
| Grade 2 | 405 (2.7) | 604 (4.0) | 1009 (3.3) | 328 (2.9) | 474 (4.2) | 802 (3.5) | 77 (2.1) | 130 (3.5) | 207 (2.8) |
| Grade 3 | 37 (0.2) | 60 (0.4) | 97 (0.3) | 29 (0.3) | 47 (0.4) | 76 (0.3) | 8 (0.2) | 13 (0.3) | 21 (0.3) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 |
| Nausea/vomiting | 1074 (7.1) | 1262 (8.3) | 2336 (7.7) | 908 (8.0) | 1068 (9.4) | 1976 (8.7) | 166 (4.4) | 194 (5.2) | 360 (4.8) |
| Grade 1 | 890 (5.9) | 1048 (6.9) | 1938 (6.4) | 752 (6.6) | 889 (7.8) | 1641 (7.2) | 138 (3.7) | 159 (4.2) | 297 (4.0) |
| Grade 2 | 172 (1.1) | 204 (1.3) | 376 (1.2) | 148 (1.3) | 173 (1.5) | 321 (1.4) | 24 (0.6) | 31 (0.8) | 55 (0.7) |
| Grade 3 | 12 (<0.1) | 10 (<0.1) | 22 (<0.1) | 8 (<0.1) | 6 (<0.1) | 14 (<0.1) | 4 (0.1) | 4 (0.1) | 8 (0.1) |
| Chills | 878 (5.8) | 1253 (8.3) | 2131 (7.0) | 730 (6.4) | 1051 (9.2) | 1781 (7.8) | 148 (4.0) | 202 (5.4) | 350 (4.7) |
| Grade 1 | 706 (4.7) | 940 (6.2) | 1646 (5.4) | 584 (5.1) | 781 (6.8) | 1365 (6.0) | 122 (3.3) | 159 (4.2) | 281 (3.7) |
| Grade 2 | 158 (1.0) | 289 (1.9) | 447 (1.5) | 138 (1.2) | 253 (2.2) | 391 (1.7) | 20 (0.5) | 36 (1.0) | 56 (0.7) |
| Grade 3 | 14 (<0.1) | 24 (0.2) | 38 (0.1) | 8 (<0.1) | 17 (0.1) | 25 (0.1) | 6 (0.2) | 7 (0.2) | 13 (0.2) |

n=Number of exposed participants who submitted any data for the event; percentages are based on the number of exposed participants who submitted any data for the event in the solicited safety set. Any = Grade 1 or higher. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 - 50 mm; G2 = 51 -100 mm; G3 = >100 mm. Toxicity grade for fever is defined as: G1 = 38 - 38.4 C; G2 = 38.5 - 38.9 C; G3 = 39 -40 C; G4 = >40 C. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S4. Solicited Adverse Reactions Within 7 Days After Second Vaccination by Grade, Solicited Safety Set

| Adverse reaction Vaccination 2 n (%) | Overall Safety Set | | | ≥18-<65 years | | | ≥65 years | | |
|--|--------------------|--------------|--------------|---------------|--------------|--------------|-------------|-------------|-------------|
| | Placebo | mRNA | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14566) | (N=14677) | (N=29243) | (N=10918) | (N=10985) | (N=21903) | N=3648 | N=3692 | 7340 |
| Any solicited AR | 6232 (42.8) | 13534 (92.2) | 19766 (67.6) | 4902 (44.9) | 10231 (93.1) | 15133 (69.1) | 1330 (36.5) | 3303 (89.5) | 4633 (63.1) |
| Grade 1 | 4354 (29.9) | 4855 (33.1) | 9209 (31.5) | 3397 (31.1) | 3294 (30.0) | 6691 (30.5) | 957 (26.2) | 1561 (42.3) | 2518 (34.3) |
| Grade 2 | 1534 (10.5) | 5781 (39.4) | 7315 (25.0) | 1248 (11.4) | 4576 (41.7) | 5824 (26.6) | 286 (7.8) | 1205 (32.6) | 1491 (20.3) |
| Grade 3 | 341 (2.3) | 2884 (19.6) | 3225 (11.0) | 255 (2.3) | 2349 (21.4) | 2604 (11.9) | 86 (2.4) | 535 (14.5) | 621 (8.5) |
| Grade 4 | 3 (<0.1) | 14 (<0.1) | 17 (<0.1) | 2 (<0.1) | 12 (0.1) | 14 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Any Local AR | 2735 (18.8) | 13006 (88.6) | 15741 (53.8) | 2244 (20.6) | 9915 (90.3) | 12159 (55.5) | 491 (13.5) | 3091 (83.8) | 3582 (48.8) |
| Grade 1 | 2581 (17.7) | 8778 (59.8) | 11359 (38.9) | 2135 (19.6) | 6410 (58.4) | 8545 (39.0) | 446 (12.2) | 2368 (64.2) | 2814 (38.4) |
| Grade 2 | 82 (0.6) | 3208 (21.9) | 3290 (11.3) | 67 (0.6) | 2703 (24.6) | 2770 (12.6) | 15 (0.4) | 505 (13.7) | 520 (7.1) |
| Grade 3 | 72 (0.5) | 1020 (7.0) | 1092 (3.7) | 42 (0.4) | 802 (7.3) | 844 (3.9) | 30 (0.8) | 218 (5.9) | 248 (3.4) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Local AR | | | | | | | | | |
| Pain | 2477 (17.0) | 12943 (88.2) | 15420 (52.7) | 2040 (18.7) | 9873 (89.9) | 11913 (54.4) | 437 (12.0) | 3070 (83.2) | 3507 (47.8) |
| Grade 1 | 2378 (16.3) | 9498 (64.7) | 11876 (40.6) | 1972 (18.1) | 6923 (63.0) | 8895 (40.6) | 406 (11.1) | 2575 (69.8) | 2981 (40.6) |
| Grade 2 | 59 (0.4) | 2841 (19.4) | 2900 (9.9) | 46 (0.4) | 2444 (22.3) | 2490 (11.4) | 13 (0.4) | 397 (10.8) | 410 (5.6) |
| Grade 3 | 40 (0.3) | 604 (4.1) | 644 (2.2) | 22 (0.2) | 506 (4.6) | 528 (2.4) | 18 (0.5) | 98 (2.7) | 116 (1.6) |
| Erythema | 56 (0.4) | 1257 (8.6) | 1313 (4.5) | 43 (0.4) | 982 (8.9) | 1025 (4.7) | 13 (0.4) | 275 (7.5) | 288 (3.9) |
| Grade 1 | 38 (0.3) | 442 (3.0) | 480 (1.6) | 28 (0.3) | 352 (3.2) | 380 (1.7) | 10 (0.3) | 90 (2.4) | 100 (1.4) |
| Grade 2 | 3 (<0.1) | 528 (3.6) | 531 (1.8) | 3 (<0.1) | 420 (3.8) | 423 (1.9) | 0 | 108 (2.9) | 108 (1.5) |
| Grade 3 | 15 (0.1) | 287 (2.0) | 302 (1.0) | 12 (0.1) | 210 (1.9) | 222 (1.0) | 3 (<0.1) | 77 (2.1) | 80 (1.1) |
| Swelling | 49 (0.3) | 1789 (12.2) | 1838 (6.3) | 36 (0.3) | 1389 (12.6) | 1425 (6.5) | 13 (0.4) | 400 (10.8) | 413 (5.6) |
| Grade 1 | 29 (0.2) | 890 (6.1) | 919 (3.1) | 24 (0.2) | 700 (6.4) | 724 (3.3) | 5 (0.1) | 190 (5.2) | 195 (2.7) |
| Grade 2 | 9 (<0.1) | 645 (4.4) | 654 (2.2) | 8 (<0.1) | 507 (4.6) | 515 (2.4) | 1 (<0.1) | 138 (3.7) | 139 (1.9) |
| Grade 3 | 11 (<0.1) | 254 (1.7) | 265 (0.9) | 4 (<0.1) | 182 (1.7) | 186 (0.8) | 7 (0.2) | 72 (2.0) | 79 (1.1) |
| Axillary swelling/tenderness* | 567 (3.9) | 2090 (14.2) | 2657 (9.1) | 470 (4.3) | 1775 (16.2) | 2245 (10.3) | 97 (2.7) | 315 (8.5) | 412 (5.6) |
| Grade 1 | 521 (3.6) | 1737 (11.8) | 2258 (7.7) | 433 (4.0) | 1469 (13.4) | 1902 (8.7) | 88 (2.4) | 268 (7.3) | 356 (4.9) |
| Grade 2 | 27 (0.2) | 286 (1.9) | 313 (1.1) | 26 (0.2) | 260 (2.4) | 286 (1.3) | 1 (<0.1) | 26 (0.7) | 27 (0.4) |
| Grade 3 | 19 (0.1) | 67 (0.5) | 86 (0.3) | 11 (0.1) | 46 (0.4) | 57 (0.3) | 8 (0.2) | 21 (0.6) | 29 (0.4) |
| Any Systemic AR | 5323 (36.5) | 11652 (79.4) | 16975 (58.1) | 4192 (38.4) | 8999 (81.9) | 13191 (60.2) | 1131 (31.0) | 2653 (71.9) | 3784 (51.6) |
| Grade 1 | 3526 (24.2) | 3723 (25.4) | 7249 (24.8) | 2734 (25.0) | 2618 (23.8) | 5352 (24.4) | 792 (21.7) | 1105 (29.9) | 1897 (25.8) |
| Grade 2 | 1512 (10.4) | 5590 (38.1) | 7102 (24.3) | 1233 (11.3) | 4441 (40.4) | 5674 (25.9) | 279 (7.6) | 1149 (31.1) | 1428 (19.5) |
| Grade 3 | 282 (1.9) | 2325 (15.8) | 2607 (8.9) | 223 (2.0) | 1928 (17.6) | 2151 (9.8) | 59 (1.6) | 397 (10.8) | 456 (6.2) |
| Grade 4 | 3 (<0.1) | 14 (<0.1) | 17 (<0.1) | 2 (<0.1) | 12 (0.1) | 14 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Systemic AR | | | | | | | | | |
| Fever | 43 (0.3) | 2278 (15.5) | 2321 (7.9) | 39 (0.4) | 1908 (17.4) | 1947 (8.9) | 4 (0.1) | 370 (10.0) | 374 (5.1) |
| Grade 1 | 33 (0.2) | 1364 (9.3) | 1397 (4.8) | 31 (0.3) | 1111 (10.1) | 1142 (5.2) | 2 (<0.1) | 253 (6.9) | 255 (3.5) |
| Grade 2 | 5 (<0.1) | 699 (4.8) | 704 (2.4) | 4 (<0.1) | 601 (5.5) | 605 (2.8) | 1 (<0.1) | 98 (2.7) | 99 (1.3) |
| Grade 3 | 2 (<0.1) | 202 (1.4) | 204 (0.7) | 2 (<0.1) | 184 (1.7) | 186 (0.8) | 0 | 18 (0.5) | 18 (0.2) |
| Grade 4 | 3 (<0.1) | 13 (<0.1) | 16 (<0.1) | 2 (<0.1) | 12 (0.1) | 14 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Headache | 3410 (23.4) | 8602 (58.6) | 12012 (41.1) | 2760 (25.3) | 6898 (62.8) | 9658 (44.1) | 650 (17.8) | 1704 (46.2) | 2354 (32.1) |

