Supplementary Appendix

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

Supplement to: El Sahly HM, Baden LR, Essink B, et al. Efficacy of the mRNA-1273 SARS-CoV-2 vaccine at completion of blinded phase. N Engl J Med 2021;385:1774-85. DOI: 10.1056/NEJMoa2113017

Supplement

Table of Contents

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Supplementary Methods

Trial oversight

The trial Investigational New Drug sponsor, Moderna, Inc. was responsible for trial design (in collaboration with the Biomedical Advanced Research and Development Authority [BARDA], NIAID, Coronavirus Vaccine Prevention Network, and study co-chairs), site selection and monitoring, and data analysis. Investigators were responsible for data collection. Authors vouch for the accuracy and completeness of the data and the fidelity of the trial to the protocol.

The issuance of the mRNA-1273 and BNT162b2 EUAs in December 2020 and the prioritization of older persons, first responders and those with comorbidities in the general population to receive the mRNA vaccines prompted the rapid redesign of the COVE study to successfully maintain participant engagement for the planned duration of 2 years in an open-label design, thus enabling the evaluation of longer-term safety and waning efficacy using established and novel study methods, such as evaluating VE in those vaccinated early as well as late in the study population. It is also important to determine correlates of protection in these ongoing studies which could inform strategies to improve vaccine responses in immunocompromised patients and potentially diminish viral evolution and reservoirs of virus in the community.

Statistical methods for primary and secondary efficacy analyses

The sample size of the study was driven by the total number of cases to demonstrate VE (mRNA-1273 vs. placebo) to prevent Covid-19. For the analysis of the primary efficacy end point, the trial was designed for the null hypothesis that the efficacy of the mRNA-1273 vaccine would be 30% or less, and a total of 151 cases of Covid-19 would provide 90% power to detect a 60% reduction in the hazard rate (i.e., 60% vaccine efficacy), with two planned interim analyses at approximately 35% and 70% of the target cases, and with a one-sided O'Brien–Fleming boundary for efficacy and an overall one-sided error rate of 0.025.

A sequential/hierarchical testing procedure was planned to control type 1 error rate over the primary efficacy and secondary efficacy endpoints. Secondary efficacy endpoints were only to be tested when the primary efficacy endpoint achieved statistical significance. Multiplicity adjustments were performed for secondary efficacy endpoints. (See Fixed-Sequence Method in the FDA guidance document at: https://www.fda.gov/files/drugs/published/Multiple-Endpoints-in-Clinical-Trials-Guidance-for-Industry.pdf). Although the above testing strategy for select secondary efficacy endpoints was pre-specified in the statistical analysis plan (SAP), at the first interim analysis (IA1), with 95 adjudicated cases based on a data snapshot on 11-Nov-2020 (results reported in Baden et al, N Engl J Med 2021;384:403-16; online Dec 2020), the VE was demonstrated for the primary efficacy endpoint, Covid-19. At the time of IA1, there were not enough severe cases (only a total 11 severe Covid-19 cases) and infection data were not available, thus, the testing strategy of these secondary efficacy endpoints was not fully implemented. In this manuscript, more comprehensive efficacy results with longer follow-up and high efficacy observed across endpoints are reported.

Efficacy analyses the primary and secondary end points were performed using the per-protocol, mITT and full analysis set populations, and participants were assessed in their assigned randomized treatment groups for all efficacy analyses. In this protocol, the primary efficacy analysis was conducted in the per-protocol (PP) set. The PP set is a commonly used and regulatory-accepted analysis set for

primary efficacy evaluations in vaccine studies. In this study, the PP set consists of all participants with negative SARS-CoV-2 status at baseline, receiving the correct 2 doses within allowable dosing windows and having no major protocol deviations. The primary efficacy endpoint is based on Covid-19 cases counted starting 14 days after the second dose, at a time when the immune response to vaccine is expected to reach a high level that is protective against Covid-19. Using the PP set (eg rather than an intent-to-treat [ITT] dataset) for the primary efficacy analysis, affords a more accurate assessment of the protective effect against Covid-19 generated by the immune response to the scheduled two doses of vaccine. The efficacy analyses were also performed in the mITT set as supportive data.

Secondary end point definitions and derivations

The analysis approach for primary and secondary efficacy endpoints are summarized in Table S4.

VE to prevent serologically confirmed SARS-CoV-2 infection or Covid-19 regardless of symptomatology or severity

For the secondary efficacy end point, serologically confirmed SARS-CoV-2 infection or Covid-19 regardless of symptomatology or severity [COV-INF], any post-baseline positive RT-PCR results were considered, including those from the scheduled NP swab tests at Day 29 visit prior to the 2nd injection as well as the those prompted by symptom(s). In addition, seroconversion due to infection was considered. The analysis population for COV-INF was the PP and the mITT set that include participants with negative SARS-CoV-2 status at baseline. Seroconversion due to infection was defined for participants with negative SARS-CoV-2 status at baseline as becoming seropositive (positive bAb specific to SARS-CoV-2 NP) as measured by *Roche Elecsys* on study (at scheduled visits post baseline). A Covid-19 case or secondary definition of Covid-19 case was always an INF case. The date of documented infection regardless of symptom [COV-INF] was the earlier of the date of positive post-baseline RT-PCR result, or date of seroconversion due to infection.

In the primary approach, documented infection was counted starting 14 days after the 2nd injection, which required a positive RT-PCR result starting 14 days after the 2nd injection, or seroconversion at day 57 visit or later.

VE to prevent asymptomatic SARS-CoV-2 infection

Asymptomatic SARS-CoV-2 infection was analyzed in the PP and mITT sets. Asymptomatic infection was identified by absence of symptoms and infections as detected by RT-PCR or seroconversion. Specifically, the absence of symptoms (no Covid-19 symptom for either primary efficacy end point of Covid-19, or secondary definition of Covid-19), and at least either seroconversion (bAb specific to SARS-CoV-2 nucleocapsid) at scheduled visits (months 1, 2, 7, 13 and 25 if applicable in Part A, participant decision visit and etc. in Part B) when blood samples for immunogenicity were collected, or by RT-PCR at scheduled visits such as pre-dose 2 at Day 29 in Part A, both RT-PCR test and bAb against SARS-CoV-2 nucleocapsid were considered.

The date of documented asymptomatic infection was the earlier date of seroconversion due to infection, or positive RT-PCR at scheduled visits, with absence of symptoms. Participants who had a symptomatic infection (Covid-19 or secondary definition of Covid-19) prior to an asymptomatic infection were censored at the time of symptomatic infection for the analysis of asymptomatic infection. In the primary approach, documented asymptomatic infection was counted starting 14 days after the 2nd injection, which required seroconversion at months 2 (day 57 visit) or later. As diseased cases (Covid-19 or secondary definition of Covid-19) are competing events for asymptomatic SARS-CoV-2 infections, competing risk method was used to estimate the vaccine efficacy of mRNA-1273,

specifically, Fine and Gray's (FG) sub-distribution hazard model will be used. Competing risk method was also be used to estimate the cumulative incidence function and the cumulative incidence of asymptomatic SARS-CoV-2 infections will be plotted.

VE to prevent Covid-19 disease regardless of prior SARS-CoV-2 infection

This endpoint was analyzed based on the FAS. The same methods described above for the primary efficacy end point were applied with cases counted starting 14 days after the second injection. Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, and after randomization were also be performed. In sensitivity analysis with cases counted starting after the second injection, participants who received only the first injection and was a case were censored at the time of Covid-19. The VE was also estimated with 1- ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases adjusting for person-time. In addition, an exploratory analysis with the same Cox model was carried out in the subgroup of FAS whose baseline SARS-CoV-2 status was positive with cases counted starting from randomization to assess the VE in those with positive baseline SARS-CoV-2 status, at baseline, if sample size permitted. Such analysis in the subgroup of FAS whose baseline SARS-CoV-2 status was negative with cases counted starting from randomization was the same as the sensitivity analysis of Covid-19 starting from randomization in the mITT set.

VE to prevent SARS-CoV-2 infection

This endpoint will be analyzed using the FAS. The same methods described above for the primary efficacy endpoint will be applied with cases counted starting 14 days after the second injection of IP. Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, and after randomization will also be performed. In sensitivity analysis with cases counted starting after the second injection, participants who received only the first injection and is a case will be censored at the time of Covid-19. The VE will also be estimated with 1- ratio of incidence rates with the 95% CI using the exact method conditional upon the total number of cases adjusting for person-time. In addition, an exploratory analysis with the same Cox model will be carried out in the subgroup of FAS whose baseline SARS-CoV-2 status is positive with cases counted starting from randomization to assess the VE in those with positive baseline SARS-CoV-2 status, at baseline, if sample size permits. Such analysis in the subgroup of FAS whose baseline SARS-CoV-2 status is negative with cases counted starting from randomization is the same as the sensitivity analysis of Covid-19 starting from randomization in mITT.

Figure S1. Study Flow Diagram of Part A (blinded phase) followed by Part B (open-label phase)

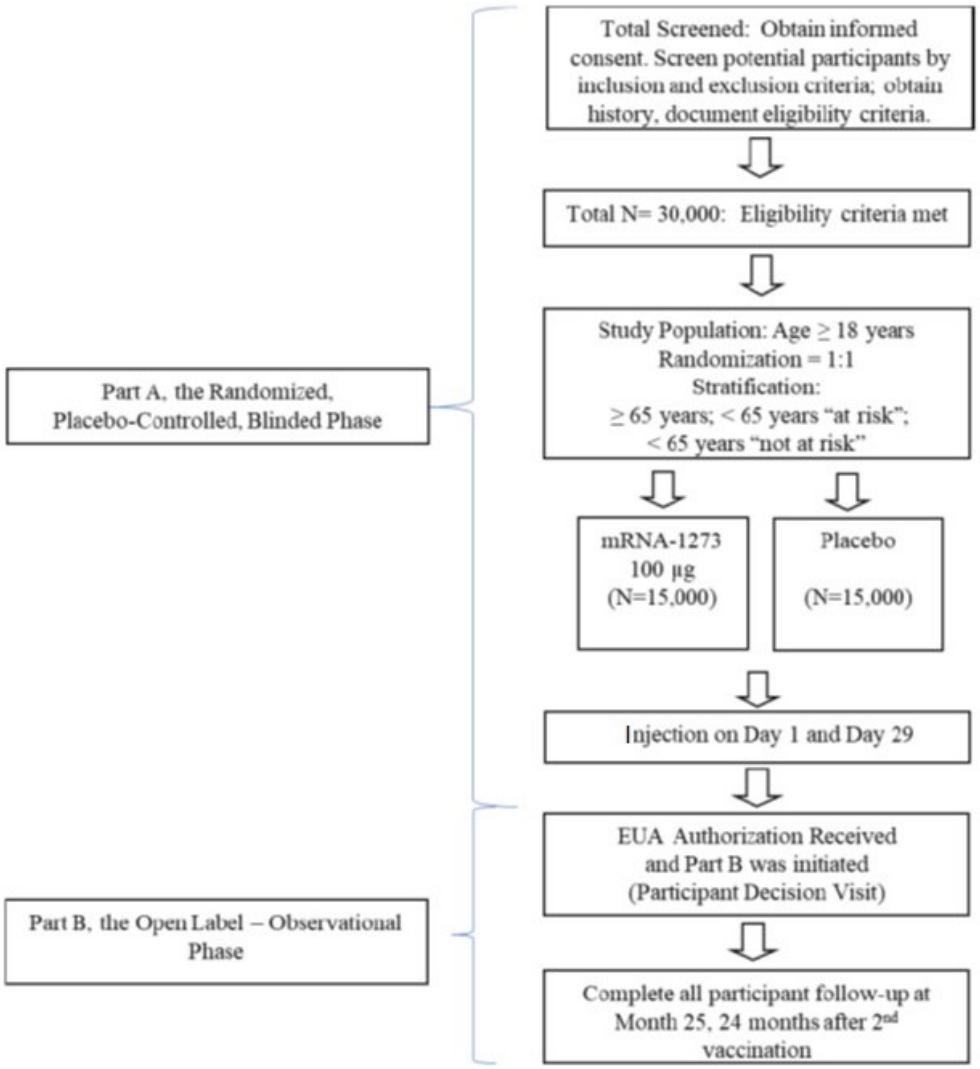

Figure S1. Study Flow Diagram of Part A (blinded phase) followed by Part B (open-label phase). EUA = Emergency Use Authorization. The ongoing 2-part Phase 3 study: Part A and Part B. Participants in Part A, the randomized, placebo-controlled, blinded phase of this study, were blinded to their treatment assignment. Given that the primary efficacy endpoint for mRNA-1273 against Covid-19 was met per the protocol-defined interim analysis (IA), Part B, the Open-Label Observational Phase of this study, was designed to offer participants who received placebo in Part A of this study and who met EUA eligibility, an option to request open-label mRNA-1273 during a Participant Decision Visit.