| | | | | | | | | | |
|-----------------|-------------|-------------|--------------|-------------|-------------|--------------|------------|-------------|-------------|
| Grade 1 | 2739 (18.8) | 4804 (32.7) | 7543 (25.8) | 2180 (20.0) | 3658 (33.3) | 5838 (26.7) | 559 (15.3) | 1146 (31.1) | 1705 (23.2) |
| Grade 2 | 509 (3.5) | 3139 (21.4) | 3648 (12.5) | 451 (4.1) | 2687 (24.5) | 3138 (14.3) | 58 (1.6) | 452 (12.3) | 510 (7.0) |
| Grade 3 | 162 (1.1) | 659 (4.5) | 821 (2.8) | 129 (1.2) | 553 (5.0) | 682 (3.1) | 33 (0.9) | 106 (2.9) | 139 (1.9) |
| Fatigue | 3403 (23.4) | 9582 (65.3) | 12985 (44.4) | 2687 (24.6) | 7430 (67.6) | 10117 (46.2) | 716 (19.6) | 2152 (58.3) | 2868 (39.1) |
| Grade 1 | 2182 (15.0) | 3432 (23.4) | 5614 (19.2) | 1700 (15.6) | 2525 (23.0) | 4225 (19.3) | 482 (13.2) | 907 (24.6) | 1389 (18.9) |
| Grade 2 | 1115 (7.7) | 4722 (32.2) | 5837 (20.0) | 901 (8.3) | 3731 (34.0) | 4632 (21.2) | 214 (5.9) | 991 (26.9) | 1205 (16.4) |
| Grade 3 | 106 (0.7) | 1428 (9.7) | 1534 (5.2) | 86 (0.8) | 1174 (10.7) | 1260 (5.8) | 20 (0.5) | 254 (6.9) | 274 (3.7) |
| Myalgia | 1809 (12.4) | 8508 (58.0) | 10317 (35.3) | 1411 (12.9) | 6769 (61.6) | 8180 (37.4) | 398 (10.9) | 1739 (47.1) | 2137 (29.1) |
| Grade 1 | 1300 (8.9) | 3239 (22.1) | 4539 (15.5) | 994 (9.1) | 2411 (22.0) | 3405 (15.6) | 306 (8.4) | 828 (22.4) | 1134 (15.5) |
| Grade 2 | 457 (3.1) | 3951 (26.9) | 4408 (15.1) | 375 (3.4) | 3245 (29.5) | 3620 (16.5) | 82 (2.2) | 706 (19.1) | 788 (10.7) |
| Grade 3 | 52 (0.4) | 1318 (9.0) | 1370 (4.7) | 42 (0.4) | 1113 (10.1) | 1155 (5.3) | 10 (0.3) | 205 (5.6) | 215 (2.9) |
| Arthralgia | 1569 (10.8) | 6284 (42.8) | 7853 (26.9) | 1172 (10.7) | 4993 (45.5) | 6165 (28.2) | 397 (10.9) | 1291 (35.0) | 1688 (23.0) |
| Grade 1 | 1142 (7.8) | 2802 (19.1) | 3944 (13.5) | 837 (7.7) | 2105 (19.2) | 2942 (13.4) | 305 (8.4) | 697 (18.9) | 1002 (13.7) |
| Grade 2 | 383 (2.6) | 2712 (18.5) | 3095 (10.6) | 298 (2.7) | 2241 (20.4) | 2539 (11.6) | 85 (2.3) | 471 (12.8) | 556 (7.6) |
| Grade 3 | 44 (0.3) | 770 (5.2) | 814 (2.8) | 37 (0.3) | 647 (5.9) | 684 (3.1) | 7 (0.2) | 123 (3.3) | 130 (1.8) |
| Nausea/vomiting | 934 (6.4) | 2785 (19.0) | 3719 (12.7) | 801 (7.3) | 2348 (21.4) | 3149 (14.4) | 133 (3.6) | 437 (11.8) | 570 (7.8) |
| Grade 1 | 756 (5.2) | 2090 (14.2) | 2846 (9.7) | 646 (5.9) | 1752 (16.0) | 2398 (11.0) | 110 (3.0) | 338 (9.2) | 448 (6.1) |
| Grade 2 | 167 (1.1) | 674 (4.6) | 841 (2.9) | 147 (1.3) | 586 (5.3) | 733 (3.3) | 20 (0.5) | 88 (2.4) | 108 (1.5) |
| Grade 3 | 11 (<0.1) | 20 (0.1) | 31 (0.1) | 8 (<0.1) | 10 (<0.1) | 18 (<0.1) | 3 (<0.1) | 10 (0.3) | 13 (0.2) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 1 (<0.1) | 1 (<0.1) |
| Chills | 809 (5.6) | 6482 (44.2) | 7291 (24.9) | 658 (6.0) | 5341 (48.6) | 5999 (27.4) | 151 (4.1) | 1141 (30.9) | 1292 (17.6) |
| Grade 1 | 626 (4.3) | 2899 (19.8) | 3525 (12.1) | 502 (4.6) | 2307 (21.0) | 2809 (12.8) | 124 (3.4) | 592 (16.0) | 716 (9.8) |
| Grade 2 | 166 (1.1) | 3392 (23.1) | 3558 (12.2) | 141 (1.3) | 2870 (26.1) | 3011 (13.8) | 25 (0.7) | 522 (14.2) | 547 (7.5) |
| Grade 3 | 17 (0.1) | 191 (1.3) | 208 (0.7) | 15 (0.1) | 164 (1.5) | 179 (0.8) | 2 (<0.1) | 27 (0.7) | 29 (0.4) |

n=Number of exposed participants who submitted any data for the event; percentages are based on the number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S5. Number of Days Reporting Solicited Adverse Reactions After First and Second Vaccinations, Solicited Safety Set

| Adverse reaction duration days | Vaccination 1 | | | Vaccination 2 | | |
|-----------------------------------|-------------------|---------------------|-----------------|-------------------|---------------------|-----------------|
| | Placebo (N=15155) | mRNA-1273 (N=15168) | Total (N=30323) | Placebo (N=14566) | mRNA-1273 (N=14677) | Total (N=29243) |
| Any solicited (n) | 7284 | 13319 | 20603 | 6232 | 13534 | 19766 |
| Mean days (SD) | 3.2 (4.2) | 3.4 (3.3) | 3.3 (3.6) | 3.4 (5.7) | 4.0 (4.8) | 3.8 (5.1) |
| Any local (n) | 2997 | 12765 | 15762 | 2735 | 13006 | 15741 |
| Mean days (SD) | 1.9 (2.6) | 2.6 (2.0) | 2.5 (2.0) | 2.1 (4.1) | 3.2 (2.9) | 3.0 (3.2) |
| Pain (n) | 2658 | 12690 | 15348 | 2477 | 12943 | 15420 |
| Mean, days (SD) | 1.7 (2.1) | 2.4 (1.4) | 2.3 (1.5) | 1.8 (3.3) | 3.0 (2.2) | 2.8 (2.4) |
| Erythema (n) | 67 | 430 | 497 | 56 | 1257 | 1313 |
| Mean, days (SD) | 3.2 (5.6) | 2.5 (4.1) | 2.6 (4.4) | 3.8 (10.6) | 2.7 (3.9) | 2.7 (4.4) |
| Swelling (n) | 52 | 932 | 984 | 49 | 1789 | 1838 |
| Mean, days (SD) | 5.1 (7.8) | 2.1 (2.2) | 2.2 (2.8) | 2.7 (4.9) | 2.6 (4.1) | 2.6 (4.2) |
| Axillary swelling/tenderness* (n) | 722 | 1553 | 2275 | 567 | 2090 | 2657 |
| Mean, days (SD) | 2.1 (2.8) | 2.3 (2.9) | 2.2 (2.9) | 2.6 (5.3) | 2.4 (3.2) | 2.4 (3.7) |
| Any Systemic AR | 6399 | 8320 | 14719 | 5323 | 11652 | 16975 |
| Mean, days (SD) | 3.1 (4.2) | 2.9 (3.7) | 3.0 (3.9) | 3.4 (5.6) | 3.1 (4.6) | 3.2 (4.9) |
| Fever (n) | 44 | 115 | 159 | 43 | 2278 | 2321 |
| Mean, days (SD) | 1.4 (0.6) | 1.3 (0.7) | 1.3 (0.7) | 1.2 (0.5) | 1.2 (1.7) | 1.2 (1.7) |
| Headache (n) | 4027 | 4951 | 8978 | 3410 | 8602 | 12012 |
| Mean, days (SD) | 2.1 (2.4) | 2.1 (2.2) | 2.1 (2.3) | 2.3 (3.3) | 2.3 (2.9) | 2.3 (3.0) |
| Fatigue (n) | 4133 | 5635 | 9768 | 3403 | 9582 | 12985 |
| Mean, days (SD) | 2.8 (3.7) | 2.7 (3.6) | 2.7 (3.6) | 3.0 (5.1) | 2.6 (3.7) | 2.7 (4.1) |
| Myalgia (n) | 2071 | 3441 | 5512 | 1809 | 8508 | 10317 |
| Mean, days (SD) | 2.7 (3.7) | 2.3 (3.2) | 2.4 (3.4) | 3.2 (6.1) | 2.1 (3.1) | 2.3 (3.8) |
| Arthralgia (n) | 1783 | 2511 | 4294 | 1569 | 6284 | 7853 |
| Mean, days (SD) | 3.2 (5.0) | 2.6 (4.1) | 2.9 (4.5) | 3.7 (7.0) | 2.3 (3.5) | 2.5 (4.5) |
| Nausea/vomiting (n) | 1074 | 1262 | 2336 | 934 | 2785 | 3719 |
| Mean, days (SD) | 1.8 (2.2) | 1.7 (1.5) | 1.7 (1.9) | 1.9 (3.8) | 1.7 (2.4) | 1.8 (2.8) |
| Chills (n) | 878 | 1253 | 2131 | 809 | 6482 | 7291 |
| Mean, days (SD) | 1.7 (1.7) | 1.5 (1.7) | 1.6 (1.7) | 1.9 (3.2) | 1.5 (1.6) | 1.5 (1.8) |

n = Number of exposed participants who reported the event on any day within 7 days of the first injection. Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continued beyond 7 days, the consecutive days a solicited adverse reaction was reported after 7 days are included. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S6. Solicited Adverse reactions by SARS-CoV-2 Baseline Status by Grade After Vaccination 1, Solicited Safety Set

| Vaccination 1 ARs n (%) | Baseline SARS-CoV-2 negative | | | Baseline SARS-CoV-2 positive | | | Missing data | | |
|-------------------------------|------------------------------|--------------|--------------|------------------------------|------------|------------|--------------|------------|------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14583) | (N=14538) | (N=29121) | (N=337) | (N=342) | (N=679) | (N=235) | (N=288) | N=523 |
| Any solicited AR | 7023 (48.2) | 12800 (88.0) | 19823 (68.1) | 137 (40.7) | 261 (76.3) | 398 (58.6) | 124 (52.8) | 258 (89.6) | 382 (73.0) |
| Grade 1 | 4978 (34.1) | 9029 (62.1) | 14007 (48.1) | 82 (24.3) | 136 (39.8) | 218 (32.1) | 87 (37.0) | 177 (61.5) | 264 (50.5) |
| Grade 2 | 1696 (11.6) | 2972 (20.4) | 4668 (16.0) | 41 (12.2) | 96 (28.1) | 137 (20.2) | 33 (14.0) | 56 (19.4) | 89 (17.0) |
| Grade 3 | 344 (2.4) | 795 (5.5) | 1139 (3.9) | 13 (3.9) | 28 (8.2) | 41 (6.0) | 4 (1.7) | 25 (8.7) | 29 (5.5) |
| Grade 4 | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 0 | 0 | 0 |
| Any Local AR | 2891 (19.8) | 12276 (84.5) | 15167 (52.1) | 60 (17.8) | 246 (71.9) | 306 (45.1) | 46 (19.6) | 243 (84.4) | 289 (55.3) |
| Grade 1 | 2738 (18.8) | 10352 (71.2) | 13090 (45.0) | 56 (16.6) | 178 (52.0) | 234 (34.5) | 43 (18.3) | 201 (69.8) | 244 (46.7) |
| Grade 2 | 80 (0.5) | 1423 (9.8) | 1503 (5.2) | 1 (0.3) | 55 (16.1) | 56 (8.2) | 1 (0.4) | 27 (9.4) | 28 (5.4) |
| Grade 3 | 73 (0.5) | 501 (3.4) | 574 (2.0) | 3 (0.9) | 13 (3.8) | 16 (2.4) | 2 (0.9) | 15 (5.2) | 17 (3.3) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Local AR | | | | | | | | | |
| Pain | 2563 (17.6) | 12207 (84.0) | 14770 (50.7) | 56 (16.6) | 244 (71.3) | 300 (44.2) | 39 (16.6) | 239 (83.0) | 278 (53.2) |
| Grade 1 | 2459 (16.9) | 10601 (72.9) | 13060 (44.9) | 54 (16.0) | 183 (53.5) | 237 (34.9) | 36 (15.3) | 206 (71.5) | 242 (46.3) |
| Grade 2 | 52 (0.4) | 1211 (8.3) | 1263 (4.3) | 1 (0.3) | 51 (14.9) | 52 (7.7) | 1 (0.4) | 22 (7.6) | 23 (4.4) |
| Grade 3 | 52 (0.4) | 395 (2.7) | 447 (1.5) | 1 (0.3) | 10 (2.9) | 11 (1.6) | 2 (0.9) | 11 (3.8) | 13 (2.5) |
| Erythema | 63 (0.4) | 409 (2.8) | 472 (1.6) | 3 (0.9) | 9 (2.6) | 12 (1.8) | 1 (0.4) | 12 (4.2) | 13 (2.5) |
| Grade 1 | 45 (0.3) | 254 (1.7) | 299 (1.0) | 1 (0.3) | 5 (1.5) | 6 (0.9) | 1 (0.4) | 8 (2.8) | 9 (1.7) |
| Grade 2 | 7 (<0.1) | 115 (0.8) | 122 (0.4) | 0 | 2 (0.6) | 2 (0.3) | 0 | 4 (1.4) | 4 (0.8) |
| Grade 3 | 11 (<0.1) | 40(0.3) | 51(0.2) | 2 (0.6) | 2 (0.6) | 4 (0.6) | 0 | 0 | 0 |
| Swelling | 49 (0.3) | 895 (6.2) | 944 (3.2) | 2 (0.6) | 19 (5.6) | 21 (3.1) | 1 (0.4) | 18 (6.3) | 19 (3.6) |
| Grade 1 | 36 (0.2) | 582 (4.0) | 618 (2.1) | 2 (0.6) | 10 (2.9) | 12 (1.8) | 1 (0.4) | 13 (4.5) | 14 (2.7) |
| Grade 2 | 7 (<0.1) | 235 (1.6) | 242 (0.8) | 0 | 8 (2.3) | 8 (1.2) | 0 | 2 (0.7) | 2 (0.4) |
| Grade 3 | 6 (<0.1) | 78 (0.5) | 84 (0.3) | 0 | 1 (0.3) | 1 (0.1) | 0 | 3 (1.0) | 3 (0.6) |
| Axillary swelling/tenderness* | 689 (4.7) | 1465 (10.1) | 2154 (7.4) | 18 (5.3) | 53 (15.5) | 71 (10.5) | 15 (6.4) | 35 (12.2) | 50 (9.6) |
| Grade 1 | 637 (4.4) | 1327 (9.1) | 1964 (6.7) | 17 (5.0) | 38 (11.1) | 55 (8.1) | 14 (6.0) | 30 (10.4) | 44 (8.4) |
| Grade 2 | 27 (0.2) | 94 (0.6) | 121 (0.4) | 0 | 11 (3.2) | 11 (1.6) | 0 | 4 (1.4) | 4 (0.8) |
| Grade 3 | 25 (0.2) | 44 (0.3) | 69 (0.2) | 1 (0.3) | 4 (1.2) | 5 (0.7) | 1 (0.4) | 1 (0.3) | 2 (0.4) |
| Any Systemic AR | 6167 (42.3) | 7954 (54.7) | 14121 (48.5) | 121 (35.9) | 210 (61.4) | 331 (48.7) | 111 (47.2) | 156 (54.2) | 267 (51.1) |
| Grade 1 | 4203 (28.8) | 5171 (35.6) | 9374 (32.2) | 69 (20.5) | 107 (31.3) | 176 (25.9) | 74 (31.5) | 94 (32.6) | 168 (32.1) |
| Grade 2 | 1665 (11.4) | 2367 (16.3) | 4032 (13.8) | 40 (11.9) | 80 (23.4) | 120 (17.7) | 34 (14.5) | 49 (17.0) | 83 (15.9) |
| Grade 3 | 294 (2.0) | 412 (2.8) | 706 (2.4) | 11 (3.3) | 22 (6.4) | 33 (4.9) | 3 (1.3) | 13 (4.5) | 16 (3.1) |
| Grade 4 | 5 (<0.1) | 4 (<0.1) | 9 (<0.1) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 0 | 0 | 0 |
| Systemic AR | | | | | | | | | |
| Fever | 38 (0.3) | 79 (0.5) | 117 (0.4) | 6 (1.8) | 32 (9.4) | 38 (5.6) | 0 | 4 (1.4) | 4 (0.8) |
| Grade 1 | 26 (0.2) | 51 (0.4) | 77 (0.3) | 3 (0.9) | 20 (5.8) | 23 (3.4) | 0 | 3 (1.0) | 3 (0.6) |
| Grade 2 | 5 (<0.1) | 16 (0.1) | 21 (<0.1) | 2 (0.6) | 9 (2.6) | 11 (1.6) | 0 | 1 (0.3) | 1 (0.2) |
| Grade 3 | 2 (<0.1) | 9 (<0.1) | 11 (<0.1) | 0 | 2 (0.6) | 2 (0.3) | 0 | 0 | 0 |
| Grade 4 | 5 (<0.1) | 3 (<0.1) | 8 (<0.1) | 1 (0.3) | 1 (0.3) | 2 (0.3) | 0 | 0 | 0 |
| Headache | 3865 (26.5) | 4723 (32.5) | 8588 (29.5) | 82 (24.3) | 131 (38.3) | 213 (31.4) | 80 (34.0) | 97 (33.7) | 177 (33.8) |
| Grade 1 | 3182 (21.8) | 3795 (26.1) | 6977 (24.0) | 59 (17.5) | 88 (25.7) | 147 (21.6) | 65 (27.7) | 70 (24.3) | 135 (25.8) |
| Grade 2 | 496 (3.4) | 679 (4.7) | 1175 (4.0) | 16 (4.7) | 31 (9.1) | 47 (6.9) | 13 (5.5) | 17 (5.9) | 30 (5.7) |
| Grade 3 | 187 (1.3) | 249 (1.7) | 436 (1.5) | 7 (2.1) | 12 (3.5) | 19 (2.8) | 2 (0.9) | 10 (3.5) | 12 (2.3) |