Figure. S2. Trial Profile during Blinded Part (A)

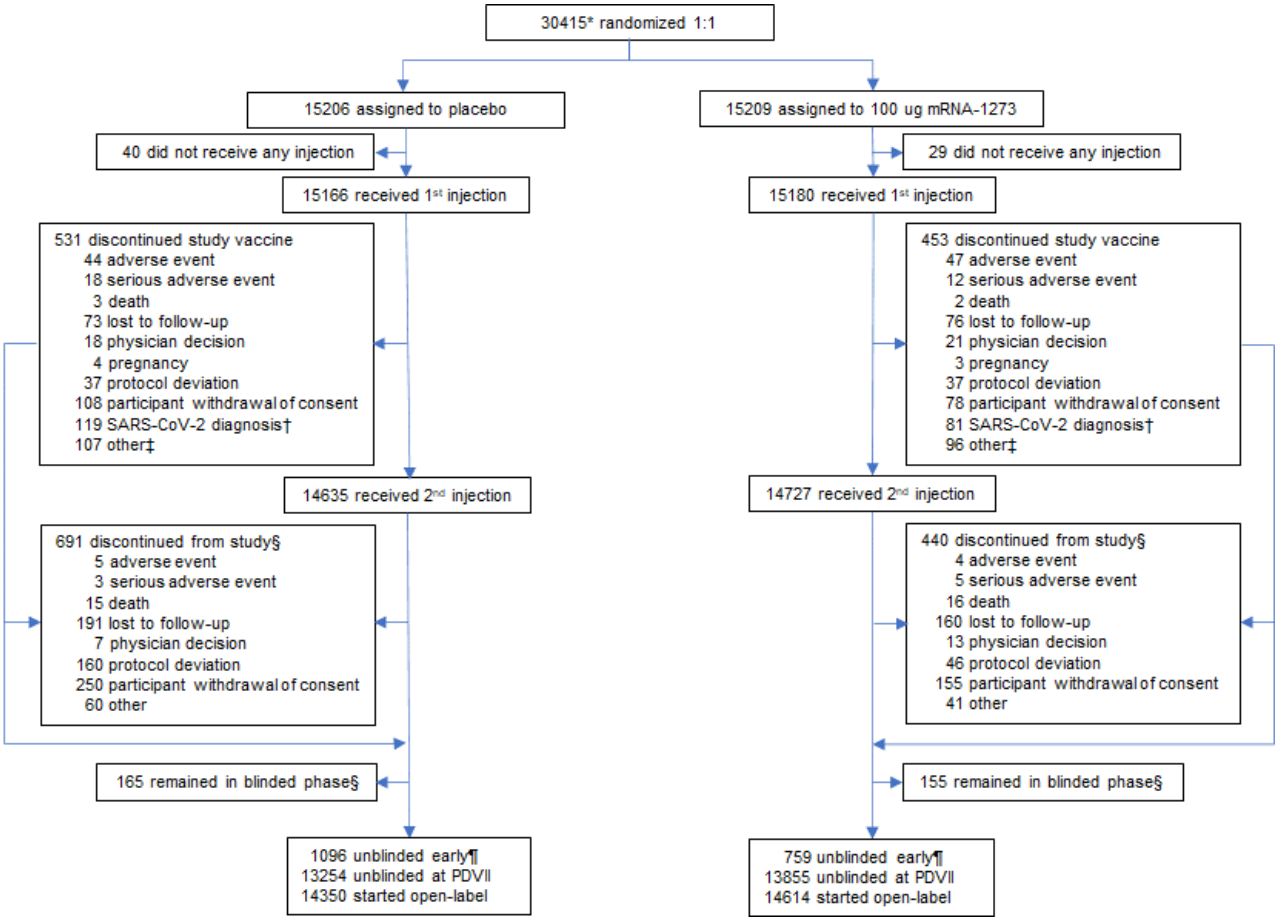

Figure S2. Trial profile during Blinded Part (A). In all groups, participants were evaluated according to the treatment group assigned. *8 participants were excluded from the original randomization set (n=30,423) and all analyses sets including 6 participants with major protocol deviations and 2 who were randomized twice. †Diagnosis of Covid-19 by detection of SARS-CoV-2 in day 1 nasopharyngeal swab or Covid-19 diagnosed prior to day 29. ‡Other includes 3 participants in the placebo and 2 in the mRNA-1273 groups who discontinued study vaccine on the first dose date and also discontinued from the study. §Includes participants who received only one injection and both injections. ¶Early unblinding included those that occurred before Dec. 29, 2020, the date of implementation of the protocol amendment at sites to offer participants unblinding at the participant decision visit (PDV) and open-label vaccination. ‖Unblinded on or after Dec. 29, 2020, the date of implementation of the protocol amendment at sites. Data cutoff date: March 26, 2021.

Figure S3. Discontinuation from Study by Month (Randomization Set)

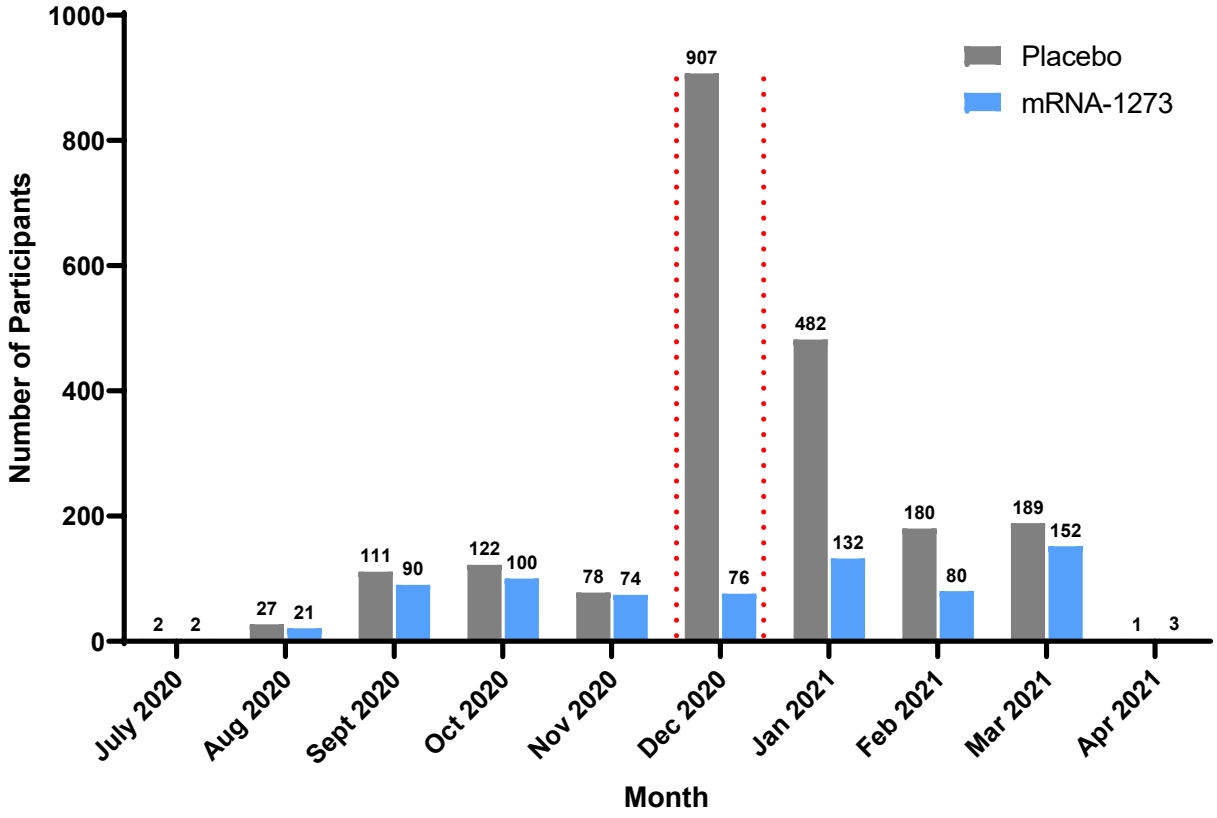

Figure S3. Discontinuation from Study by Month (Randomization Set. Number of participants who discontinued the study by month from July 2020 through April 2021. Data cutoff date: March 26, 2021.

Figure S4. Solicited Injection-site and Systemic Adverse Events and Grades in Overall and Age Groups

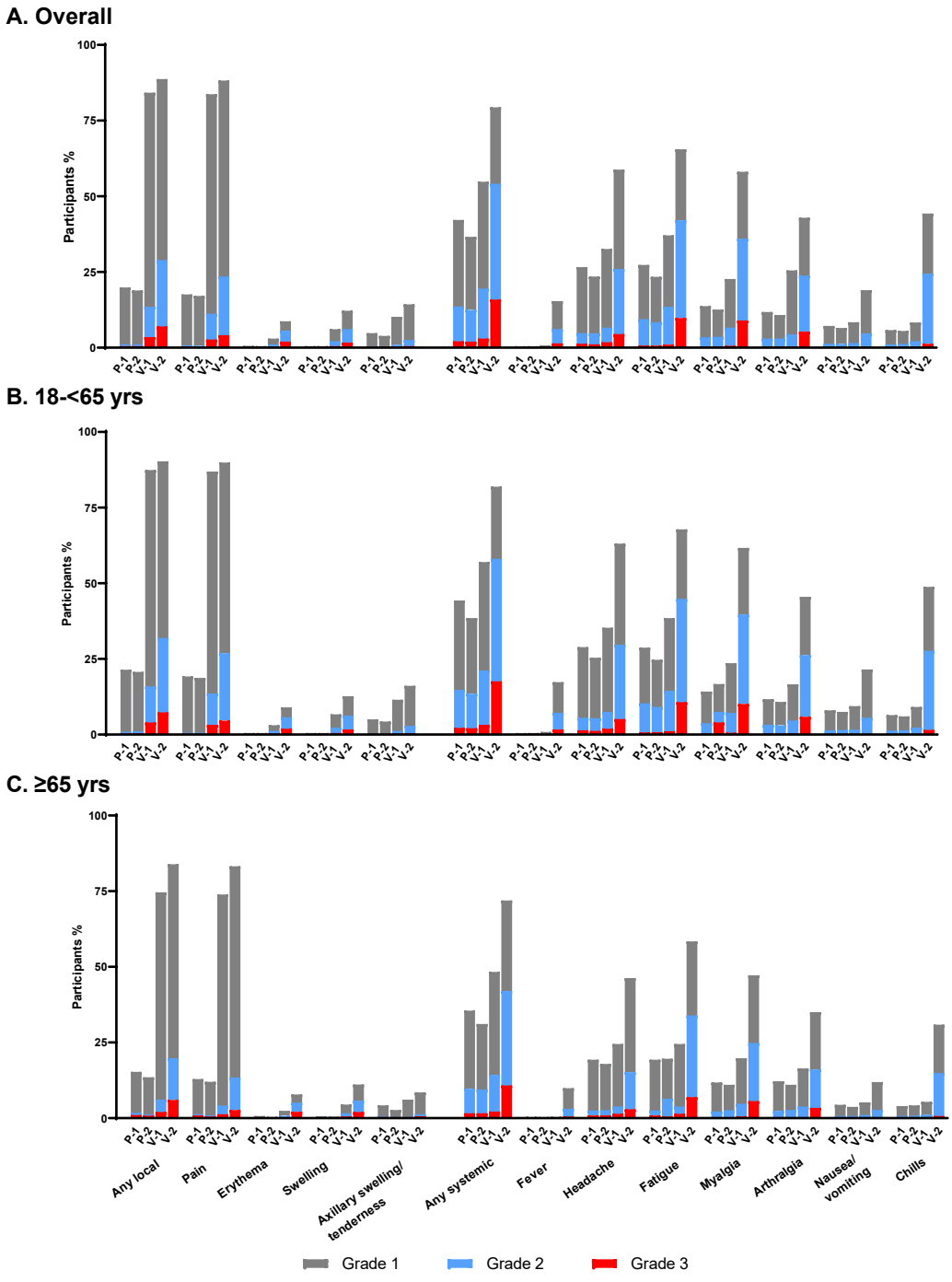

Figure S4. Solicited local and systemic adverse events in age groups. Percentage of participants in overall study (A), and those 18-<65 yrs (B) and ≥65 yrs (C) who experienced solicited local and systemic adverse events within 7 days post-injections 1 and 2 in the solicited safety set. P-1 and P-2 = placebo injections 1 and 2. V-1 and V-2 = mRNA-1273 vaccine injections 1 and 2**.** Data cutoff: March 26, 2021.

Figure S5. Covid-19 Starting after Randomization by Time Period in Per-protocol Set

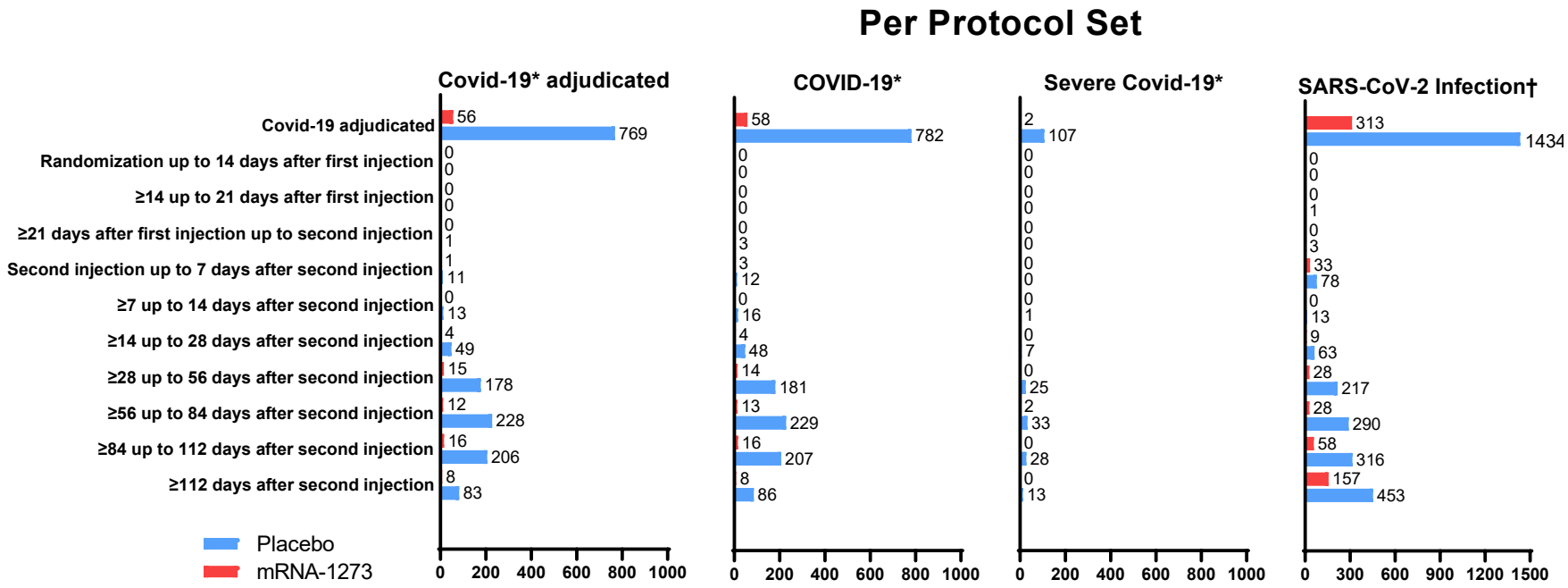

Figure S5. Covid-19 Starting after Randomization by Time Period in Per-protocol Set. *With censoring rules for with the censoring rules for efficacy analyses. Covid-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had a positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participant was censored at the date with positive RT-PCR or Elecsys.†Includes participant decision visit data. Data-cutoff date: March 26, 2021.

Table S1. Criteria for Covid-19 Case Definition

Covid-19 Case	Criteria
Primary Efficacy	• At least TWO of the following systemic symptoms: Fever (≥ 38ºC), chills, myalgia, headache, sore throat, new olfactory and taste disorder(s), OR • At least ONE of the following respiratory signs/symptoms: cough, shortness of breath or difficulty breathing, OR clinical or radiographical evidence of pneumonia; AND • At least one NP swab, nasal swab, or saliva sample (or respiratory sample, if hospitalized) positive for SARS-CoV-2 by RT-PCR.
Severe	• Confirmed Covid-19 per Primary Efficacy End point case definition, plus any of the following: ▪ Clinical signs indicative of severe systemic illness, respiratory rate ≥ 30 per minute, Heart Rate ≥ 125 beats per minute, SpO2 ≤ 93% on room air at sea level or PaO2/FIO2 < 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.
SARS-CoV-2 infection	SARS-CoV-2 infection was evaluated in participants with baseline negative SARS-CoV-2 status at baseline and cases defined by post-baseline ▪ Positive RT-PCR results either at scheduled day 29 visit or prompted by symptoms OR ▪ Becoming seropositive (positive bAb specific to SARS-CoV-2 NP) as measured by Roche Elecsys on study (at scheduled visits) ▪ Symptomatic Covid-19 cases (Covid-19 case or secondary definition of Covid-19 case) always considered an infection case
Asymptomatic SARS-CoV-2 infection	• Asymptomatic infection is identified by absence of symptoms and infections as detected by RT-PCR or seroconversion. Specifically: ▪ Absence of symptoms (no Covid-19 symptom for either primary efficacy endpoint of Covid-19, or secondary definition of Covid-19), ▪ AND at least one from below: • Becoming seropositive (bAb specific to SARS-CoV-2 nucleocapsid, Roche Elecsys) at scheduled visits (months 1, 2, 7, 13 and 25 if applicable in Part A, Participant Decision Visit and etc. in Part B), when blood samples for immunogenicity are collected, or • By RT-PCR at scheduled visits such as pre-dose 2 at day 29 in Part A, both RT- PCR test and bAb against SARS-CoV-2 nucleocapsid will be considered.

Table S2. Grading of Covid-19 Symptoms

Grading	All Symptoms	For Nausea/Vomiting ONLY	For Sense of Smell/Taste ONLY
None	No symptom		
Mild	I had the symptom, but I could still do my normal activities	I was able to eat and drink normally	I had the symptom, but I retained some taste/smell
Moderate	The symptom really bothered me. It was hard to do my normal activities	It bothered me enough that I did not eat or drink normally	My taste/smell was significantly affected
Severe	The symptom was very bad. I was not able to do activities that I usually do	I could not eat or drink	I have no taste or smell

Table S3. Description of Analysis populations

Population	Description
Randomization Set	All participants who are randomized, regardless of the participants' treatment status in the study.
Full Analysis Set (FAS)	All randomized participants who received at least one dose of placebo or vaccine. Participants will be analyzed according to the group to which they were randomized.
Modified Intent-to-Treat (mITT) Set	All participants in the FAS who had no immunologic or virologic evidence of prior Covid-19 (ie, negative NP swab test at Day 1, and/or bAb against SARS-CoV-2 nucleocapsid below LOD or LLOQ) at Day 1 before the first dose of placebo or vaccine. Participants will be analyzed according to the group to which they were randomized.
Per-protocol (PP) Set	All participants in the mITT Set who received planned doses of placebo or vaccine per schedule and have no major protocol deviations, as determined and documented by Sponsor prior to database lock and unblinding, that impact critical or key study data. Participants will be analyzed according to the group to which they were randomized.
Solicited Safety Set	The Solicited Safety Set consists of all randomized participants who received at least one dose of placebo or vaccine and contributed any solicited AE data. The Solicited Safety Set will be used for the analyses of solicited AEs and participants will be included in the group corresponding tothe treatment that they actually received.
Safety Set	All randomized participants who received at least one dose of placebo or vaccine. The Safety Set will be used for all analyses of safety except for the solicited AEs. Participants will be included in the group corresponding to the treatment that they actually received.

Table S4. Statistical Analysis Methods for Efficacy End points

End point	Statistical Analysis Methods
Primary end point: • Vaccine Efficacy (VE) of mRNA-1273 to prevent Covid-19	• Primary analysis: VE will be estimated with 1 - HR (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjusted for stratification factor based on the PP Set, with cases counted starting 14 days after the second injection • Analysis using the same model based on the mITT Set. • Sensitivity analysis using the same model based on the PP Set, with cases counted starting either immediately after the second injection or immediately after the first injection • Subgroup analysis of the primary efficacy end point will be performed to assess consistency of VE, such as in the age groups ≥18 and <65 years and ≥65 years • Supportive analysis of VE to be estimated with 1 - ratio of incidence rates with 95% CI using the exact method conditional upon the total number of cases • Supportive analysis of VE to be estimated with cumulative incidence ratio
Secondary end points: • Vaccine efficacy of mRNA-1273 to prevent severe Covid-19 • Vaccine efficacy of mRNA-1273 to prevent serologically confirmed SARS-CoV-2 infection or Covid-19 regardless of symptomatology or severity • Vaccine efficacy of mRNA-1273 to prevent Covid-19 using a secondary definition of symptoms • Vaccine efficacy of mRNA-1273 to prevent death due to Covid-19 • Vaccine efficacy of mRNA-1273 to prevent Covid-19 after the first injection • Vaccine efficacy of mRNA-1273 to prevent asymptomatic SARS-CoV-2 infection	• Similar analysis method as for the primary end point analysis. For each of the secondary end points: ▪ Primary analysis: VE will be estimated with 1 - HR (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjusting for stratification factor based on the PP Set, with cases counted starting 14 days after the second injection ▪ Analysis using the same model based on the mITT Set. ▪ Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, immediately after the first injection, and immediately after randomization. • Vaccine efficacy and 95% CI based on the case incidence will be estimated with 1 - ratio of incidence rates using the exact method conditional upon the total number of cases.
• Vaccine efficacy of mRNA-1273 to prevent Covid-19 in all study participants, regardless of evidence of prior SARS-CoV-2 infection	The FAS population will be used for this secondary objective, using similar analysis methods as for theprimary end point analysis. • Primary analysis: VE will be estimated with 1 - HR (mRNA-1273 vs placebo) using a Cox proportional hazard regression model with treatment group as a fixed effect and adjusting forstratification factor based on the FAS, with cases counted starting 14 days after the second injection. Sensitivity analyses with cases counted starting immediately after the second injection, 14 days after the first injection, immediately after the first injection, and immediately after randomization.

Table S5. Demographics and Characteristics of Population

A. Overall Full-Analysis Population

Characteristics n (%)	Placebo N=15166	mRNA-1273 N=15180	Total N=30346
Sex			
Male	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	7109 (46.9)	7263 (42.8)	14372 (47.4)
Age at Screening (yr)			
Mean (range)	51.3 (18-95)	51.4 (18-95)	51.4 (18-95)
Age (yr) and health risk for severe Covid-19*			
≥18 and <65 and Not at Risk	8882 (58.6)	8888 (58.6)	17770 (58.6)
≥18 and <65 and at Risk	2535 (16.7)	2530 (16.7)	5065 (16.7)
≥65	3749 (24.7)	3762 (24.8)	7511 (24.8)
Ethnicity			
Hispanic or Latino	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not reported or unknown	136 (0.9)	142 (0.9)	278 (0.9)
Race‡			
White	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Other Pacific Islander	32 (0.2)	36 (0.2)	68 (0,.2)
Multiracial	319 (2.10	319 (2.1)	638 (2.1)
Other	294 (1.9)	299 (2.00	593 (2.0)
Not reported or unknown	129 (0.9)	159 (1.0)	288 (0.9)
Baseline SARS-CoV-2 Status†			
Negative	14745 (97.2)	14746 (97.1)	29491 (97.2)
Positive	337 (2.2)	347 (2.3)	684 (2.3)
Missing	84 (0.6)	87 (0.6)	171 (0.6)
Baseline RT-PCR Results			
Negative	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	95 (0.6)	88 (0.6)	183 (0.6)
Missing	76 (0.5)	79 (0.5)	155 (0.5)
Baseline bAb Anti-SARS-CoV-2			
Negative	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	303 (2.0)	309 (2.0)	612 (2.0)
Missing	19 (0.1)	24 (0.2)	43 (0.1)
Risk Factor for Severe Covid-19 at Screening‡			
Chronic lung disease	749 (4.9)	712 (4.7)	1461 (4.8)
Significant cardiac disease	742 (4.9)	762 (5.0)	1504 (5.0)
Severe obesity	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver disease	96 (0.6)	104 (0.7)	200 (0.7)
HIV	91 (0.6)	94 (0.6)	185 (0.6)
Body Mass Index, (kg/m^2)			
n	15081	15092	30173
Mean (SD)	29.32 (6.7)	29.32 (6.8)	29.32 (6.8)

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. Percentages based on the full analysis set (FAS). *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. Data cutoff: March 26, 2021.

B. Demographics and Characteristics by Age Group Stratification

Characteristic n (%)	≥18-<65 yr and not at risk			≥18-<65 yr and at risk			≥65 yr			Overall		
	Placebo N=8882	mRNA-1273 N=8888	Total N=17770	Placebo N=2535	mRNA-1273 N=2530	Total N=5065	Placebo N=3749	mRNA-1273 N=3762	Total N=7511	Placebo N=15166	mRNA-1273 N=15180	Total N=30346
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	4628 (52.1)	4541 (51.1)	9169 (51.6)	1329 (52.4)	1303 (51.5)	2632 (52.0)	2100 (56.0)	2073 (55.1)	4173 (55.6)	8057 (53.1)	7917 (52.2)	15974 (52.6)
Female	4254 (47.9)	4347 (48.9)	8601 (48.4)	1206 (47.6)	1227 (48.5)	2433 (48.0)	1649 (44.0)	1689 (44.9)	3338 (44.4)	7109 (46.9)	7263 (47.8)	14372 (47.4)
Race												
White	6790 (76.4)	6757 (76.0)	13547 (76.2)	1872 (73.8)	1900 (75.1)	3772 (74.5)	3339 (89.1)	3374 (89.7)	6713 (89.4)	12001 (79.1)	12031 (79.3)	24032 (79.2)
Black or African American	901 (10.1)	971 (10.9)	1872 (10.5)	414 (16.3)	374 (14.8)	788 (15.6)	216 (5.8)	222 (5.9)	438 (5.8)	1531 (10.1)	1567 (10.3)	3098 (10.2)
Asian	579 (6.5)	503 (5.7)	1082 (6.1)	83 (3.3)	87 (3.4)	170 (3.4)	77 (2.1)	66 (1.8)	143 (1.9)	739 (4.9)	656 (4.3)	1395 (4.6)
American Indian or Alaska Native	72 (0.8)	65 (0.7)	137 (0.8)	23 (0.9)	27 (1.1)	50 (1.0)	26 (0.7)	21 (0.6)	47 (0.6)	121 (0.8)	113 (0.7)	234 (0.8)
Native Hawaiian or Pacific Islander	20 (0.2)	26 (0.3)	46 (0.3)	9 (0.4)	7 (0.3)	16 (0.3)	3 (<0.1)	3 (<0.1)	6 (<0.1)	32 (0.2)	36 (0.2)	68 (0,.2)
Multiracial	232 (2.6)	236 (2.7)	468 (2.6)	52 (2.1)	51 (2.0)	103 (2.0)	35 (0.9)	32 (0.9)	67 (0.9)	319 (2.1)	319 (2.1)	638 (2.1)
Other	211 (2.4)	220 (2.5)	431 (2.4)	51 (2.0)	56 (2.2)	107 (2.1)	32 (0.9)	23 (0.6)	55 (0.7)	294 (1.9)	299 (2.0)	593 (2.0)
Not reported	42 (0.5)	67 (0.8)	109 (0.6)	18 (0.7)	17 (0.7)	35 (0.7)	14 (0.4)	13 (0.3)	27 (0.4)	74 (0.5)	97 (0.6)	171 (0.6)
Unknown	35 (0.4)	43 (0.5)	78 (0.4)	13 (0.5)	11 (0.4)	24 (0.5)	7 (0.2)	8 (0.2)	15 (0.2)	55 (0.4)	62 (0.4)	117 (0.4)
Race and Ethnicity Group*												
White	4978 (56.0)	5004 (56.3)	9982 (56.2)	1427 (56.3)	1458 (57.6)	2885 (57.0)	3063 (81.7)	3071 (81.6)	6134 (81.7)	9468 (62.4)	9533 (62.8)	19001 (62.6)
Communities of color	3896 (43.9)	3870 (43.5)	7766 (43.7)	1103 (43.5)	1066 (42.1)	2169 (42.8)	673 (18.0)	685 (18.2)	1358 (18.1)	5672 (37.4)	5621 (37.0)	11293 (37.2)
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	2222 (25.0)	2211 (24.9)	4433 (24.9)	553 (21.8)	557 (22.0)	1110 (21.9)	334 (8.9)	353 (9.4)	687 (9.1)	3109 (20.5)	3121 (20.6)	6230 (20.5)
Not Hispanic or Latino	6588 (74.2)	6597 (74.2)	13185 (74.2)	1959 (77.3)	1955 (77.3)	3914 (77.3)	3374 (90.0)	3365 (89.4)	6739 (89.7)	11921 (78.6)	11917 (78.5)	23838 (78.6)
Not Reported	42 (0.5)	58 (0.7)	100 (0.6)	15 (0.6)	14 (0.6)	29 (0.6)	26 (0.7)	33 (0.9)	59 (0.8)	83 (0.5)	105 (0.7)	188 (0.6)
Unknown	30 (0.3)	22 (0.2)	52 (0.3)	8 (0.3)	4 (0.2)	12 (0.2)	15 (0.4)	11 (0.3)	26 (0.3)	53 (0.3)	37 (0.2)	90 (0.3)
BMI kg/m2, mean (SD)	28.0 (5.1)	27.9 (5.3)	27.9 (5.2)	35.0 (9.1)	35.2 (9.5)	35.1 (9.3)	28.7 (5.9)	28.7 (5.8)	28.7 (5.9)	29.3 (6.7)	29.3 (6.8)	29.3 (6.8)
At risk for Severe Covid-19 at Screening												