| | | | | | | | | | |
|-----------------|-------------|-------------|-------------|-----------|------------|------------|-----------|------------|------------|
| Fatigue | 3988 (27.4) | 5400 (37.2) | 9388 (32.2) | 72 (21.4) | 134 (39.2) | 206 (30.3) | 73 (31.1) | 101 (35.1) | 174 (33.3) |
| Grade 1 | 2618 (18.0) | 3468 (23.9) | 6086 (20.9) | 40 (11.9) | 69 (20.2) | 109 (16.1) | 51 (21.7) | 62 (21.5) | 113 (21.6) |
| Grade 2 | 1271 (8.7) | 1793 (12.3) | 3064 (10.5) | 28 (8.3) | 56 (16.4) | 84 (12.4) | 20 (8.5) | 36 (12.5) | 56 (10.7) |
| Grade 3 | 99 (0.7) | 138 (0.9) | 237 (0.8) | 4 (1.2) | 9 (2.6) | 13 (1.9) | 2 (0.9) | 3 (1.0) | 5 (1.0) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Myalgia | 1987 (13.6) | 3244 (22.3) | 5231 (18.0) | 47 (13.9) | 124 (36.3) | 171 (25.2) | 37 (15.7) | 73 (25.3) | 110 (21.0) |
| Grade 1 | 1510 (10.4) | 2318 (15.9) | 3828 (13.1) | 27 (8.0) | 70 (20.5) | 97 (14.3) | 30 (12.8) | 57 (19.8) | 87 (16.6) |
| Grade 2 | 433 (3.0) | 845 (5.8) | 1278 (4.4) | 18 (5.3) | 48 (14.0) | 66 (9.7) | 6 (2.6) | 13 (4.5) | 19 (3.6) |
| Grade 3 | 44 (0.3) | 81 (0.6) | 125 (0.4) | 2 (0.6) | 6 (1.8) | 8 (1.2) | 1 (0.4) | 3 (1.0) | 4 (0.8) |
| Arthralgia | 1707 (11.7) | 2381 (16.4) | 4088 (14.0) | 40 (11.9) | 85 (24.9) | 125 (18.4) | 36 (15.3) | 45 (15.6) | 81 (15.5) |
| Grade 1 | 1294 (8.9) | 1761 (12.1) | 3055 (10.5) | 21 (6.2) | 53 (15.5) | 74 (10.9) | 26 (11.1) | 32 (11.1) | 58 (11.1) |
| Grade 2 | 379 (2.6) | 565 (3.9) | 944 (3.2) | 17 (5.0) | 27 (7.9) | 44 (6.5) | 9 (3.8) | 12 (4.2) | 21 (4.0) |
| Grade 3 | 34 (0.2) | 54 (0.4) | 88 (0.3) | 2 (0.6) | 5 (1.5) | 7 (1.0) | 1 (0.4) | 1 (0.3) | 2 (0.4) |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Nausea/vomiting | 1033 (7.1) | 1193 (8.2) | 2226 (7.6) | 26 (7.7) | 42 (12.3) | 68 (10.0) | 15 (6.4) | 27 (9.4) | 42 (8.0) |
| Grade 1 | 860 (5.9) | 998 (6.9) | 1858 (6.4) | 18 (5.3) | 30 (8.8) | 48 (7.1) | 12 (5.1) | 20 (6.9) | 32 (6.1) |
| Grade 2 | 161 (1.1) | 186 (1.3) | 347 (1.2) | 8 (2.4) | 12 (3.5) | 20 (2.9) | 3 (1.3) | 6 (2.1) | 9 (1.7) |
| Grade 3 | 12 (<0.1) | 9 (<0.1) | 21 (<0.1) | 0 | 0 | 0 | 0 | 1 (0.3) | 1 (0.2) |
| Chills | 836 (5.7) | 1144 (7.9) | 1980 (6.8) | 27 (8.0) | 80 (23.4) | 107 (15.8) | 15 (6.4) | 29 (10.1) | 44 (8.4) |
| Grade 1 | 675 (4.6) | 878 (6.0) | 1553 (5.3) | 17 (5.0) | 43 (12.6) | 60 (8.8) | 14 (6.0) | 19 (6.6) | 33 (6.3) |
| Grade 2 | 148 (1.0) | 246 (1.7) | 394 (1.4) | 9 (2.7) | 34 (9.9) | 43 (6.3) | 1 (0.4) | 9 (3.1) | 10 (1.9) |
| Grade 3 | 13 (<0.1) | 20 (0.1) | 33 (0.1) | 1 (0.3) | 3 (0.9) | 4 (0.6) | 0 | 1 (0.3) | 1 (0.2) |

CI = Confidence intervals. N1 = Number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed participants who submitted any data for the event. 95% CI is calculated using the Clopper-Pearson method. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = > 40 C.

*Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S7. Solicited Adverse reactions by SARS-CoV-2 Baseline Status by Grade After Vaccination 2, Solicited Safety Set