Yes	139 (1.6)	131 (1.5)	270 (1.5)	2185 (86.2)	2192 (86.6)	4377 (86.4)	1133 (30.2)	1125 (29.9)	2258 (30.1)	3457 (22.8)	3448 (22.7)	6905 (22.8)
No	8743 (98.4)	8757 (98.5)	17500 (98.5)	350 (13.8)	338 (13.4)	688 (13.6)	2616 (69.8)	2637 (70.1)	5253 (69.9)	11709 (77.2)	11732 (77.3)	23441 (77.2)
Baseline RT-PCR												
Negative	8785 (98.9)	8774 (98.7)	17559 (98.8)	2490 (98.2)	2499 (98.8)	4989 (98.5)	3720 (99.2)	3740 (99.4)	7460 (99.3)	14995 (98.9)	15013 (98.9)	30008 (98.9)
Positive	65 (0.7)	65 (0.7)	130 (0.7)	20 (0.8)	16 (0.6)	36 (0.7)	10 (0.3)	7 (0.2)	17 (0.2)	95 (0.6)	88 (0.6)	183 (0.6)
Missing	32 (0.4)	49 (0.6)	81 (0.5)	25 (1.0)	15 (0.6)	40 (0.8)	19 (0.5)	15 (0.4)	34 (0.5)	76 (0.5)	79 (0.5)	155 (0.5)
Baseline bAb Anti-SARS-CoV-2												
Negative	8660 (97.5)	8647 (97.3)	17307 (97.4)	2468 (97.4)	2482 (98.1)	4950 (97.7)	3716 (99.1)	3718 (98.8)	7434 (99.0)	14844 (97.9)	14847 (97.8)	29691 (97.8)
Positive	213 (2.4)	233 (2.6)	446 (2.5)	61 (2.4)	43 (1.7)	104 (2.1)	29 (0.8)	33 (0.9)	62 (0.8)	303 (2.0)	309 (2.0)	612 (2.0)
Missing	9 (0.1)	8 (<0.1)	17 (<0.1)	6 (0.2)	5 (0.2)	11 (0.2)	4 (0.1)	11 (0.3)	15 (0.2)	19 (0.1)	24 (0.2)	43 (0.1)
Baseline SARS-CoV-2 Status†												
Negative	8608 (96.9)	8575 (96.5)	17183 (96.7)	2442 (96.3)	2467 (97.5)	4909 (96.9)	3695 (98.6)	3704 (98.5)	7399 (98.5)	14745 (97.2)	14746 (97.1)	29491 (97.2)
Positive	236 (2.7)	263 (3.0)	499 (2.8)	67 (2.6)	48 (1.9)	115 (2.3)	34 (0.9)	36 (1.0)	70 (0.9)	337 (2.2)	347 (2.3)	684 (2.3)
Missing	38 (0.4)	50 (0.6)	88 (0.5)	26 (1.0)	15 (0.6)	41 (0.8)	20 (0.5)	22 (0.6)	42 (0.6)	84 (0.6)	87 (0.6)	171 (0.6)
Age Subgroup at Screening, mean (SD), yr												
≥18 and <65	43.8 (12.33)	44.0 (12.40)	43.9 (12.36)	2532 (99.9)	2524 (99.8)	5056 (99.8)	1 (<0.1)	1 (<0.1)	2 (<0.1)	11413 (75.3)	11413 (75.2)	22826 (75.2)
≥65 and <75	2 (<0.1)	0	2 (<0.1)	2 (<0.1)	5 (0.2)	7 (0.1)	3008 (80.2)	3105 (82.5)	6113 (81.4)	3012 (19.9)	3110 (20.5)	6122 (20.2)
≥75 and <85	0	0	0	1 (<0.1)	1 (<0.1)	2 (<0.1)	691 (18.4)	615 (16.3)	1306 (17.4)	692 (4.6)	616 (4.1)	1308 (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	14 (0.2)	19 (0.2)	33 (0.2)	491 (19.4)	455 (18.0)	946 (18.7)	244 (6.5)	238 (6.3)	482 (6.4)	749 (4.9)	712 (4.7)	1461 (4.8)
Significant cardiac disease	10 (0.1)	11 (0.1)	21 (0.1)	282 (11.1)	312 (12.3)	594 (11.7)	450 (12.0)	439 (11.7)	889 (11.8)	742 (4.9)	762 (5.0)	1504 (5.0)
Severe obesity	67 (0.8)	61 (0.7)	128 (0.7)	837 (33.0)	836 (33.0)	1673 (33.0)	154 (4.1)	173 (4.6)	327 (4.4)	1058 (7.0)	1070 (7.0)	2128 (7.0)
Diabetes	36 (0.4)	34 (0.4)	70 (0.4)	878 (34.6)	887 (35.1)	1765 (34.8)	543 (14.5)	539 (14.3)	1082 (14.4)	1457 (9.6)	1460 (9.6)	2917 (9.6)
Liver disease	9 (0.1)	8 (<0.1)	17 (<0.1)	61 (2.4)	76 (3.0)	137 (2.7)	26 (0.7)	20 (0.5)	46 (0.6)	96 (0.6)	104 (0.7)	200 (0.7)
HIV	14 (0.2)	11 (0.1)	25 (0.1)	61 (2.4)	66 (2.6)	127 (2.5)	16 (0.4)	17 (0.5)	33 (0.4)	91 (0.6)	94 (0.6)	185 (0.6)
Occupational Risk	7994 (90.0)	7969 (89.7)	15963 (89.8)	2172 (85.7)	2156 (85.2)	4328 (85.4)	2385 (63.6)	2371 (63.0)	4756 (63.3)	12551 (82.8)	12496 (82.3)	25047 (82.5)
Healthcare Workers	2744 (30.9)	2744 (30.9)	5488 (30.9)	596 (23.5)	596 (23.6)	1192 (23.5)	503 (13.4)	466 (12.4)	969 (12.9)	3843 (25.3)	3806 (25.1)	7649 (25.2)
Emergency Response	219 (2.5)	234 (2.6)	453 (2.5)	58 (2.3)	48 (1.9)	106 (2.1)	19 (0.5)	20 (0.5)	39 (0.5)	296 (2.0)	302 (2.0)	598 (2.0)
Retail/Restaurant	694 (7.8)	684 (7.7)	1378 (7.8)	188 (7.4)	173 (6.8)	361 (7.1)	99 (2.6)	100 (2.7)	199 (2.6)	981 (6.5)	957 (6.3)	1938 (6.4)

Manufacturing and Production	307 (3.5)	290 (3.3)	597 (3.4)	84 (3.3)	101 (4.0)	185 (3.7)	30 (0.8)	35 (0.9)	65 (0.9)	421 (2.8)	426 (2.8)	847 (2.8)
Warehouse Shipping and Fulfillment	121 (1.4)	138 (1.6)	259 (1.5)	42 (1.7)	43 (1.7)	85 (1.7)	12 (0.3)	9 (0.2)	21 (0.3)	175 (1.2)	190 (1.3)	365 (1.2)
Transportation and Delivery	318 (3.6)	337 (3.8)	655 (3.7)	100 (3.9)	97 (3.8)	197 (3.9)	62 (1.7)	50 (1.3)	112 (1.5)	480 (3.2)	484 (3.2)	964 (3.2)
Border Protection and Military Personnel	51 (0.6)	53 (0.6)	104 (0.6)	12 (0.5)	12 (0.5)	24 (0.5)	6 (0.2)	3 (<0.1)	9 (0.1)	69 (0.5)	68 (0.4)	137 (0.5)
Personal Care and In-Home Services	329 (3.7)	303 (3.4)	632 (3.6)	78 (3.1)	102 (4.0)	180 (3.6)	61 (1.6)	67 (1.8)	128 (1.7)	468 (3.1)	472 (3.1)	940 (3.1)
Hospitality and Tourism Workers	145 (1.6)	164 (1.8)	309 (1.7)	39 (1.5)	37 (1.5)	76 (1.5)	43 (1.1)	37 (1.0)	80 (1.1)	227 (1.5)	238 (1.6)	465 (1.5)
Pastoral, Social or Public Health Workers	264 (3.0)	297 (3.3)	561 (3.2)	102 (4.0)	90 (3.6)	192 (3.8)	138 (3.7)	148 (3.9)	286 (3.8)	504 (3.3)	535 (3.5)	1039 (3.4)
Educators and Students	1118 (12.6)	1090 (12.3)	2208 (12.4)	270 (10.7)	276 (10.9)	546 (10.8)	169 (4.5)	185 (4.9)	354 (4.7)	1557 (10.3)	1551 (10.2)	3108 (10.2)
Other	2606 (29.3)	2601 (29.3)	5207 (29.3)	793 (31.3)	817 (32.3)	1610 (31.8)	1431 (38.2)	1432 (38.1)	2863 (38.1)	4830 (31.8)	4850 (31.9)	9680 (31.9)
Location and Living Circumstances Risk	7490 (84.3)	7537 (84.8)	15027 (84.6)	2095 (82.6)	2065 (81.6)	4160 (82.1)	3104 (82.8)	3130 (83.2)	6234 (83.0)	12689 (83.7)	12732 (83.9)	25421 (83.8)
Nursing Home or Assisted Living Facility	6 (<0.1)	12 (0.1)	18 (0.1)	3 (0.1)	12 (0.5)	15 (0.3)	20 (0.5)	11 (0.3)	31 (0.4)	29 (0.2)	35 (0.2)	64 (0.2)
Multi-Family Dwelling	269 (3.0)	306 (3.4)	575 (3.2)	79 (3.1)	91 (3.6)	170 (3.4)	65 (1.7)	66 (1.8)	131 (1.7)	413 (2.7)	463 (3.1)	876 (2.9)
High Density Housing	877 (9.9)	842 (9.5)	1719 (9.7)	196 (7.7)	196 (7.7)	392 (7.7)	240 (6.4)	253 (6.7)	493 (6.6)	1313 (8.7)	1291 (8.5)	2604 (8.6)
Low Density, Multi-Family Setting	958 (10.8)	945 (10.6)	1903 (10.7)	278 (11.0)	303 (12.0)	581 (11.5)	256 (6.8)	244 (6.5)	500 (6.6)	1492 (9.8)	1492 (9.8)	2984 (9.8)
Single Family Home	4773 (53.7)	4813 (54.2)	9586 (53.9)	1380 (54.4)	1304 (51.5)	2684 (53.0)	2257 (60.2)	2281 (60.6)	4538 (60.4)	8410 (55.5)	8398 (55.3)	16808 (55.4)
Other	1313 (14.8)	1336 (15.0)	2649 (14.9)	334 (13.2)	314 (12.4)	648 (12.8)	529 (14.1)	547 (14.5)	1076 (14.3)	2176 (14.3)	2197 (14.5)	4373 (14.4)

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. Data cutoff: March 26, 2021.

Table S6. Solicited Adverse Events Overall and Age Groups by Grade, 1st Injection, Solicited Safety Set

n (%)	Overall		≥18-<65 years		≥65 yrs	
	Placebo N=15151	mRNA-1273 N=15166	Placebo N=11402	mRNA-1273 N=11406	Placebo N=3749	mRNA-1273 N=3760
Any solicited AE	7285 (48.1)	13317 (87.8)	5737 (50.3)	10262 (90.0)	1548 (41.3)	3055 (81.3)
Grade 1	5134 (33.9)	9329 (61.5)	3993 (35.0)	6951 (60.9)	1141 (30.4)	2378 (63.2)
Grade 2	1782 (11.8)	3134 (20.7)	1466 (12.9)	2601 (22.8)	316 (8.4)	533 (14.2)
Grade 3	363 (2.4)	849 (5.6)	274 (2.4)	705 (6.2)	89 (2.4)	144 (3.8)
Grade 4	6 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	2 (<0.1)	0
Any Local AE	3009 (19.9)	12765 (84.2)	2436 (21.4)	9961 (87.4)	573 (15.3)	2804 (74.6)
Grade 1	2842 (18.8)	10725 (70.7)	2334 (20.5)	8151 (71.5)	508 (13.6)	2574 (68.5)
Grade 2	89 (0.6)	1511 (10.0)	63 (0.6)	1358 (11.9)	26 (0.7)	153 (4.1)
Grade 3	78 (0.5)	529 (3.5)	39 (0.3)	452 (4.0)	39 (1.0)	77 (2.0)
Grade 4	0	0	0	0	0	0
Local AE						
Pain	2665 (17.6)	12688 (83.7)	2183 (19.1)	9908 (86.9)	482 (12.9)	2780 (73.9)
Grade 1	2551 (16.8)	10985 (72.5)	2116 (18.6)	8360 (73.3)	435 (11.6)	2625 (69.8)
Grade 2	59 (0.4)	1287 (8.5)	44 (0.4)	1182 (10.4)	15 (0.4)	105 (2.8)
Grade 3	55 (0.4)	416 (2.7)	23 (0.2)	366 (3.2)	32 (0.9)	50 (1.3)
Erythema	77 (0.5)	445 (2.9)	54 (0.5)	354 (3.1)	23 (0.6)	91 (2.4)
Grade 1	57 (0.4)	281 (1.9)	39 (0.3)	222 (1.9)	18 (0.5)	59 (1.6)
Grade 2	7 (<0.1)	122 (0.8)	4 (<0.1)	98 (0.9)	3 (<0.1)	24 (0.6)
Grade 3	13 (<0.1)	42 (0.3)	11 (<0.1)	34 (0.3)	2 (<0.1)	8 (0.2)
Swelling	65 (0.4)	935 (6.2)	42 (0.4)	766 (6.7)	23 (0.6)	169 (4.5)
Grade 1	50 (0.3)	608 (4.0)	35 (0.3)	499 (4.4)	15 (0.4)	109 (2.9)
Grade 2	9 (<0.1)	245 (1.6)	4 (<0.1)	205 (1.8)	5 (0.1)	40 (1.1)
Grade 3	6 (<0.1)	82 (0.5)	3 (<0.1)	62 (0.5)	3 (<0.1)	20 (0.5)
Axillary swelling/tenderness*	722 (4.8)	1553 (10.2)	567 (5.0)	1322 (11.6)	155 (4.1)	231 (6.1)
Grade 1	668 (4.4)	1394 (9.2)	534 (4.7)	1180 (10.3)	134 (3.6)	214 (5.7)
Grade 2	27 (0.2)	110 (0.7)	20 (0.2)	105 (0.9)	7 (0.2)	5 (0.1)
Grade 3	27 (0.2)	49 (0.3)	13 (0.1)	37 (0.3)	14 (0.4)	12 (0.3)
Any Systemic AE	6397 (42.2)	8316 (54.8)	5063 (44.4)	6499 (57.0)	1334 (35.6)	1817 (48.3)
Grade 1	4334 (28.6)	5358 (35.3)	3367 (29.5)	4079 (35.8)	967 (25.8)	1279 (34.0)
Grade 2	1746 (11.5)	2504 (16.5)	1442 (12.6)	2050 (18.0)	304 (8.1)	454 (12.1)
Grade 3	311 (2.1)	449 (3.0)	250 (2.2)	365 (3.2)	61 (1.6)	84 (2.2)
Grade 4	6 (<0.1)	5 (<0.1)	4 (<0.1)	5 (<0.1)	2 (<0.1)	0
Systemic AE						
Fever	44 (0.3)	112 (0.7)	37 (0.3)	102 (0.9)	7 (0.2)	10 (0.3)
Grade 1	28 (0.2)	73 (0.5)	25 (0.2)	66 (0.6)	3 (<0.1)	7 (0.2)
Grade 2	8 (<0.1)	24 (0.2)	7 (<0.1)	22 (0.2)	1 (<0.1)	2 (<0.1)
Grade 3	2 (<0.1)	11 (<0.1)	1 (<0.1)	10 (<0.1)	1 (<0.1)	1 (<0.1)
Grade 4	6 (<0.1)	4 (<0.1)	4 (<0.1)	4 (<0.1)	2 (<0.1)	0
Headache	4026 (26.6)	4950 (32.6)	3303 (29.0)	4028 (35.3)	723 (19.3)	922 (24.5)
Grade 1	3297 (21.8)	3947 (26.0)	2668 (23.4)	3168 (27.8)	629 (16.8)	779 (20.7)
Grade 2	532 (3.5)	730 (4.8)	472 (4.1)	640 (5.6)	60 (1.6)	90 (2.4)
Grade 3	197 (1.3)	273 (1.8)	163 (1.4)	220 (1.9)	34 (0.9)	53 (1.4)
Fatigue	4133 (27.3)	5636 (37.2)	3281 (28.8)	4385 (38.5)	852 (22.7)	1251 (33.3)
Grade 1	2705 (17.9)	3585 (23.6)	2100 (18.4)	2732 (24.0)	605 (16.2)	853 (22.7)
Grade 2	1323 (8.7)	1899 (12.5)	1098 (9.6)	1531 (13.4)	225 (6.0)	368 (9.8)
Grade 3	105 (0.7)	151 (1.0)	83 (0.7)	121 (1.1)	22 (0.6)	30 (0.8)
Grade 4	0	1 (<0.1)	0	1 (<0.1)	0	0
Myalgia	2069 (13.7)	3442 (22.7)	1625 (14.3)	2700 (23.7)	444 (11.9)	742 (19.7)
Grade 1	1560 (10.3)	2442 (16.1)	1200 (10.5)	1874 (16.4)	360 (9.6)	568 (15.1)
Grade 2	462 (3.1)	909 (6.0)	387 (3.4)	752 (6.6)	75 (2.0)	157 (4.2)
Grade 3	47 (0.3)	91 (0.6)	38 (0.3)	74 (0.6)	9 (0.2)	17 (0.5)
Arthralgia	1784 (11.8)	2510 (16.6)	1327 (11.6)	1892 (16.6)	457 (12.2)	618 (16.4)

Grade 1	1333 (8.8)	1842 (12.1)	966 (8.5)	1368 (12.0)	367 (9.8)	474 (12.6)
Grade 2	413 (2.7)	607 (4.0)	331 (2.9)	476 (4.2)	82 (2.2)	131 (3.5)
Grade 3	38 (0.3)	60 (0.4)	30 (0.3)	47 (0.4)	8 (0.2)	13 (0.3)
Grade 4	0	1 (<0.1)	0	1 (<0.1)	0	0
Nausea/vomiting	1075 (7.1)	1262 (8.3)	908 (8.0)	1068 (9.4)	167 (4.5)	194 (5.2)
Grade 1	887 (5.9)	1047 (6.9)	749 (6.6)	889 (7.8)	138 (3.7)	158 (4.2)
Grade 2	175 (1.2)	205 (1.4)	151 (1.3)	173 (1.5)	24 (0.6)	32 (0.9)
Grade 3	13 (<0.1)	10 (<0.1)	8 (<0.1)	6 (<0.1)	5 (0.1)	4 (0.1)
Chills	878 (5.8)	1251 (8.3)	730 (6.4)	1050 (9.2)	148 (4.0)	201 (5.3)
Grade 1	706 (4.7)	938 (6.2)	584 (5.1)	780 (6.8)	122 (3.3)	158 (4.2)
Grade 2	158 (1.0)	289 (1.9)	138 (1.2)	253 (2.2)	20 (0.5)	36 (1.0)
Grade 3	14 (<0.1)	24 (0.2)	8 (<0.1)	17 (0.1)	6 (0.2)	7 (0.2)

n=Number of exposed participants who submitted any 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. Data cutoff: March 26, 2021.

Table S7. Solicited Adverse Events Overall and Age Groups by Grade, 2nd Injection, Solicited Safety Set

Adverse events n (%)	Overall		≥18-<65 years		≥65 years	
	Placebo N=14578	mRNA N=14691	Placebo N=10929	mRNA-1273 N=11000	Placebo N=3649	mRNA-1273 N=3691
Any solicited AE	6255 (42.9)	13556 (92.3)	4921 (45.0)	10252 (93.2)	1334 (36.6)	3304 (89.5)
Grade 1	4346 (29.8)	4847 (33.0)	3392 (31.0)	3290 (29.9)	954 (26.1)	1557 (42.2)
Grade 2	1558 (10.7)	5800 (39.5)	1266 (11.6)	4592 (41.7)	292 (8.0)	1208 (32.7)
Grade 3	348 (2.4)	2895 (19.7)	261 (2.4)	2358 (21.4)	87 (2.4)	537 (14.5)
Grade 4	3 (<0.1)	14 (<0.1)	2 (<0.1)	12 (0.1)	1 (<0.1)	2 (<0.1)
Any Local AE	2757 (18.9)	13029 (88.7)	2262 (20.7)	9936 (90.3)	495 (13.6)	3093 (83.8)
Grade 1	2594 (17.8)	8789 (59.8)	2145 (19.6)	6424 (58.4)	449 (12.3)	2365 (64.1)
Grade 2	88 (0.6)	3217 (21.9)	73 (0.7)	2709 (24.6)	15 (0.4)	508 (13.8)
Grade 3	75 (0.5)	1023 (7.0)	44 (0.4)	803 (7.3)	31 0.8)	220 6.0)
Grade 4	0	0	0	0	0	0
Local AE						
Pain	2486 (17.1)	12964 (88.3)	2048 (18.7)	9893 (89.9)	438 (12.0)	3071 (83.2)
Grade 1	2384 (16.4)	9508 (64.7)	1978 (18.1)	6933 (63.0)	406 (11.1)	2575 (69.8)
Grade 2	61 (0.4)	2850 (19.4)	48 (0.4)	2454 (22.3)	13 (0.4)	396 (10.7)
Grade 3	41 (0.3)	606 (4.1)	22 (0.2)	506 (4.6)	19 (0.5)	100 (2.7)
Erythema	68 (0.5)	1274 (8.7)	53 (0.5)	989 (9.0)	15 (0.4	285 (7.7)
Grade 1	48 (0.3)	456 (3.1)	36 (0.3)	358 (3.3)	12 (0.3)	98 (2.7)
Grade 2	5 (<0.1)	531 (3.6)	5 (<0.1)	421 (3.8)	0	110 (3.0)
Grade 3	15 (0.1)	287 (2.0)	12 (0.1)	210 (1.9)	3 (<0.1)	77 (2.1)
Swelling	60 (0.4)	1807 (12.3)	46 (0.4)	1399 (12.7)	14 (0.4)	408 (11.1)
Grade 1	38 (0.3)	900 (6.1)	32 (0.3)	706 (6.4)	6 (0.2)	194 (5.3)
Grade 2	10 (<0.1)	652 (4.4)	9 (<0.1)	510 (4.6)	1 (<0.1)	142 (3.8)
Grade 3	12 (<0.1)	255 (1.7)	5 (<0.1)	183 (1.7)	7 (0.2)	72 (2.0)
Axillary swelling/tenderness*	571 (3.9)	2092 (14.2)	474 (4.3)	1777 (16.2)	97 (2.7)	315 (8.5)
Grade 1	523 (3.6)	1735 (11.8)	435 (4.0)	1468 (13.3)	88 (2.4)	267 (7.2)
Grade 2	28 (0.2)	289 (2.0)	27 (0.2)	262 (2.4)	1 (<0.1)	27 (0.7)
Grade 3	20 (0.1)	68 (0.5)	12 (0.1)	47 (0.4)	8 (0.2)	21 (0.6)
Any Systemic AE	5343 (36.7)	11678 (79.5)	4208 (38.5)	9023 (82.0)	1135 (31.1)	2655 (71.9)
Grade 1	3519 (24.1)	3717 (25.3)	2731 (25.0)	2615 (23.8)	788 (21.6)	1102 (29.9)
Grade 2	1535 (10.5)	5611 (38.2)	1248 (11.4)	4458 (40.5)	287 (7.9)	1153 (31.2)
Grade 3	286 (2.0)	2336 (15.9)	227 (2.1)	1938 (17.6)	59 (1.6)	398 (10.8)
Grade 4	3 (<0.1)	14 (<0.1)	2 (<0.1)	12 (0.1)	1 (<0.1)	2 (<0.1)
Systemic AE						
Fever	43 (0.3)	2276 (15.5)	38 (0.3)	1909 (17.4)	5 (0.1)	367 (9.9)
Grade 1	33 (0.2)	1363 (9.3)	30 (0.3)	1112 (10.1)	3 (<0.1)	251 (6.8)
Grade 2	5 (<0.1)	697 (4.7)	4 (<0.1)	600 (5.5)	1 (<0.1)	97 (2.6)
Grade 3	2 (<0.1)	203 (1.4)	2 (<0.1)	185 (1.7)	0	18 (0.5)
Grade 4	3 (<0.1)	13 (<0.1)	2 (<0.1)	12 (0.1)	1 (<0.1)	1 (<0.1)
Headache	3427 (23.5)	8637 (58.8)	2775 (25.4)	6929 (63.0)	652 (17.9)	1708 (46.3)
Grade 1	2740 (18.8)	4815 (32.8)	2182 (20.0)	3669 (33.4)	558 (15.3)	1146 (31.1)
Grade 2	522 (3.6)	3156 (21.5)	461 (4.2)	2701 (24.6)	61 (1.7)	455 (12.3)
Grade 3	165 (1.1)	666 (4.5)	132 (1.2)	559 (5.1)	33 (0.9)	107 (2.9)
Fatigue	3418 (23.5)	9607 (65.4)	2701 (24.7)	7453 (67.8)	717 (19.6)	2154 (58.4)
Grade 1	2181 (15.0)	3431 (23.4)	1701 (15.6)	2527 (23.0)	480 (13.2)	904 (24.5)
Grade 2	1129 (7.7)	4743 (32.3)	912 (8.3)	3748 (34.1)	217 (5.9)	995 (27.0)
Grade 3	108 (0.7)	1433 (9.8)	88 (0.8)	1178 (10.7)	20 (0.5)	255 (6.9)
Myalgia	1824 (12.5)	8529 (58.1)	1425 (13.0)	6789 (61.7)	399 (10.9)	1740 (47.2)
Grade 1	1307 (9.0)	3242 (22.1)	1002 (9.2)	2415 (22.0)	305 (8.4)	827 (22.4)
Grade 2	465 (3.2)	3966 (27.0)	381 (3.5)	3258 (29.6)	84 (2.3)	708 (19.2)
Grade 3	52 (0.4)	1321 (9.0)	42 (0.4)	1116 (10.1)	10 (0.3)	205 (5.6)
Arthralgia	1579 (10.8)	6303 (42.9)	1180 (10.8)	5010 (45.6)	399 (10.9)	1293 (35.1)
Grade 1	1143 (7.8)	2809 (19.1)	841 (7.7)	2111 (19.2)	302 (8.3)	698 (18.9)
Grade 2	392 (2.7)	2719 (18.5)	302 (2.8)	2249 (20.4)	90 (2.5)	470 (12.7)
Grade 3	44 (0.3)	775 (5.3)	37 (0.3)	650 (5.9)	7 (0.2)	125 (3.4)
Nausea/vomiting	941 (6.5)	2794 (19.0)	807 (7.4)	2355 (21.4)	134 (3.7)	439 (11.9)
Grade 1	761 (5.2)	2094 (14.3)	651 (6.0)	1755 (16.0)	110 (3.0)	339 (9.2)

Grade 2	169 (1.2)	678 (4.6)	148 (1.4)	589 (5.4)	21 (0.6)	89 (2.4)
Grade 3	11 (<0.1)	21 (0.1)	8 (<0.1)	11 (0.1)	3 (<0.1)	10 (0.3)
Grade 4	0	1 (<0.1)	0	0	0	1 (<0.1)
Chills	813 (5.6)	6500 (44.3)	662 (6.1)	5357 (48.7)	151 (4.1)	1143 (31.0)
Grade 1	629 (4.3)	2907 (19.8)	505 (4.6)	2316 (21.1)	124 (3.4)	591 (16.0)
Grade 2	167 (1.1)	3402 (23.2)	142 (1.3)	2877 (26.2)	25 (0.7)	525 (14.2)
Grade 3	17 (0.1)	191 (1.3)	15 (0.1)	164 (1.5)	2 (<0.1)	27 (0.7)

n=Number of exposed participants who submitted any 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. Data cutoff: March 26, 2021.