| Vaccination 2 ARs n (%) | Baseline SARS-CoV-2 negative | | | Baseline SARS-CoV-2 positive | | | Missing data | | |
|-------------------------------|------------------------------|--------------|--------------|------------------------------|------------|------------|--------------|------------|------------|
| | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total | Placebo | mRNA-1273 | Total |
| | (N=14119) | (N=14183) | (N=28302) | (N=232) | (N=230) | (N=462) | (N=215) | (N=264) | N=479 |
| Any solicited AR | 6056 (42.9) | 13101 (92.4) | 19157 (67.7) | 81 (34.9) | 186 (80.9) | 267 (57.8) | 95 (44.2) | 247 (93.6) | 342 (71.4) |
| Grade 1 | 4235 (30.0) | 4676 (33.0) | 8911 (31.5) | 51 (22.0) | 91 (39.6) | 142 (30.7) | 68 (31.6) | 88 (33.3) | 156 (32.6) |
| Grade 2 | 1485 (10.5) | 5609 (39.5) | 7094 (25.1) | 27 (11.6) | 66 (28.7) | 93 (20.1) | 22 (10.2) | 106 (40.2) | 128 (26.7) |
| Grade 3 | 333 (2.4) | 2802 (19.8) | 3135 (11.1) | 3 (1.3) | 29 (12.6) | 32 (6.9) | 5 (2.3) | 53 (20.1) | 58 (12.1) |
| Grade 4 | 3 (<0.1) | 14 (<0.1) | 17 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Any Local AR | 2650 (18.8) | 12594 (88.8) | 15244 (53.9) | 42 (18.2) | 172 (74.8) | 214 (46.4) | 43 (20.0) | 240 (90.9) | 283 (59.1) |
| Grade 1 | 2505 (17.7) | 8489 (59.9) | 10994 (38.9) | 35 (15.2) | 125 (54.3) | 160 (34.7) | 41 (19.1) | 164 (62.1) | 205 (42.8) |
| Grade 2 | 77 (0.5) | 3122 (22.0) | 3199 (11.3) | 5 (2.2) | 35 (15.2) | 40 (8.7) | 0 | 51 (19.3) | 51 (10.6) |
| Grade 3 | 68 (0.5) | 983 (6.9) | 1051 (3.7) | 2 (0.9) | 12 (5.2) | 14 (3.0) | 2 (0.9) | 25 (9.5) | 27 (5.6) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Local AR | | | | | | | | | |
| Pain | 2403 (17.0) | 12536 (88.4) | 14939 (52.8) | 36 (15.6) | 169 (73.5) | 205 (44.5) | 38 (17.7) | 238 (90.2) | 276 (57.6) |
| Grade 1 | 2310 (16.4) | 9194 (64.8) | 11504 (40.7) | 32 (13.9) | 125 (54.3) | 157 (34.1) | 36 (16.7) | 179 (67.8) | 215 (44.9) |
| Grade 2 | 56 (0.4) | 2758 (19.5) | 2814 (9.9) | 3 (1.3) | 36 (15.7) | 39 (8.5) | 0 | 47 (17.8) | 47 (9.8) |
| Grade 3 | 37 (0.3) | 584 (4.1) | 621 (2.2) | 1 (0.4) | 8 (3.5) | 9 (2.0) | 2 (0.9) | 12 (4.5) | 14 (2.9) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Erythema | 52 (0.4) | 1227 (8.7) | 1279 (4.5) | 1 (0.4) | 8 (3.5) | 9 (2.0) | 3 (1.4) | 22 (8.3) | 25 (5.2) |
| Grade 1 | 35 (0.2) | 434 (3.1) | 469 (1.7) | 0 | 2 (0.9) | 2 (0.4) | 3 (1.4) | 6 (2.3) | 9 (1.9) |
| Grade 2 | 3 (<0.1) | 521 (3.7) | 524 (1.9) | 0 | 3 (1.3) | 3 (0.7) | 0 | 4 (1.5) | 4 (0.8) |
| Grade 3 | 14 (<0.1) | 272 (1.9) | 286 (1.0) | 1 (0.4) | 3 (1.3) | 4 (0.9) | 0 | 12 (4.5) | 12 (2.5) |
| Swelling | 47 (0.3) | 1746 (12.3) | 1793 (6.3) | 1 (0.4) | 11 (4.8) | 12 (2.6) | 1 (0.5) | 32 (12.1) | 33 (6.9) |
| Grade 1 | 28 (0.2) | 874 (6.2) | 902 (3.2) | 0 | 4 (1.7) | 4 (0.9) | 1 (0.5) | 12 (4.5) | 13 (2.7) |
| Grade 2 | 8 (<0.1) | 629 (4.4) | 637 (2.3) | 1 (0.4) | 5 (2.2) | 6 (1.3) | 0 | 11 (4.2) | 11 (2.3) |
| Grade 3 | 11 (<0.1) | 243 (1.7) | 254 (0.9) | 0 | 2 (0.9) | 2 (0.4) | 0 | 9 (3.4) | 9 (1.9) |
| Axillary swelling/tenderness* | 546 (3.9) | 2018 (14.2) | 2564 (9.1) | 11 (4.8) | 30 (13.0) | 41 (8.9) | 10 (4.7) | 42 (15.9) | 52 (10.9) |
| Grade 1 | 503 (3.6) | 1682 (11.9) | 2185 (7.7) | 8 (3.5) | 20 (8.7) | 28 (6.1) | 10 (4.7) | 35 (13.3) | 45 (9.4) |
| Grade 2 | 24 (0.2) | 271 (1.9) | 295 (1.0) | 3 (1.3) | 8 (3.5) | 11 (2.4) | 0 | 7 (2.7) | 7 (1.5) |
| Grade 3 | 19 (0.1) | 65 (0.5) | 84 (0.3) | 0 | 2 (0.9) | 2 (0.4) | 0 | 0 | 0 |
| Any Systemic AR | 5168 (36.6) | 11290 (79.6) | 16458 (58.2) | 71 (30.6) | 150 (65.2) | 221 (47.8) | 84 (39.1) | 212 (80.3) | 296 (61.8) |
| Grade 1 | 3427 (24.3) | 3593 (25.3) | 7020 (24.8) | 42 (18.1) | 61 (26.5) | 103 (22.3) | 57 (26.5) | 69 (26.1) | 126 (26.3) |
| Grade 2 | 1462 (10.4) | 5414 (38.2) | 6876 (24.3) | 28 (12.1) | 68 (29.6) | 96 (20.8) | 22 (10.2) | 108 (40.9) | 130 (27.1) |
| Grade 3 | 276 (2.0) | 2269 (16.0) | 2545 (9.0) | 1 (0.4) | 21 (9.1) | 22 (4.8) | 5 (2.3) | 35 (13.3) | 40 (8.4) |
| Grade 4 | 3 (<0.1) | 14 (<0.1) | 17 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Systemic AR | | | | | | | | | |
| Fever | 42 (0.3) | 2223 (15.7) | 2265 (8.0) | 1 (0.4) | 31 (13.5) | 32 (6.9) | 0 | 24 (9.1) | 24 (5.0) |
| Grade 1 | 32 (0.2) | 1326 (9.4) | 1358 (4.8) | 1 (0.4) | 20 (8.7) | 21 (4.6) | 0 | 18 (6.8) | 18 (3.8) |
| Grade 2 | 5 (<0.1) | 685 (4.8) | 690 (2.4) | 0 | 9 (3.9) | 9 (2.0) | 0 | 5 (1.9) | 5 (1.0) |
| Grade 3 | 2 (<0.1) | 199 (1.4) | 201 (0.7) | 0 | 2 (0.9) | 2 (0.4) | 0 | 1 (0.4) | 1 (0.2) |
| Grade 4 | 3 (<0.1) | 13 (<0.1) | 16 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Headache | 3311 (23.5) | 8348 (58.9) | 11659 (41.2) | 43 (18.6) | 97 (42.2) | 140 (30.4) | 56 (26.0) | 157 (59.5) | 213 (44.5) |
| Grade 1 | 2655 (18.8) | 4648 (32.8) | 7303 (25.8) | 36 (15.6) | 60 (26.1) | 96 (20.8) | 48 (22.3) | 96 (36.4) | 144 (30.1) |
| Grade 2 | 497 (3.5) | 3058 (21.6) | 3555 (12.6) | 7 (3.0) | 31 (13.5) | 38 (8.2) | 5 (2.3) | 50 (18.9) | 55 (11.5) |
| Grade 3 | 159 (1.1) | 642 (4.5) | 801 (2.8) | 0 | 6 (2.6) | 6 (1.3) | 3 (1.4) | 11 (4.2) | 14 (2.9) |

| | | | | | | | | | |
|-----------------|-------------|-------------|--------------|-----------|------------|------------|-----------|------------|------------|
| Fatigue | 3294 (23.3) | 9310 (65.7) | 12604 (44.5) | 53 (22.9) | 104 (45.2) | 157 (34.1) | 56 (26.0) | 168 (63.6) | 224 (46.8) |
| Grade 1 | 2115 (15.0) | 3332 (23.5) | 5447 (19.3) | 30 (13.0) | 42 (18.3) | 72 (15.6) | 37 (17.2) | 58 (22.0) | 95 (19.8) |
| Grade 2 | 1077 (7.6) | 4583 (32.3) | 5660 (20.0) | 22 (9.5) | 50 (21.7) | 72 (15.6) | 16 (7.4) | 89 (33.7) | 105 (21.9) |
| Grade 3 | 102 (0.7) | 1395 (9.8) | 1497 (5.3) | 1 (0.4) | 12 (5.2) | 13 (2.8) | 3 (1.4) | 21 (8.0) | 24 (5.0) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Myalgia | 1738 (12.3) | 8229 (58.0) | 9967 (35.2) | 32 (13.9) | 115 (50.0) | 147 (31.9) | 39 (18.1) | 164 (62.1) | 203 (42.4) |
| Grade 1 | 1252 (8.9) | 3117 (22.0) | 4369 (15.4) | 20 (8.7) | 59 (25.7) | 79 (17.1) | 28 (13.0) | 63 (23.9) | 91 (19.0) |
| Grade 2 | 436 (3.1) | 3828 (27.0) | 4264 (15.1) | 12 (5.2) | 45 (19.6) | 57 (12.4) | 9 (4.2) | 78 (29.5) | 87 (18.2) |
| Grade 3 | 50 (0.4) | 1284 (9.1) | 1334 (4.7) | 0 | 11 (4.8) | 11 (2.4) | 2 (0.9) | 23 (8.7) | 25 (5.2) |
| Arthralgia | 1516 (10.7) | 6083 (42.9) | 7599 (26.9) | 24 (10.4) | 76 (33.0) | 100 (21.7) | 29 (13.5) | 125 (47.3) | 154 (32.2) |
| Grade 1 | 1102 (7.8) | 2717 (19.2) | 3819 (13.5) | 17 (7.4) | 37 (16.1) | 54 (11.7) | 23 (10.7) | 48 (18.2) | 71 (14.8) |
| Grade 2 | 371 (2.6) | 2613 (18.4) | 2984 (10.5) | 7 (3.0) | 35 (15.2) | 42 (9.1) | 5 (2.3) | 64 (24.2) | 69 (14.4) |
| Grade 3 | 43 (0.3) | 753 (5.3) | 796 (2.8) | 0 | 4 (1.7) | 4 (0.9) | 1 (0.5) | 13 (4.9) | 14 (2.9) |
| Grade 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Nausea/vomiting | 912 (6.5) | 2700 (19.0) | 3612 (12.8) | 13 (5.6) | 34 (14.8) | 47 (10.2) | 9 (4.2) | 51 (19.3) | 60 (12.5) |
| Grade 1 | 740 (5.2) | 2022 (14.3) | 2762 (9.8) | 10 (4.3) | 26 (11.3) | 36 (7.8) | 6 (2.8) | 42 (15.9) | 48 (10.0) |
| Grade 2 | 161 (1.1) | 658 (4.6) | 819 (2.9) | 3 (1.3) | 7 (3.0) | 10 (2.2) | 3 (1.4) | 9 (3.4) | 12 (2.5) |
| Grade 3 | 11 (<0.1) | 19 (0.1) | (0.1) | 0 | 1 (0.4) | 1 (0.2) | 0 | 0 | 0 |
| Grade 4 | 0 | 1 (<0.1) | 1 (<0.1) | 0 | 0 | 0 | 0 | 0 | 0 |
| Chills | 778 (5.5) | 6292 (44.4) | 7070 (25.0) | 17 (7.4) | 78 (33.9) | 95 (20.6) | 14 (6.5) | 112 (42.4) | 126 (26.3) |
| Grade 1 | 604 (4.3) | 2807 (19.8) | 3411 (12.1) | 14 (6.1) | 39 (17.0) | 53 (11.5) | 8 (3.7) | 53 (20.1) | 61 (12.7) |
| Grade 2 | 157 (1.1) | 3296 (23.2) | 3453 (12.2) | 3 (1.3) | 39 (17.0) | 42 (9.1) | 6 (2.8) | 57 (21.6) | 63 (13.2) |
| Grade 3 | 17 (0.1) | 189 (1.3) | 206 (0.7) | 0 | 0 | 0 | 0 | 2 (0.8) | 2 (0.4) |