Table S8. Solicited Adverse Events by Sex, 1st and 2nd Injections, Solicited Safety Set

	Injection 1				Injection 2			
	Male		Female		Male		Female	
Adverse events n (%)	Placebo N=8050	mRNA-1273 N=7906	Placebo N=7101	mRNA-1273 N=7260	Placebo N=7731	mRNA-1273 N=7646	Placebo N=6847	mRNA-1273 N=7045
Any solicited AE	3625 (45.0)	6761 (85.5)	3660 (51.5)	6556 (90.3)	2963 (38.3)	6921 (90.5)	3292 (48.1)	6635 (94.2)
Grade 1	2654 (33.0)	5060 (64.0)	2480 (34.9)	4269 (58.8)	2140 (27.7)	2945 (38.5)	2206 (32.2)	1902 (27.0)
Grade 2	822 (10.2)	1354 (17.1)	960 (13.5)	1780 (24.5)	683 (8.8)	2846 (37.2)	875 (12.8)	2954 (41.9)
Grade 3	145 (1.8)	346 (4.4)	218 (3.1)	503 (6.9)	138 (1.8)	1126 (14.7)	210 (3.1)	1769 (25.1)
Grade 4	4 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	10 (0.1)
Any Local AE	1481 (18.4)	6446 (81.5)	1528 (21.5)	6319 (87.1)	1320 (17.1)	6606 (86.4)	1437 (21.0)	6423 (91.2)
Grade 1	1391 (17.3)	5623 (71.1)	1451 (20.4)	5102 (70.3)	1239 (16.0)	4982 (65.2)	1355 (19.8)	3807 (54.1)
Grade 2	49 (0.6)	601 (7.6)	40 (0.6)	910 (12.5)	40 (0.5)	1249 (16.3)	48 (0.7)	1968 (27.9)
Grade 3	41 (0.5)	222 (2.8)	37 (0.5)	307 (4.2)	41 (0.5)	375 (4.9)	34 (0.5)	648 (9.2)
Local AE								
Pain	1288 (16.0)	6408 (81.1)	1377 (19.4)	6280 (86.5)	1178 (15.2)	6571 (85.9)	1308 (19.1)	6393 (90.8)
Grade 1	1228 (15.3)	5747 (72.7)	1323 (18.6)	5238 (72.2)	1126 (14.6)	5280 (69.1)	1258 (18.4)	4228 (60.0)
Grade 2	33 (0.4)	498 (6.3)	26 (0.4)	789 (10.9)	28 (0.4)	1074 (14.0)	33 (0.5)	1776 (25.2)
Grade 3	27 (0.3)	163 (2.1)	28 (0.4)	253 (3.5)	24 (0.3)	217 (2.8)	17 (0.2)	389 (5.5)
Erythema	50 (0.6)	167 (2.1)	27 (0.4)	278 (3.8)	38 (0.5)	436 (5.7)	30 (0.4)	838 (11.9)
Grade 1	37 (0.5)	106 (1.3)	20 (0.3)	175 (2.4)	30 (0.4)	181 (2.4)	18 (0.3)	275 (3.9)
Grade 2	3 (<0.1)	38 (0.5)	4 (<0.1)	84 (1.2)	3 (<0.1)	148 (1.9)	2 (<0.1)	383 (5.4)
Grade 3	10 (0.1)	23 (0.3)	3 (<0.1)	19 (0.3)	5 (<0.1)	107 (1.4)	10 (0.1)	180 (2.6)
Swelling	41 (0.5)	423 (5.4)	24 (0.3)	512 (7.1)	30 (0.4)	735 (9.6)	30 (0.4)	1072 (15.2)
Grade 1	30 (0.4)	275 (3.5)	20 (0.3)	333 (4.6)	21 (0.3)	415 (5.4)	17 (0.2)	485 (6.9)
Grade 2	6 (<0.1)	106 (1.3)	3 (<0.1)	139 (1.9)	3 (<0.1)	235 (3.1)	7 (0.1)	417 (5.9)
Grade 3	5 (<0.1)	42 (0.5)	1 (<0.1)	40 (0.6)	6 (<0.1)	85 (1.1)	6 (<0.1)	170 (2.4)
Axillary swelling/tenderness*	384 (4.8)	726 (9.2)	338 (4.8)	827 (11.4)	290 (3.8)	890 (11.6)	281 (4.1)	1202 (17.1)
Grade 1	361 (4.5)	675 (8.5)	307 (4.3)	719 (9.9)	266 (3.4)	777 (10.2)	257 (3.8)	958 (13.6)
Grade 2	12 (0.1)	34 (0.4)	15 (0.2)	76 (1.0)	13 (0.2)	92 (1.2)	15 (0.2)	197 (2.8)
Grade 3	11 (0.1)	17 (0.2)	16 (0.2)	32 (0.4)	11 (0.1)	21 (0.3)	9 (0.1)	47 (0.7)
Any Systemic AE	3153 (39.2)	4010 (50.7)	3244 (45.7)	4306 (59.3)	2482 (32.1)	5804 (75.9)	2861 (41.8)	5874 (83.4)
Grade 1	2237 (27.8)	2743 (34.7)	2097 (29.5)	2615 (36.0)	1706 (22.1)	2146 (28.1)	1813 (26.5)	1571 (22.3)
Grade 2	798 (9.9)	1093 (13.8)	948 (13.4)	1411 (19.4)	669 (8.7)	2752 (36.0)	866 (12.6)	2859 (40.6)
Grade 3	114 (1.4)	173 (2.2)	197 (2.8)	276 (3.8)	105 (1.4)	902 (11.8)	181 (2.6)	1434 (20.4)
Grade 4	4 (<0.1)	1 (<0.1)	2 (<0.1)	4 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	10 (0.1)
Systemic AE								

Fever	15 (0.2)	50 (0.6)	29 (0.4)	62 (0.9)	22 (0.3)	1000 (13.1)	21 (0.3)	1276 (18.1)
Grade 1	7 (<0.1)	33 (0.4)	21 (0.3)	40 (0.6)	15 (0.2)	609 (8.0)	18 (0.3)	754 (10.7)
Grade 2	2 (<0.1)	10 (0.1)	6 (<0.1)	14 (0.2)	4 (<0.1)	294 (3.8)	1 (<0.1)	403 (5.7)
Grade 3	2 (<0.1)	6 (<0.1)	0	5 (<0.1)	1 (<0.1)	93 (1.2)	1 (<0.1)	110 (1.6)
Grade 4	4 (<0.1)	1 (<0.1)	2 (<0.1)	3 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	9 (0.1)
Headache	1844 (22.9)	2215 (28.0)	2182 (30.7)	2735 (37.7)	1494 (19.3)	4043 (52.9)	1933 (28.2)	4594 (65.2)
Grade 1	1595 (19.8)	1863 (23.6)	1702 (24.0)	2084 (28.7)	1243 (16.1)	2535 (33.2)	1497 (21.9)	2280 (32.4)
Grade 2	188 (2.3)	259 (3.3)	344 (4.8)	471 (6.5)	201 (2.6)	1286 (16.8)	321 (4.7)	1870 (26.6)
Grade 3	61 0.8)	93 (1.2)	136 (1.9)	180 (2.5)	50 (0.6)	222 (2.9)	115 (1.7)	444 (6.3)
Fatigue	2041 (25.4)	2667 (33.7)	2092 (29.5)	2969 (40.9)	1620 (21.0)	4700 (61.5)	1798 (26.3)	4907 (69.7)
Grade 1	1396 (17.4)	1786 (22.6)	1309 (18.4)	1799 (24.8)	1076 (13.9)	1876 (24.5)	1105 (16.1)	1555 (22.1)
Grade 2	602 (7.5)	812 (10.3)	721 (10.2)	1087 (15.0)	494 (6.4)	2260 (29.6)	635 (9.3)	2483 (35.3)
Grade 3	43 (0.5)	69 (0.9)	62 (0.9)	82 (1.1)	50 (0.6)	564 (7.4)	58 (0.8)	869 (12.3)
Grade 4	0	0	0	1 (<0.1)	0	0	0	0
Myalgia	1067 (13.3)	1760 (22.3)	1002 (14.1)	1682 (23.2)	883 (11.4)	4226 (55.3)	941 (13.7)	4303 (61.1)
Grade 1	831 (10.3)	1288 (16.3)	729 (10.3)	1154 (15.9)	646 (8.4)	1847 (24.2)	661 (9.7)	1395 (19.8)
Grade 2	216 (2.7)	434 (5.5)	246 (3.5)	475 (6.5)	213 (2.8)	1894 (24.8)	252 (3.7)	2072 (29.4)
Grade 3	20 (0.2)	38 (0.5)	27 (0.4)	53 (0.7)	24 (0.3)	485 (6.3)	28 (0.4)	836 (11.9)
Arthralgia	935 (11.6)	1305 (16.5)	849 (12.0)	1205 (16.6)	757 (9.8)	3126 (40.9)	822 (12.0)	3177 (45.1)
Grade 1	723 (9.0)	987 (12.5)	610 (8.6)	855 (11.8)	562 (7.3)	1591 (20.8)	581 (8.5)	1218 (17.3)
Grade 2	195 (2.4)	295 (3.7)	218 (3.1)	312 (4.3)	177 (2.3)	1274 (16.7)	215 (3.1)	1445 (20.5)
Grade 3	17 (0.2)	23 (0.3)	21 (0.3)	37 (0.5)	18 (0.2)	261 (3.4)	26 (0.4)	514 (7.3)
Grade 4	0	0	0	1 (<0.1)	0	0	0	0
Nausea/vomiting	456 (5.7)	504 (6.4)	619 (8.7)	758 (10.4)	390 (5.0)	1032 (13.5)	551 (8.0)	1762 (25.0)
Grade 1	375 (4.7)	427 (5.4)	512 (7.2)	620 (8.5)	315 (4.1)	817 (10.7)	446 (6.5)	1277 (18.1)
Grade 2	74 (0.9)	73 (0.9)	101 (1.4)	132 (1.8)	69 (0.9)	210 (2.7)	100 (1.5)	468 (6.6)
Grade 3	7 (<0.1)	4 (<0.1)	6 (<0.1)	6 (<0.1)	6 (<0.1)	5 (<0.1)	5 (<0.1)	16 (0.2)
Chills	431 (5.4)	625 (7.9)	447 (6.3)	626 (8.6)	369 (4.8)	3173 (41.5)	444 (6.5)	3327 (47.2)
Grade 1	353 (4.4)	475 (6.0)	353 (5.0)	463 (6.4)	294 (3.8)	1568 (20.5)	335 (4.9)	1339 (19.0)
Grade 2	72 (0.9)	141 (1.8)	86 (1.2)	148 (2.0)	68 (0.9)	1522 (19.9)	99 (1.4)	1880 (26.7)
Grade 3	6 (<0.1)	9 (0.1)	8 (0.1)	15 (0.2)	7 (<0.1)	83 (1.1)	10 (0.1)	108 (1.5)

n=Number of exposed participants who submitted any 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. Data cutoff: March 26, 2021.

Table S9. Solicited Adverse Events by Severe Covid-19 Risk After 1st and 2nd Injections, Solicited Safety Set

	Injection 1				Injection 2			
	At Risk		Not at risk		At Risk		Not at risk	
n (%)	Placebo N=3454	mRNA-1273 N=3439	Placebo N=11697	mRNA-1273 N=11727	Placebo N=3323	mRNA-1273 N=3362	Placebo N=11255	mRNA-1273 N=11329
Any solicited AE	1659 (48.0)	2925 (85.1)	5626 (48.1)	10392 (88.6)	1462 (44.0)	3001 (89.3)	4793 (42.6)	10555 (93.2)
Grade 1	1110 (32.1)	2060 (59.9)	4024 (34.4)	7269 (62.0)	996 (30.0)	1305 (38.8)	3350 (29.8)	3542 (31.3)
Grade 2	455 (13.2)	674 (19.6)	1327 (11.3)	2460 (21.0)	378 (11.4)	1127 (33.5)	1180 (10.5)	4673 (41.2)
Grade 3	94 (2.7)	190 (5.5)	269 (2.3)	659 (5.6)	86 (2.6)	566 (16.8)	262 (2.3)	2329 (20.6)
Grade 4	0	1 (<0.1)	6 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	11 (<0.1)
Any Local AE	700 (20.3)	2723 (79.2)	2309 (19.7)	10042 (85.7)	622 (18.7)	2852 (84.9)	2135 (19.0)	10177 (89.8)
Grade 1	647 (18.7)	2349 (68.3)	2195 (18.8)	8376 (71.4)	577 (17.4)	2016 (60.0)	2017 (17.9)	6773 (59.8)
Grade 2	27 (0.8)	268 (7.8)	62 (0.5)	1243 (10.6)	20 (0.6)	618 (18.4)	68 (0.6)	2599 (22.9)
Grade 3	26 (0.8)	106 (3.1)	52 (0.4)	423 (3.6)	25 (0.8)	218 (6.5)	50 (0.4)	805 (7.1)
Local AE								
Pain	613 (17.8)	2709 (78.8)	2052 (17.5)	9979 (85.1)	552 (16.6)	2833 (84.3)	1934 (17.2)	10131 (89.4)
Grade 1	576 (16.7)	2408 (70.0)	1975 (16.9)	8577 (73.2)	518 (15.6)	2179 (64.9)	1866 (16.6)	7329 (64.7)
Grade 2	17 (0.5)	218 (6.3)	42 (0.4)	1069 (9.1)	18 (0.5)	528 (15.7)	43 (0.4)	2322 (20.5)
Grade 3	20 (0.6)	83 (2.4)	35 (0.3)	333 (2.8)	16 (0.5)	126 (3.8)	25 (0.2)	480 (4.2)
Erythema	21 (0.6)	104 (3.0)	56 (0.5)	341 (2.9)	15 (0.5)	285 (8.5)	53 (0.5)	989 (8.7)
Grade 1	16 (0.5)	70 (2.0)	41 (0.4)	211 (1.8)	9 (0.3)	101 (3.0)	39 (0.3)	355 (3.1)
Grade 2	2 (<0.1)	28 (0.8)	5 (<0.1)	94 (0.8)	1 (<0.1)	119 (3.5)	4 (<0.1)	412 (3.6)
Grade 3	3 (<0.1)	6 (0.2)	10 (<0.1)	36 (0.2)	5 (0.2)	65 (1.9)	10 (<0.1)	222 (2.0)
Swelling	21 (0.6)	196 (5.7)	44 (0.4)	739 (6.3)	19 (0.6)	431 (12.8)	41 (0.4)	1376 (12.1)
Grade 1	15 (0.4)	130 (3.8)	35 (0.3)	478 (4.1)	13 (0.4)	213 (6.3)	25 (0.2)	687 (6.1)
Grade 2	5 (0.1)	51 (1.5)	4 (<0.1)	194 (1.7)	3 (<0.1)	159 (4.7)	7 (<0.1)	493 (4.4)
Grade 3	1 (<0.1)	15 (0.4)	5 (<0.1)	67 (0.6)	3 (<0.1)	59 (1.8)	9 (<0.1)	196 (1.7)
Axillary swelling/tenderness*	188 (5.4)	337 (9.8)	534 (4.6)	1216 (10.4)	149 (4.5)	448 (13.3)	422 (3.7)	1644 (14.5)
Grade 1	172 (5.0)	304 (8.8)	496 (4.2)	1090 (9.3)	139 (4.2)	364 (10.8)	384 (3.4)	1371 (12.1)
Grade 2	9 (0.3)	16 (0.5)	18 (0.2)	94 (0.8)	5 (0.2)	61 (1.8)	23 (0.2)	228 (2.0)
Grade 3	7 (0.2)	17 (0.5)	20 (0.2)	32 (0.3)	5 (0.2)	23 (0.7)	15 (0.1)	45 (0.4)
Any Systemic AE	1470 (42.6)	1900 (55.2)	4927 (42.1)	6416 (54.7)	1262 (38.0)	2416 (71.9)	4081 (36.3)	9262 (81.8)
Grade 1	952 (27.6)	1210 (35.2)	3382 (28.9)	4148 (35.4)	818 (24.6)	900 (26.8)	2701 (24.0)	2817 (24.9)
Grade 2	441 (12.8)	571 (16.6)	1305 (11.2)	1933 (16.5)	378 (11.4)	1064 (31.7)	1157 (10.3)	4547 (40.1)
Grade 3	77 (2.2)	118 (3.4)	234 (2.0)	331 (2.8)	64 (1.9)	449 (13.4)	222 (2.0)	1887 (16.7)
Grade 4	0	1 (<0.1)	6 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	11 (<0.1)
Systemic AE								
Fever	7 (0.2)	23 (0.7)	37 (0.3)	89 (0.8)	10 (0.3)	390 (11.6)	33 (0.3)	1886 (16.7)
Grade 1	6 (0.2)	13 (0.4)	22 (0.2)	60 (0.5)	7 (0.2)	228 (6.8)	26 (0.2)	1135 (10.0)
Grade 2	1 (<0.1)	7 (0.2)	7 (<0.1)	17 (0.1)	1 (<0.1)	115 (3.4)	4 (<0.1)	582 (5.1)
Grade 3	0	2 (<0.1)	2 (<0.1)	9 (<0.1)	0	44 (1.3)	2 (<0.1)	159 (1.4)

Grade 4	0	1 (<0.1)	6 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	10 (<0.1)
Headache	890 (25.8)	1090 (31.7)	3136 (26.8)	3860 (32.9)	769 (23.1)	1697 (50.5)	2658 (23.6)	6940 (61.3)
Grade 1	718 (20.8)	860 (25.0)	2579 (22.1)	3087 (26.3)	609 (18.3)	1006 (29.9)	2131 (18.9)	3809 (33.6)
Grade 2	124 (3.6)	154 (4.5)	408 (3.5)	576 (4.9)	126 (3.8)	548 (16.3)	396 (3.5)	2608 (23.0)
Grade 3	48 (1.4)	76 (2.2)	149 (1.3)	197 (1.7)	34 (1.0)	143 (4.3)	131 (1.2)	523 (4.6)
Fatigue	960 (27.8)	1294 (37.6)	3173 (27.1)	4342 (37.0)	809 (24.4)	1914 (57.0)	2609 (23.2)	7693 (67.9)
Grade 1	597 (17.3)	821 (23.9)	2108 (18.0)	2764 (23.6)	501 (15.1)	728 (21.7)	1680 (14.9)	2703 (23.9)
Grade 2	335 (9.7)	431 (12.5)	988 (8.4)	1468 (12.5)	280 (8.4)	912 (27.2)	849 (7.5)	3831 (33.8)
Grade 3	28 (0.8)	42 (1.2)	77 (0.7)	109 (0.9)	28 (0.8)	274 (8.2)	80 (0.7)	1159 (10.2)
Grade 4	0	0	0	1 (<0.1)	0	0	0	0
Myalgia	554 (16.0)	815 (23.7)	1515 (13.0)	2627 (22.4)	482 (14.5)	1670 (49.7)	1342 (11.9)	6859 (60.5)
Grade 1	411 (11.9)	575 (16.7)	1149 (9.8)	1867 (15.9)	344 (10.4)	707 (21.0)	963 (8.6)	2535 (22.4)
Grade 2	133 (3.9)	215 (6.3)	329 (2.8)	694 (5.9)	127 (3.8)	743 (22.1)	338 (3.0)	3223 (28.5)
Grade 3	10 (0.3)	25 (0.7)	37 (0.3)	66 (0.6)	11 (0.3)	220 (6.5)	41 (0.4)	1101 (9.7)
Arthralgia	514 (14.9)	635 (18.5)	1270 (10.9)	1875 (16.0)	424 (12.8)	1271 (37.8)	1155 (10.3)	5032 (44.4)
Grade 1	366 (10.6)	439 (12.8)	967 (8.3)	1403 (12.0)	310 (9.3)	613 (18.2)	833 (7.4)	2196 (19.4)
Grade 2	139 (4.0)	177 (5.1)	274 (2.3)	430 (3.7)	103 (3.1)	511 (15.2)	289 (2.6)	2208 (19.5)
Grade 3	9 (0.3)	19 (0.6)	29 (0.2)	41 (0.3)	11 (0.3)	147 (4.4)	33 (0.3)	628 (5.5)
Grade 4	0	0	0	1 (<0.1)	0	0	0	0
Nausea/vomiting	289 (8.4)	312 (9.1)	786 (6.7)	950 (8.1)	269 (8.1)	547 (16.3)	672 (6.0)	2247 (19.8)
Grade 1	244 (7.1)	251 (7.3)	643 (5.5)	796 (6.8)	219 (6.6)	409 (12.2)	542 (4.8)	1685 (14.9)
Grade 2	44 (1.3)	56 (1.6)	131 (1.1)	149 (1.3)	48 (1.4)	129 (3.8)	121 (1.1)	549 (4.8)
Grade 3	1 (<0.1)	5 (0.1)	12 (0.1)	5 (<0.1)	2 (<0.1)	9 (0.3)	9 (<0.1)	12 (0.1)
Grade 4	0	0	0	0	0	0	0	1 (<0.1)
Chills	222 (6.4)	276 (8.0)	656 (5.6)	975 (8.3)	191 (5.7)	1160 (34.5)	622 (5.5)	5340 (47.1)
Grade 1	184 (5.3)	203 (5.9)	522 (4.5)	735 (6.3)	150 (4.5)	547 (16.3)	479 (4.3)	2360 (20.8)
Grade 2	36 (1.0)	64 (1.9)	122 (1.0)	225 (1.9)	38 (1.1)	577 (17.2)	129 (1.1)	2825 (24.9)
Grade 3	2 (<0.1)	9 (0.3)	12 (0.1)	15 (0.1)	3 (<0.1)	36 (1.1)	14 (0.1)	155 (1.4)

n=Number of exposed participants who submitted any for the event; percentages are based on the number of exposed participants who submitted any data for the event in the solicited safety set. At risk includes those ≥65 years and those <65 years who were considered at increased risk for severe Covid-19 illness having at least 1 of the following CDC-defined risk factors at screening: chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma, significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension), severe obesity (body mass index ≥ 40 kg/m2), diabetes (Type 1, Type 2 or gestational), liver disease, Human Immunodeficiency Virus (HIV) infection. Not at risk includes those <65 years without risk factors. 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. Data cutoff: March 26, 2021.

Table S10. Number of Days Reporting Solicited Adverse Events After 1st and 2nd Injections, Solicited Safety Set

	Vaccination 1			Vaccination 2		
Duration days	**Placebo N=15151**	**mRNA-1273 N=15166**	**Total N=30317**	**Placebo N=14578**	**mRNA-1273 N=14691**	**Total N=29269**
Any solicited (n)	7285	13317	20602	6255	13556	19811
Mean days (SD)	3.3 (5.4)	3.5 (4.2)	3.4 (4.6)	3.7 (8.7)	4.2 (7.8)	4.0 (8.1)
Any local (n)	3009	12765	15774	2757	13029	15786
Mean days (SD)	2.0 (2.9)	2.7 (2.2)	2.5 (2.4)	2.2 (6.4)	3.2 (3.3)	3.0 (4.0)
Pain (n)	2665	12688	15353	2486	12964	15450
Mean, days (SD)	1.7 (2.3)	2.5 (1.6)	2.3 (1.8)	1.9 (4.9)	3.0 (2.5)	2.8 (3.0)
Erythema (n)	77	445	522	68	1274	1342
Mean, days (SD)	4.2 (6.2)	2.8 (4.0)	3.0 (4.4)	3.8 (5.3)	2.7 (2.7)	2.7 (2.9)
Swelling (n)	65	935	1000	60	1807	1867
Mean, days (SD)	6.8 (8.8)	2.2 (2.7)	2.5 (3.6)	4.2 (5.3)	2.5 (2.1)	2.5 (2.3)
Axillary swelling/tenderness* (n)	722	1553	2275	571	2092	2663
Mean, days (SD)	2.1 (2.9)	2.3 (3.3)	2.3 (3.2)	3.0 (11.5)	2.5 (5.2)	2.6 (7.0)
Any Systemic AR	6397	8316	14713	5343	11678	17021
Mean, days (SD)	3.3 (5.5)	3.1 (4.8)	3.2 (5.1)	3.7 (8.7)	3.4 (7.9)	3.5 (8.2)
Fever (n)	44	112	156	43	2276	2319
Mean, days (SD)	1.4 (0.6)	1.3 (1.0)	1.3 (0.9)	1.4 (1.6)	1.1 (0.4)	1.1 (0.5)
Headache (n)	4026	4950	8976	3427	8637	12064
Mean, days (SD)	2.2 (2.8)	2.1 (2.4)	2.2 (2.6)	2.4 (5.0)	2.4 (4.8)	2.4 (4.9)
Fatigue (n)	4133	5636	9769	3418	9607	13025
Mean, days (SD)	2.9 (4.4)	2.8 (3.9)	2.8 (4.1)	3.3 (8.3)	2.8 (6.5)	2.9 (7.0)
Myalgia (n)	2069	3442	5511	1824	8529	10353
Mean, days (SD)	2.8 (3.9)	2.4 (3.6)	2.5 (3.7)	3.7 (9.8)	2.2 (4.2)	2.4 (5.7)
Arthralgia (n)	1784	2510	4294	1579	6303	7882
Mean, days (SD)	3.5 (7.5)	2.9 (6.7)	3.1 (7.0)	4.1 (10.0)	2.3 (4.7)	2.7 (6.2)
Nausea/vomiting (n)	1075	1262	2337	941	2794	3735
Mean, days (SD)	1.8 (2.1)	1.7 (1.7)	1.7 (1.9)	2.0 (5.8)	1.7 (3.7)	1.8 (4.3)
Chills (n)	878	1251	2129	813	6500	7313
Mean, days (SD)	1.7 (1.9)	1.5 (1.7)	1.6 (1.8)	2.2 (7.4)	1.5 (2.3)	1.6 (3.3)

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 event 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. Data-cutoff date: March 26, 2021.

Table S11. Solicited Adverse Events by SARS-CoV-2 Baseline Status and grade, 1st Injection, Solicited Safety Set

	Baseline SARS-CoV-2 negative		Baseline SARS-CoV-2 positive		Missing data	
	Placebo	mRNA-1273	Placebo	mRNA-1273	Placebo	mRNA-1273
n (%)	N=14730	N=14733	N=337	N=346	N=84	N=87
Any solicited AE	7105 (48.2)	12976 (88.1)	138 (40.9)	265 (76.6)	42 (50.0)	76 (87.4)
Grade 1	5015 (34.0)	9136 (62.0)	83 (24.6)	137 (39.6)	36 (42.9)	56 (64.4)
Grade 2	1736 (11.8)	3022 (20.5)	41 (12.2)	98 (28.3)	5 (6.0)	14 (16.1)
Grade 3	349 (2.4)	814 (5.5)	13 (3.9)	29 (8.4)	1 (1.2)	6 (6.9)
Grade 4	5 (<0.1)	4 (<0.1)	1 (0.3)	1 (0.3)	0	0
Any Local AE	2934 (19.9)	12442 (84.5)	60 (17.8)	250 (72.3)	15 (17.9)	73 (83.9)
Grade 1	2771 (18.8)	10481 (71.2)	56 (16.6)	180 (52.0)	15 (17.9)	64 (73.6)
Grade 2	88 (0.6)	1449 (9.8)	1 (0.3)	56 (16.2)	0	6 (6.9)
Grade 3	75 (0.5)	512 (3.5)	3 (0.9)	14 (4.0)	0	3 (3.4)
Local AE						
Pain	2596 (17.6)	12369 (84.0)	56 (16.6)	247 (71.4)	13 (15.5)	72 (82.8)
Grade 1	2484 (16.9)	10735 (72.9)	54 (16.0)	184 (53.2)	13 (15.5)	66 (75.9)
Grade 2	58 (0.4)	1232 (8.4)	1 (0.3)	52 (15.0)	0	3 (3.4)
Grade 3	54 (0.4)	402 (2.7)	1 (0.3)	11 (3.2)	0	3 (3.4)
Erythema	74 (0.5)	429 (2.9)	3 (0.9)	10 (2.9)	0	6 (6.9)
Grade 1	56 (0.4)	272 (1.8)	1 (0.3)	6 (1.7)	0	3 (3.4)
Grade 2	7 (<0.1)	117 (0.8)	0	2 (0.6)	0	3 (3.4)
Grade 3	11 (<0.1)	40 (0.3)	2 (0.6)	2 (0.6)	0	0
Swelling	63 (0.4)	910 (6.2)	2 (0.6)	19 (5.5)	0	6 (6.9)
Grade 1	48 (0.3)	593 (4.0)	2 (0.6)	10 (2.9)	0	5 (5.7)
Grade 2	9 (<0.1)	236 (1.6)	0	8 (2.3)	0	1 (1.1)
Grade 3	6 (<0.1)	81 (0.5)	0	1 (0.3)	0	0
Axillary swelling/tenderness*	701 (4.8)	1487 (10.1)	18 (5.3)	56 (16.2)	3 (3.6)	10 (11.5)
Grade 1	648 (4.4)	1344 (9.1)	17 (5.0)	40 (11.6)	3 (3.6)	10 (11.5)
Grade 2	27 (0.2)	98 (0.7)	0	12 (3.5)	0	0
Grade 3	26 (0.2)	45 (0.3)	1 (0.3)	4 (1.2)	0	0
Any Systemic AE	6239 (42.4)	8053 (54.7)	122 (36.2)	214 (61.8)	36 (42.9)	49 (56.3)
Grade 1	4234 (28.7)	5214 (35.4)	70 (20.8)	108 (31.2)	30 (35.7)	36 (41.4)
Grade 2	1701 (11.5)	2412 (16.4)	40 (11.9)	82 (23.7)	5 (6.0)	10 (11.5)
Grade 3	299 (2.0)	423 (2.9)	11 (3.3)	23 (6.6)	1 (1.2)	3 (3.4)
Grade 4	5 (<0.1)	4 (<0.1)	1 (0.3)	1 (0.3)	0	0
Systemic AE						
Fever	38 (0.3)	78 (0.5)	6 (1.8)	33 (9.5)	0	1 (1.2)
Grade 1	25 (0.2)	52 (0.4)	3 (0.9)	20 (5.8)	0	1 (1.2)
Grade 2	6 (<0.1)	14 (<0.1)	2 (0.6)	10 (2.9)	0	0
Grade 3	2 (<0.1)	9 (<0.1)	0	2 (0.6)	0	0
Grade 4	5 (<0.1)	3 (<0.1)	1 (0.3)	1 (0.3)	0	0
Headache	3917 (26.6)	4787 (32.5)	83 (24.6)	134 (38.7)	26 (31.0)	29 (33.3)
Grade 1	3214 (21.8)	3833 (26.0)	60 (17.8)	89 (25.7)	23 (27.4)	25 (28.7)
Grade 2	514 (3.5)	695 (4.7)	16 (4.7)	33 (9.5)	2 (2.4)	2 (2.3)