CI = Confidence intervals. N1 = Number of exposed participants who submitted any data for the event. Any = Grade 1 or higher. Percentages are based on the number of exposed participants who submitted any data for the event. 95% CI is calculated using the Clopper-Pearson method. Toxicity grade for Erythema (Redness) is defined as: G1 = 25 — 50 mm; G2 = 51 — 100 mm; G3 = > 100 mm. Toxicity grade for Fever is defined as: G1 = 38 — 38.4 C; G2 = 38.5 — 38.9 C; G3 = 39 — 40 C; G4 = >40 C. *Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Table S8. Unsolicited Adverse Events 28 Days after Any Injection, Overall Safety Set

| Unsolicited Adverse Event n (%) | Overall Safety Set | | | ≥18-<65 years | | | ≥65 years | | |
|---|--------------------|----------------------|------------------|----------------------|------------------------|--------------------|-------------------|---------------------|-----------------|
| | Placebo N=15166 | mRNA-1273 N=15185 | Total N=30351 | Placebo (N=11416) | mRNA-1273 (N=11415) | Total (N=22831) | Placebo N=3750 | mRNA-1273 N=3770 | Total N=7520 |
| Regardless of relationship to study vaccination | | | | | | | | | |
| All | 3277 (21.6) | 3632 (23.9) | 6909 (22.8) | 2463 (21.6) | 2674 (23.4) | 5137 (22.5) | 814 (21.7) | 958 (25.4) | 1772 (23.6) |
| Serious | 89 (0.6) | 93 (0.6) | 182 (0.6) | 46 (0.4) | 54 (0.5) | 100 (0.4) | 43 (1.1) | 39 (1.0) | 82 (1.1) |
| Fatal | 3 (<0.1) | 2 (<0.1) | 5 (<0.1) | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Medically-attended | 1465 (9.7) | 1372 (9.0) | 2837 (9.3) | 1051 (9.2) | 991 (8.7) | 2042 (8.9) | 414 (11.0) | 381 (10.1) | 795 (10.6) |
| Leading to discontinuation from study vaccine* | 80 (0.5) | 50 (0.3) | 130 (0.4) | 62 (0.5) | 37 (0.3) | 99 (0.4) | 18 (0.5) | 13 (0.3) | 31 (0.4) |
| Leading to discontinuation from study† | 2 (<0.1) | 2 (<0.1) | 4 (<0.1) | 0 | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) | 1 (<0.1) | 3 (<0.1) |
| Severe | 202 (1.3) | 234 (1.5) | 436 (1.4) | 132 (1.2) | 156 (1.4) | 288 (1.3) | 70 (1.9) | 78 (2.1) | 148 (2.0) |
| | | | | | | | | | |
| Related to study vaccination | | | | | | | | | |
| All | 686 (4.5) | 1242 (8.2) | 1928 (6.4) | 526 (4.6) | 938 (8.2) | 1464 (6.4) | 160 (4.3) | 304 (8.1) | 464 (6.2) |
| Serious | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) | 3 (<0.1) | 4 (<0.1) | 7 (<0.1) | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Fatal | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Medically-attended | 83 (0.5) | 140 (0.9) | 223 (0.7) | 68 (0.6) | 110 (1.0) | 178 (0.8) | 15 (0.4) | 30 (0.8) | 45 (0.6) |
| Leading to discontinuation from study vaccine* | 15 (<0.1) | 18 (0.1) | 33 (0.1) | 10 (<0.1) | 14 (0.1) | 24 (0.1) | 5 (0.1) | 4 (0.1) | 9 (0.1) |
| Leading to discontinuation from study† | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Severe | 28 (0.2) | 71 (0.5) | 99 (0.3) | 19 (0.2) | 49 (0.4) | 68 (0.3) | 9 (0.2) | 22 (0.6) | 31 (0.4) |

An adverse event is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on overall safety set. *AEs leading to study discontinuation 28 days after first dose. †AEs leading to discontinuation from study after either dose.

Tables S9-11. Unsolicited Adverse Events, Overall Safety Set

Table S9. Summary of Unsolicited AE Reported by $\geq 1\%$ of Participants in Any Treatment Group up to 28 Days After Any Injection

| System Organ Class Preferred Term n (%) | Placebo (N=15166) | mRNA-1273 (N=15185) |
|--|--------------------------|----------------------------|
| Number of participants reporting unsolicited AEs | 3277 (21.6) | 3632 (23.9) |
| Number of unsolicited AEs | 6085 | 6798 |
| Nervous system disorders | 622 (4.1) | 684 (4.5) |
| Headache | 458 (3.0) | 466 (3.1) |
| Respiratory, thoracic and mediastinal disorders | 583 (3.8) | 536 (3.5) |
| Cough | 156 (1.0) | 164 (1.1) |
| Oropharyngeal pain | 203 (1.3) | 147 (1.0) |
| Gastrointestinal disorders | 440 (2.9) | 478 (3.1) |
| Diarrhea | 162 (1.1) | 189 (1.2) |
| Musculoskeletal and connective tissue disorders | 617 (4.1) | 671 (4.4) |
| Arthralgia | 167 (1.1) | 207 (1.4) |
| Myalgia | 181 (1.2) | 200 (1.3) |
| General disorders and administration site conditions | 622 (4.1) | 1006 (6.6) |
| Fatigue | 336 (2.2) | 372 (2.4) |
| Injection site pain | 54 (0.4) | 151 (1.0) |
| <p>AE = adverse event. An AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0.</p> | | |

Table S10. Unsolicited Severe AEs Reported by ≥ 5 Participants in Any Treatment Group up to 28 Days After Any Injection, Overall Safety Set

| System Organ Class Preferred Term n (%) | Placebo (N=15166) | mRNA-1273 (N=15185) |
|---|------------------------------|--------------------------------|
| Number of participants reporting unsolicited severe AEs | 202 (1.3) | 234 (1.5) |
| Nervous system disorders | 21 (0.1) | 30 (0.2) |
| Headache | 12 (<0.1) | 20 (0.1) |
| Cardiac disorders | 13 (<0.1) | 13 (<0.1) |
| Bradycardia | 5 (<0.1) | 4 (<0.1) |
| Atrial Fibrillation | 3 (<0.1) | 4 (<0.1) |
| Vascular disorders | 43 (0.3) | 30 (0.2) |
| Hypertension | 32 (0.2) | 23 (0.2) |
| Musculoskeletal and connective tissue disorders | 24 (0.2) | 23 (0.2) |
| Myalgia | 2 (<0.1) | 10 (<0.1) |
| Arthralgia | 2 (<0.1) | 8 (<0.1) |
| Back pain | 7 (<0.1) | 1 (<0.1) |
| General disorders and administration site conditions | 13 (<0.1) | 49 (0.3) |
| Fatigue | 6 (<0.1) | 12 (<0.1) |
| Injection site erythema | 0 | 11 (<0.1) |
| Injection site pain | 1 (<0.1) | 3 (<0.1) |
| Investigations | 13 (<0.1) | 23 (0.2) |
| Blood pressure increased | 6 (<0.1) | 11 (<0.1) |
| Blood pressure systolic increased | 7 (<0.1) | 7 (<0.1) |
| An AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages were based on the number of safety set participants. All AEs were coded using MedDRA Version 23.0. | | |

Table S11. Serious AEs Reported by Preferred Term in Any Treatment Group, Overall Safety Set

| System Organ Class Preferred Term n (%) | Placebo (N=15166) | mRNA-1273 N=15185 |
|--|--------------------------|--------------------------|
| Number of participants reporting serious AEs | 153 (1.0) | 147 (1.0) |
| Number of serious AEs | 211 | 207 |
| Atrial fibrillation | 5 (<0.1) | 5 (<0.1) |
| Myocardial infarction | 3 (<0.1) | 5 (<0.1) |
| Pneumonia | 7 (<0.1) | 5 (<0.1) |
| Pulmonary embolism | 5 (<0.1) | 4 (<0.1) |
| Abdominal pain upper | 0 | 3 (<0.1) |
| Cardiac failure congestive | 3 (<0.1) | 3 (<0.1) |
| Cerebrovascular accident | 1 (<0.1) | 3 (<0.1) |
| Cholecystitis | 0 | 3 (<0.1) |
| Dehydration | 3 (<0.1) | 3 (<0.1) |
| Dyspnoea | 0 | 3 (<0.1) |
| Nausea | 1 (<0.1) | 3 (<0.1) |
| Nephrolithiasis | 0 | 3 (<0.1) |
| Prostate cancer | 3 (<0.1) | 3 (<0.1) |
| Acute respiratory failure | 2 (<0.1) | 2 (<0.1) |
| Acute coronary syndrome | 0 | 2 (<0.1) |
| Acute myocardial infarction | 4 (<0.1) | 2 (<0.1) |
| Appendicitis | 3 (<0.1) | 2 (<0.1) |
| Arthritis | 1 (<0.1) | 2 (<0.1) |
| Cervical vertebral fracture | 0 | 2 (<0.1) |
| Chest pain | 1 (<0.1) | 2 (<0.1) |
| Colitis | 1 (<0.1) | 2 (<0.1) |
| Coronary artery disease | 2 (<0.1) | 2 (<0.1) |
| Deep vein thrombosis | 0 | 2 (<0.1) |
| Diarrhoea | 1 (<0.1) | 2 (<0.1) |
| Embolic stroke | 0 | 2 (<0.1) |
| Fall | 3 (<0.1) | 2 (<0.1) |
| Hiatus hernia | 1 (<0.1) | 2 (<0.1) |
| Hypertension | 1 (<0.1) | 2 (<0.1) |
| Respiratory Failure | 1 (<0.1) | 2 (<0.1) |
| Road traffic accident | 1 (<0.1) | 2 (<0.1) |
| Seizure | 0 | 2 (<0.1) |
| Spinal stenosis | 1 (<0.1) | 2 (<0.1) |
| Subdural hematoma | 0 | 2 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) |
| Syncope | 4 (<0.1) | 2 (<0.1) |
| Acute kidney injury | 3 (<0.1) | 1 (<0.1) |
| Covid-19 | 15 (<0.1) | 1 (<0.1) |
| Hip fracture | 2 (<0.1) | 1 (<0.1) |
| Thyroidectomy | 0 | 1 (<0.1) |
| Abdominal pain | 2 (<0.1) | 0 |
| Anaemia | 2 (<0.1) | 0 |
| Ankle fracture | 3 (<0.1) | 0 |
| Chronic obstructive pulmonary disease | 4 (<0.1) | 0 |
| Confusional state | 2 (<0.1) | 0 |
| Depression | 3 (<0.1) | 0 |
| Diverticulitis | 2 (<0.1) | 0 |
| Hypertensive emergency | 2 (<0.1) | 0 |
| Intervertebral disc protrusion | 1 (<0.1) | 0 |
| Intraductal proliferative breast lesion | 2 (<0.1) | 0 |
| Major depression | 2 (<0.1) | 0 |
| Urinary tract infection | 4 (<0.1) | 0 |

AE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0.

Table S12. Unsolicited Adverse Events of Hypersensitivity, Overall Safety Set

| Preferred term n (%) | Placebo | mRNA-1273 |
|---|-----------|-----------|
| | (N=15166) | (N=15185) |
| Participants reporting hypersensitivity | 166 (1.1) | 233 (1.5) |
| Allergic sinusitis | 1 (<0.1) | 2 (<0.1) |
| Anaphylactic reaction | 1 (<0.1) | 1 (<0.1) |
| Angioedema | 3 (<0.1) | 1 (<0.1) |
| Bronchospasm | 0 | 1 (<0.1) |
| Conjunctivitis allergic | 2 (<0.1) | 2 (<0.1) |
| Dermatitis | 8 (<0.1) | 8 (<0.1) |
| Dermatitis allergic | 3 (<0.1) | 2 (<0.1) |
| Dermatitis atopic | 7 (<0.1) | 4 (<0.1) |
| Dermatitis bullous | 2 (<0.1) | 0 |
| Dermatitis contact | 29 (0.2) | 21 (0.1) |
| Drug hypersensitivity | 4 (<0.1) | 4 (<0.1) |
| Eczema | 4 (<0.1) | 3 (<0.1) |
| Exfoliative rash | 0 | 1 (<0.1) |
| Eye swelling | 2 (<0.1) | 2 (<0.1) |
| Hand dermatitis | 0 | 2 (<0.1) |
| Hypersensitivity | 4 (<0.1) | 5 (<0.1) |
| Idiopathic urticaria | 1 (<0.1) | 0 |
| Injection related reaction | 1 (<0.1) | 1 (<0.1) |
| Injection site rash | 1 (<0.1) | 37 (0.2) |
| Injection site urticaria | 0 | 15 (<0.1) |
| Laryngeal oedema | 1 (<0.1) | 0 |
| Lip swelling | 2 (<0.1) | 2 (<0.1) |
| Palatal oedema | 1 (<0.1) | 0 |
| Periorbital oedema | 1 (<0.1) | 0 |
| Periorbital swelling | 2 (<0.1) | 0 |
| Rash | 34 (0.2) | 45 (0.3) |
| Rash erythematous | 2 (<0.1) | 6 (<0.1) |
| Rash follicular | 1 (<0.1) | 0 |
| Rash macular | 4 (<0.1) | 6 (<0.1) |
| Rash maculo-papular | 2 (<0.1) | 11 (<0.1) |
| Rash pruritic | 4 (<0.1) | 6 (<0.1) |
| Rash vesicular | 0 | 3 (<0.1) |
| Rhinitis allergic | 13 (<0.1) | 10 (<0.1) |
| Serum sickness | 1 (<0.1) | 0 |
| Swelling face | 2 (<0.1) | 4 (<0.1) |
| Swelling of eyelid | 1 (<0.1) | 2 (<0.1) |
| Swollen tongue | 0 | 2 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) |
| Urticaria | 23 (0.2) | 27 (0.2) |
| Urticaria papular | 5 (<0.1) | 3 (<0.1) |
| Vaccination site rash | 0 | 1 (<0.1) |

Percentages are based on the number of participants in the safety set. Preferred term by MedDRA version 23.0. Hypersensitivity was identified through selected SMQ.

Table S13. Covid-19 Symptoms and Severity, Per-protocol Set

| Covid-19 Symptom n (%) | All Covid-19 cases | | Severe Covid-19 cases | |
|--|--------------------|-------------------|-----------------------|-----------------|
| | Placebo (N=185) | mRNA-1273 (N=11)* | Placebo (N=30) | mRNA-1273 (N=0) |
| Number of participants with any symptom | 185 (100) | 11 (100) | 30 (100) | 0 |
| Respiratory symptom | | | | |
| Clinical evidence of pneumonia | 4 (2.2) | 0 | 4 (13.3) | 0 |
| Cough | 155 (83.8) | 6 (54.5) | 28 (93.3) | 0 |
| Difficulty breathing | 55 (29.7) | 1 (9.1) | 16 (53.3) | 0 |
| Radiographical evidence of pneumonia | 3 (1.6) | 0 | 3 (10.0) | 0 |
| Shortness of breath | 78 (42.2) | 2 (18.2) | 23 (76.7) | 0 |
| Systemic symptom | | | | |
| Body aches | 111 (60.0) | 7 (63.6) | 26 (86.7) | 0 |
| Chills | 95 (51.4) | 4 (36.4) | 19 (63.3) | 0 |
| Diarrhea | 70 (37.8) | 2 (18.2) | 14 (46.7) | 0 |
| Fatigue | 156 (84.3) | 9 (81.8) | 27 (90.0) | 0 |
| Fever† | 54 (29.2) | 2 (18.2) | 13 (43.3) | 0 |
| Headache | 145 (78.4) | 10 (90.9) | 25 (83.3) | 0 |
| Muscle aches (myalgia) | 114 (61.6) | 5 (45.5) | 24 (80.0) | 0 |
| Nasal congestion | 138 (74.6) | 8 (72.7) | 21 (70.0) | 0 |
| Nausea | 65 (35.1) | 3 (27.3) | 13 (43.3) | 0 |
| New loss of smell | 115 (62.2) | 3 (27.3) | 16 (53.3) | 0 |
| New loss of taste | 106 (57.3) | 3 (27.3) | 15 (50.0) | 0 |
| Runny nose (rhinorrhea) | 121 (65.4) | 6 (54.5) | 18 (60.0) | 0 |
| Sore throat | 85 (45.9) | 7 (63.6) | 15 (50.0) | 0 |
| Vomiting | 18 (9.7) | 1 (9.1) | 7 (23.3) | 0 |
| Number of participants with any severe symptom | 32 (17.3) | 0 | 30 (100) | 0 |
| Acute renal dysfunction | 2 (1.1) | 0 | 2 (6.7) | 0 |
| Acute Respiratory Distress Syndrome | 1 (0.5) | 0 | 1 (3.3) | 0 |
| ECMO | 0 | 0 | 0 | 0 |
| High-flow oxygen | 1 (0.5) | 0 | 1 (3.3) | 0 |
| Mechanical ventilation | 0 | 0 | 0 | 0 |
| Non-Invasive ventilation | 1 (0.5) | 0 | 1 (3.3) | 0 |
| Admission to an intensive care unit due to SARS-CoV-2 | 1 (0.5) | 0 | 1 (3.3) | 0 |
| Heart Rate ≥125 beats per minute | 0 | 0 | 0 | 0 |
| Hepatic dysfunction | 0 | 0 | 0 | 0 |
| Neurologic dysfunction | 1 (0.5) | 0 | 1 (3.3) | 0 |
| Oxygen saturation ≤93‡ | 28 (15.1) | 0 | 27 (90.0) | 0 |
| Oxygen saturation SpO2 ≤93% on room air at sea level | 29 (15.7) | 0 | 28 (93.3) | 0 |
| PaO2/FiO2 ratio <300 mmHg | 0 | 0 | 0 | 0 |
| Respiratory failure | 1 (0.5) | 0 | 1 (3.3) | 0 |
| Respiratory rate ≥30 per minute | 0 | 0 | 0 | 0 |
| Systolic blood pressure <90 mmHg, diastolic blood Pressure <60 mmHg | 5 (2.7) | 0 | 4 (13.3) | 0 |
| Vasopressors required | 0 | 0 | 0 | 0 |
| <p>Note symptoms are shown for participants with all cases of 196 Covid-19 and those 30 that were considered severe cases. All symptoms reported are included, regardless of relationship with the positive RT-PCR test used to define the case of Covid-19 in PP set. Participants can be counted in more than one category. *There were 7 Covid-19 cases reported before 14 days post-dose 2. †Derived based on temperature collected on case report form (CRF) symptoms. ‡Derived based on oxygen saturation collected on CRF symptom log page.</p> | | | | |

Table S14. Characteristics of Participants with Severe Covid-19 Cases, Per-protocol Set

| Characteristics n (%) | Covid-19 cases Placebo N=30 |
|---|--------------------------------|
| Sex | |
| Female | 17 (57) |
| Male | 13 (43) |
| Age, years | |
| Mean (range) | 54.4 (23-80) |
| ≥65 years | 10 (33) |
| Race/Ethnicity | |
| White, not Hispanic or Latino | 24 (80) |
| White, Hispanic or Latino | 2 (7) |
| Black/African American, Not Hispanic or Latino | 1 (3) |
| Not reported/other, Hispanic or Latino | 2 (7) |
| Multiple, Not Hispanic or Latino | 1 (3) |
| Hospitalized | 9 (30) |
| ICU | 2 (7) |
| Co-morbid conditions (chronic lung, severe obesity, cardiac, diabetes, hypertension and/or asthma) | 20 (67) |
| Clinical signs indicative of severe system illness | |
| Oxygen saturation ≤93%* | 28 (93) |
| Respiratory failure or Acute Respiratory Distress Syndrome | 6 (20) |
| Significant acute renal or neurologic dysfunction | 2 (7) |
| *Derived based on oxygen saturation collected on CRF symptom log page. Covid-19 cases in the PP set. Data from December 3 rd , 2020. | |

Table S15. Serious and Severe Treatment-related AEs Up to 28 days after Any Injection, Overall Safety Set

| System organ class, preferred term n (%) | Placebo N=15166 | mRNA-1273 N=15185 | Total (N=30351) |
|---|--------------------|----------------------|--------------------|
| Serious AEs | | | |
| Incidence of unsolicited AEs | 4 (<0.1) | 6 (<0.1) | 10 (<0.1) |
| Autonomic nervous system imbalance | 0 | 1 (<0.1) | 1 (<0.1) |
| Paraesthesia | 1 (<0.1) | 0 | 1 (<0.1) |
| Dyspnoea | 0 | 1 (<0.1) | 1 (<0.1) |
| Pulmonary embolism | 1 (<0.1) | 0 | 1 (<0.1) |
| Nausea | 0 | 1 (<0.1) | 1 (<0.1) |
| Vomiting | 0 | 1 (<0.1) | 1 (<0.1) |
| Rheumatoid arthritis | 0 | 1 (<0.1) | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Swelling face | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Edema peripheral | 0 | 1 (<0.1) | 1 (<0.1) |
| Feeling hot | 1 (<0.1) | 0 | 1 (<0.1) |
| Immunization anxiety-related reaction | 1 (<0.1) | 0 | 1 (<0.1) |
| Procedural haemorrhage | 1 (<0.1) | 0 | 1 (<0.1) |
| Severe AEs | | | |
| Incidence of unsolicited severe AEs | 28 (0.2) | 71 (0.5) | 99 (0.3) |
| Lymphadenopathy | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Type IV hypersensitivity reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Headache | 8 (<0.1) | 9 (<0.1) | 17 9<0.1) |
| Dizziness | 1 (<0.1) | 1 (<0.1) | 2 (<0.1) |
| Movement disorder | 0 | 1 (<0.1) | 1 (<0.1) |
| Syncope | 0 | 1 (<0.1) | 1 (<0.1) |
| Migraine | 1 (<0.1) | 0 | 1 (<0.1) |
| Vertigo | 0 | 0 | 1 (<0.1) |
| Hypertension | 9 (<0.1) | 4 (<0.1) | 13 (<0.1) |
| Nausea | 0 | 1 (<0.1) | 1 (<0.1) |
| Dermatitis | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Rash macular | 0 | 1 (<0.1) | 1 (<0.1) |
| Myalgia | 0 | 6 (<0.1) | 6 (<0.1) |
| Arthralgia | 2 (<0.1) | 3 (<0.1) | 5 (<0.1) |
| Muscle spasms | 0 | 2 (<0.1) | 2 (<0.1) |
| Neck pain | 0 | 1 (<0.1) | 1 (<0.1) |
| Pain in extremity | 0 | 1 (<0.1) | 1 (<0.1) |
| Temporomandibular joint syndrome | 0 | 1 (<0.1) | 1 (<0.1) |
| Back pain | 1 (<0.1) | 0 | 1 (<0.1) |
| Polymyalgia rheumatica | 1 (<0.1) | 0 | 1 (<0.1) |
| Injection site erythema | 0 | 11 (<0.1) | 11 (<0.1) |
| Fatigue | 2 (<0.1) | 9 (<0.1) | 11 (<0.1) |
| Injection site swelling | 0 | 4 (<0.1) | 4 (<0.1) |
| Injection site macule | 0 | 3 (<0.1) | 3 (<0.1) |
| Chills | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site lymphadenopathy | 0 | 2 (<0.1) | 2 (<0.1) |
| Injection site pain | 1 (<0.1) | 2 (<0.1) | 3 (<0.1) |
| Adverse drug reaction | 0 | 1 (<0.1) | 1 (<0.1) |
| Chest discomfort | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site induration | 0 | 1 (<0.1) | 1 (<0.1) |
| Injection site rash | 0 | 1 (<0.1) | 1 (<0.1) |
| Malaise | 0 | 1 (<0.1) | 1 (<0.1) |
| Pyrexia | 0 | 1 (<0.1) | 1 (<0.1) |
| Swelling face | 0 | 1 (<0.1) | 1 (<0.1) |
| Asthenia | 1 (<0.1) | 0 | 1 (<0.1) |
| Blood pressure increased | 2 (<0.1) | 5 (<0.1) | 7 (<0.1) |
| Blood pressure systolic increased | 0 | 1 (<0.1) | 1 (<0.1) |
| Adverse event (AE) was defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of participants in the safety set. All AEs were coded using MedDRA Version 23.0. | | | |

Table S16. Efficacy of Key Secondary Endpoints, Per-protocol Set

| Secondary endpoint | Placebo (N=14073) | mRNA-1273 (N=14134) |
|--|----------------------|------------------------|
| Severe Covid-19 starting 14 days after second injection, adjudicated | | |
| n, events, PP | 30 | 0 |
| VE based on Hazard Ratio (95% CI)* | | 1.00 (NE-1.00) |
| Covid-19 after the first dose† | | |
| n, events, PP | 225 | 11 |
| VE based on Hazard Ratio (95% CI) | | 0.952 (0.912-0.974) |
| Secondary definition of Covid-19 starting 14 days after second injection‡ | | |
| n, events, PP | 221 | 11 |
| VE based on Hazard Ratio (95% CI) | | 0.951 (0.911-0.973) |
| Covid-19 after the second injection regardless of prior SARS-CoV-2 infection, adjudicated | | |
| n/N events§ FAS | 187/15170 | 12/15181 |
| VE based on Hazard Ratio (95% CI) | | 0.936 (0.886-0.965) |
| PP=per-protocol set; FAS=full analysis set. *Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs placebo), and 95% CI estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor. †Inclusive of second doses. ‡Secondary case definition of Covid-19 was defined as including systemic symptoms: fever (temperature ≥ 38°C) or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle aches or body aches, headache, new loss of taste or smell, sore throat, nasal congestion or rhinorrhea, nausea or vomiting or diarrhea AND a positive NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) for SARS-CoV-2 by RT-PCR. §n and N are based on the number of participants in the FAS. | | |

Table S17. Vaccine Efficacy by SARS-COV-2 Status, Modified Intent-to-Treat

| Baseline SARS-CoV-2 Status n (%) | Placebo | mRNA-1273 |
|---|-------------------|---------------------|
| Negative | N=14598 | N=14550 |
| Number with Covid-19 | 185 (1.3) | 12 (<0.1) |
| Number censored | 14413 (98.7) | 14538 (>99.9) |
| VE Based on HR (95% CI) | | 0.936 (0.885-0.964) |
| Person-Years | 3382.9 | 3390.1 |
| Incidence rate per 1,000 Person-Years (95% CI) | 54.7 (47.1- 63.2) | 3.6 (1.8-6.2) |
| VE based on incidence rate (95% CI) | | 0.935 (0.884-0.967) |
| Positive | N=337 | N=343 |
| Number with Covid-19 | 1 (0.3) | 0 |
| Number Censored | 336 (99.7) | 343 (100) |
| VE Based on HR (95% CI) | | 1.000 (NE-1.000) |
| Person-Years | 71.9 | 71.4 |
| Incidence rate per 1,000 Person-Years (95% CI)* | 13.9 (0.4-77.5) | 0.0 (NE-51.7) |
| VE based on incidence rate (95% CI) | | 1.000 (-38.3-NE) |
| <p>HR=hazard ratio. VE=vaccine efficacy. VE was defined as 1 - hazard ratio (mRNA-1273 vs. placebo); 95% CI were estimated using a stratified Cox proportional hazard model with Efron's method of tie handling with the treatment group as a covariate, adjusting for stratification factor if applicable in mITT set. Person-years was defined as the total years from randomization date to the date of Covid-19, last date of study participation, or efficacy data cutoff date, whichever was earlier. *Incidence rate was defined as the number of participants with an event divided by the number of participants at risk, adjusted by person-years (total time at risk) in each treatment group; the 95% CI was calculated using the exact method (Poisson distribution) adjusted by person-years and VE was defined as 1 — ratio of incidence rate (mRNA-1273 vs. placebo). Baseline SARS-CoV-2 Status was considered positive based on immunologic or virologic evidence of prior Covid-19, defined as positive RT-PCR test or bAb result at day 1; negative was defined as negative RT-PCR test and bAb results at day 1. Covid-19 cases were diagnosed by symptoms and RT-PCR.</p> | | |

Table S18. Preliminary Analysis of Infection from Randomization, Modified Intent-to-Treat

| | Placebo N=14598 | mRNA-1273 N=14550 | Vaccine efficacy (95% CI) |
|---|----------------------------|------------------------------|--------------------------------------|
| Symptomatic Covid-19 | 293 | 20 | |
| Covid -19 | 269 | 19 | |
| Secondary definition of Covid -19 | 24 | 1 | |
| Positive RT-PCR at scheduled pre-dose 2* | 39 | 15 | |
| Total infection (symptomatic or RT-PCR+ at pre-dose 2) | 332 | 35 | 89.6% (85.2%-92.6%) [†] |
| Person-years [‡] | 3365.6 | 3386.6 | |
| Incidence rate (95% CI) [§] | 98.6 (88.3-109.8) | 10.3 (7.2-14.4) | 89.5% (85.1%-92.8%) |
| <p>Preliminary analysis of infection from randomization performed based on the modified intent-to-treat set (data cut-off November 25, 2020). Infection was defined as symptomatic Covid-19, either Covid-19 (positive RT-PCR with two eligible systemic or one eligible respiratory symptom), or secondary/CDC definition of Covid-19 requiring one symptom, or, asymptomatic infection, as measured by positive RT-PCR at the scheduled pre-Dose 2 visit.). *Positive RT-PCR at the scheduled pre-Dose 2 visit and no Covid-19 symptoms. [†]From stratified Cox proportional model adjusting for the stratification factor. [‡]Person-years defined as the total years from randomization date to the date of Covid-19, last date of study participation, or efficacy data cutoff date, whichever was earlier. [§]Incidence rate was defined as the number of participants with an event divided by the number at risk adjusted by person-years (total time at risk) in each treatment group and 95% CI calculated using the exact method (Poisson distribution) conditional on total number of events adjusted by person-years.</p> | | | |