Grade 3	189 (1.3)	259 (1.8)	7 (2.1)	12 (3.5)	1 (1.2)	2 (2.3)
Fatigue	4038 (27.4)	5466 (37.1)	72 (21.4)	138 (39.9)	23 (27.4)	32 (36.8)
Grade 1	2646 (18.0)	3490 (23.7)	40 (11.9)	71 (20.5)	19 (22.6)	24 (27.6)
Grade 2	1292 (8.8)	1834 (12.5)	28 (8.3)	57 (16.5)	3 (3.6)	8 (9.2)
Grade 3	100 (0.7)	141 (1.0)	4 (1.2)	10 (2.9)	1 (1.2)	0
Grade 4	0	1 (<0.1)	0	0	0	0
Myalgia	2011 (13.7)	3295 (22.4)	47 (13.9)	128 (37.0)	11 (13.1)	19 (21.8)
Grade 1	1524 (10.3)	2355 (16.0)	27 (8.0)	71 (20.5)	9 (10.7)	16 (18.4)
Grade 2	443 (3.0)	857 (5.8)	18 (5.3)	50 (14.5)	1 (1.2)	2 (2.3)
Grade 3	44 (0.3)	83 (0.6)	2 (0.6)	7 (2.0)	1 (1.2)	1 (1.1)
Arthralgia	1735 (11.8)	2406 (16.3)	40 (11.9)	88 (25.4)	9 (10.7)	16 (18.4)
Grade 1	1305 (8.9)	1776 (12.1)	21 (6.2)	54 (15.6)	7 (8.3)	12 (13.8)
Grade 2	395 (2.7)	574 (3.9)	17 (5.0)	29 (8.4)	1 (1.2)	4 (4.6)
Grade 3	35 (0.2)	55 (0.4)	2 (0.6)	5 (1.4)	1 (1.2)	0
Grade 4	0	1 (<0.1)	0	0	0	0
Nausea/vomiting	1044 (7.1)	1210 (8.2)	25 (7.4)	43 (12.4)	6 (7.1)	9 (10.3)
Grade 1	866 (5.9)	1009 (6.9)	17 (5.0)	30 (8.7)	4 (4.8)	8 (9.2)
Grade 2	165 (1.1)	191 (1.3)	8 (2.4)	13 (3.8)	2 (2.4)	1 (1.1)
Grade 3	13 (<0.1)	10 (<0.1)	0	0	0	0
Chills	846 (5.7)	1162 (7.9)	27 (8.0)	81 (23.4)	5 (6.0)	8 (9.2)
Grade 1	684 (4.6)	891 (6.0)	17 (5.0)	43 (12.4)	5 (6.0)	4 (4.6)
Grade 2	149 (1.0)	250 (1.7)	9 (2.7)	35 (10.1)	0	4 (4.6)
Grade 3	13 (<0.1)	21 (0.1)	1 (0.3)	3 (0.9)	0	0

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. Data-cutoff date: March 26, 2021.

Table S12. Solicited Adverse Events by SARS-CoV-2 Baseline Status and Grade, 2nd Injection, Solicited Safety Set

n (%)	Baseline SARS-CoV-2 negative		Baseline SARS-CoV-2 positive		Missing data	
	Placebo N=14267	mRNA-1273 N=14378	Placebo N=233	mRNA-1273 N=232	Placebo N=78	mRNA-1273 N=81
Any solicited AE	6141 (43.0)	13294 (92.5)	82 (35.2)	187 (80.6)	32 (41.0)	75 (92.6)
Grade 1	4269 (29.9)	4739 (33.0)	52 (22.3)	90 (38.8)	25 (32.1)	18 (22.2)
Grade 2	1524 (10.7)	5692 (39.6)	27 (11.6)	68 (29.3)	7 (9.0)	40 (49.4)
Grade 3	345 (2.4)	2849 (19.8)	3 (1.3)	29 (12.5)	0	17 (21.0)
Grade 4	3 (<0.1)	14 (<0.1)	0	0	0	0
Any Local AE	2699 (18.9)	12783 (88.9)	42 (18.1)	172 (74.1)	16 (20.5)	74 (91.4)
Grade 1	2543 (17.8)	8620 (60.0)	35 (15.1)	125 (53.9)	16 (20.5)	44 (54.3)
Grade 2	83 (0.6)	3160 (22.0)	5 (2.2)	36 (15.5)	0	21 (25.9)
Grade 3	73 (0.5)	1003 (7.0)	2 (0.9)	11 (4.7)	0	9 (11.1)
Local AR						
Pain	2435 (17.1)	12722 (88.5)	36 (15.5)	169 (72.8)	15 (19.2)	73 (90.1)
Grade 1	2337 (16.4)	9330 (64.9)	32 (13.8)	126 (54.3)	15 (19.2)	52 (64.2)
Grade 2	58 (0.4)	2797 (19.5)	3 (1.3)	36 (15.5)	0	17 (21.0)
Grade 3	40 (0.3)	595 (4.1)	1 (0.4)	7 (3.0)	0	4 (4.9)
Erythema	66 (0.5)	1259 (8.8)	1 (0.4)	9 (3.9)	1 (1.3)	6 (7.4)
Grade 1	47 (0.3)	452 (3.1)	0	2 (0.9)	1 (1.3)	2 (2.5)
Grade 2	5 (<0.1)	527 (3.7)	0	4 (1.7)	0	0
Grade 3	14 (<0.1)	280 (1.9)	1 (0.4)	3 (1.3)	0	4 (4.9)
Swelling	59 (0.4)	1783 (12.4)	1 (0.4)	11 (4.7)	0	13 (16.0)
Grade 1	38 (0.3)	890 (6.2)	0	4 (1.7)	0	6 (7.4)
Grade 2	9 (<0.1)	642 (4.5)	1 (0.4)	5 (2.2)	0	5 (6.2)
Grade 3	12 (<0.1)	251 (1.7)	0	2 (0.9)	0	2 (2.5)
Axillary swelling/tenderness*	557 (3.9)	2047 (14.2)	11 (4.7)	32 (13.8)	3 (3.8)	13 (16.0)
Grade 1	512 (3.6)	1704 (11.9)	8 (3.4)	22 (9.5)	3 (3.8)	9 (11.1)
Grade 2	25 (0.2)	277 (1.9)	3 (1.3)	8 (3.4)	0	4 (4.9)
Grade 3	20 (0.1)	66 (0.5)	0	2 (0.9)	0	0
Any Systemic AE	5241 (36.7)	11459 (79.7)	73 (31.3)	152 (65.5)	29 (37.2)	67 (82.7)
Grade 1	3453 (24.2)	3642 (25.3)	44 (18.9)	61 (26.3)	22 (28.2)	14 (17.3)
Grade 2	1500 (10.5)	5498 (38.2)	28 (12.0)	70 (30.2)	7 (9.0)	43 (53.1)
Grade 3	285 (2.0)	2305 (16.0)	1 (0.4)	21 (9.1)	0	10 (12.3)
Grade 4	3 (<0.1)	14 (<0.1)	0	0	0	0
Systemic AE						
Fever	42 (0.3)	2235 (15.6)	1 (0.4)	31 (13.4)	0	10 (12.5)
Grade 1	32 (0.2)	1340 (9.3)	1 (0.4)	20 (8.6)	0	3 (3.8)
Grade 2	5 (<0.1)	682 (4.7)	0	9 (3.9)	0	6 (7.5)
Grade 3	2 (<0.1)	200 (1.4)	0	2 (0.9)	0	1 (1.3)
Grade 4	3 (<0.1)	13 (<0.1)	0	0	0	0
Headache	3363 (23.6)	8488 (59.1)	43 (18.5)	98 (42.2)	21 (26.9)	51 (63.0)
Grade 1	2688 (18.8)	4725 (32.9)	35 (15.1)	61 (26.3)	17 (21.8)	29 (35.8)

Grade 2	510 (3.6)	3105 (21.6)	8 (3.4)	31 (13.4)	4 (5.1)	20 (24.7)
Grade 3	165 (1.2)	658 (4.6)	0	6 (2.6)	0	2 (2.5)
Fatigue	3344 (23.4)	9446 (65.7)	54 (23.3)	106 (45.7)	20 (25.6)	55 (67.9)
Grade 1	2134 (15.0)	3375 (23.5)	31 (13.4)	42 (18.1)	16 (20.5)	14 (17.3)
Grade 2	1103 (7.7)	4655 (32.4)	22 (9.5)	52 (22.4)	4 (5.1)	36 (44.4)
Grade 3	107 (0.8)	1416 (9.9)	1 (0.4)	12 (5.2)	0	5 (6.2)
Myalgia	1775 (12.4)	8357 (58.1)	34 (14.7)	117 (50.4)	15 (19.2)	55 (67.9)
Grade 1	1271 (8.9)	3166 (22.0)	22 (9.5)	60 (25.9)	14 (17.9)	16 (19.8)
Grade 2	452 (3.2)	3886 (27.0)	12 (5.2)	46 (19.8)	1 (1.3)	34 (42.0)
Grade 3	52 (0.4)	1305 (9.1)	0	11 (4.7)	0	5 (6.2)
Arthralgia	1543 (10.8)	6181 (43.0)	26 (11.2)	77 (33.2)	10 (12.8)	45 (55.6)
Grade 1	1115 (7.8)	2758 (19.2)	19 (8.2)	37 (15.9)	9 (11.5)	14 (17.3)
Grade 2	384 (2.7)	2655 (18.5)	7 (3.0)	36 (15.5)	1 (1.3)	28 (34.6)
Grade 3	44 (0.3)	768 (5.3)	0	4 (1.7)	0	3 (3.7)
Nausea/vomiting	922 (6.5)	2741 (19.1)	13 (5.6)	33 (14.2)	6 (7.7)	20 (24.7)
Grade 1	747 (5.2)	2052 (14.3)	10 (4.3)	25 (10.8)	4 (5.1)	17 (21.0)
Grade 2	164 (1.1)	668 (4.6)	3 (1.3)	7 (3.0)	2 (2.6)	3 (3.7)
Grade 3	11 (<0.1)	20 (0.1)	0	1 (0.4)	0	0
Grade 4	0	1 (<0.1)	0	0	0	0
Chills	790 (5.5)	6384 (44.4)	19 (8.2)	80 (34.5)	4 (5.1)	36 (44.4)
Grade 1	610 (4.3)	2854 (19.9)	16 (6.9)	40 (17.2)	3 (3.8)	13 (16.0)
Grade 2	163 (1.1)	3340 (23.2)	3 (1.3)	40 (17.2)	1 (1.3)	22 (27.2)
Grade 3	17 (0.1)	190 (1.3)	0	0	0	1 (1.2)

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. Data-cutoff date: March 26, 2021.

Table S13. Solicited Adverse Events Occurring after Day 8 or Beyond Post-Injection, Safety Set

Category	1st injection		2nd injection	
	Placebo N=15151	mRNA-1273 N=15166	Placebo N=14578	mRNA-1273 N=14691
Any local AE occurring at day 8 or beyond	158 (1.0)	514 (3.4)	199 (1.4)	356 (2.4)
Started within 7 days of injection and continued beyond 7 days	130 (0.9)	351 (2.3)	122 (0.8)	308 (2.1)
Solicited AE within 7 days, and re-started on day 8 or afterwards	10 (<0.1)	83 (0.5)	20 (0.1)	38 (0.3)
No solicited AE within 7 days and AE started on day 8 or afterwards	18 (0.1)	80 (0.5)	57 (0.4)	10 (<0.1)
Pain at day 8 or beyond	70 (0.5)	156 (1.0)	116 (0.8)	186 (1.3)
Started within 7 days of the injection and continued beyond 7 days	56 (0.4)	102 (0.7)	58 (0.4)	155 (1.1)
Solicited AE within 7 days, and re-started on day 8 or afterwards	6 (<0.1)	53 (0.3)	17 (0.1)	31 (0.2)
No solicited AE within 7 days, and AE started on day 8 or afterwards	8 (<0.1)	1 (<0.1)	41 (0.3)	0
Erythema (redness) occurred at day 8 or beyond	27 (0.2)	117 (0.8)	21 (0.1)	78 (0.5)
Started within 7 days of the injection and continued beyond 7 days	20 (0.1)	34 (0.2)	13 (<0.1)	70 (0.5)
Solicited AE within 7 days, and re-started on day 8 or afterwards	0	15 (<0.1)	0	2 (<0.1)
No solicited AE within 7 days, and AE started on day 8 or afterwards	7 (<0.1)	68 (0.4)	8 (<0.1)	6 (<0.1)
Swelling (hardness) occurred at day 8 or beyond	25 (0.2)	88 (0.6)	22 (0.2)	76 (0.5)
Started within 7 days of the injection and continued beyond 7 days	22 (0.1)	33 (0.2)	16 (0.1)	70 (0.5)
Solicited AE within 7 days, and re-started on day 8 or afterwards	0	19 (0.1)	0	2 (<0.1)
No solicited AE within 7 days, and AE started on day 8 or afterwards	3 (<0.1)	36 (0.2)	6 (<0.1)	4 (<0.1)
Axillary swelling or tenderness occurred at day 8 or beyond	62 (0.4)	243 (1.6)	57 (0.4)	101 (0.7)
Started within 7 days of the injection and continued beyond 7 days	54 (0.4)	223 (1.5)	48 (0.3)	90 (0.6)
Solicited AE within 7 days, and re-started on day 8 or afterwards	5 (<0.1)	12 (<0.1)	4 (<0.1)	7 (<0.1)
No solicited AE within 7 days, and AE started on day 8 or afterwards	3 (<0.1)	8 (<0.1)	5 (<0.1)	4 (<0.1)

Participants with solicited adverse events on day 8 or beyond, independent of the start date. Data-cutoff date:: March 26, 2021

Table S14. Summary of Unsolicited AEs Overall and Age Groups Up to 28 days After Any Injection, Safety Set

Unsolicited Adverse Event n (%)	Overall Safety Set		≥18-<65 years		≥65 years	
	Placebo N=15162	mRNA-1273 N=15184	Placebo (N=11411)	mRNA-1273 (N=11415)	Placebo N=3750	mRNA-1273 N=3770
Regardless of relationship to study vaccination						
All	4338 (28.6)	4752 (31.3)	3275 (28.7)	3515 (30.8)	1063 (28.3)	1237 (32.8)
Serious	104 (0.7)	98 (0.6)	54 (0.5)	59 (0.5)	50 (1.3)	39 (1.0)
Fatal	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Medically-attended	1940 (12.8)	1819 (12.0)	1419 (12.4)	1311 (11.5)	521 (13.9)	508 (13.5)
Leading to discontinuation from study vaccine*	92 (0.6)	61 (0.4)	70 (0.6)	49 (0.4)	22 (0.6)	12 (0.3)
Leading to discontinuation from study†	6 (<0.1)	9 (<0.1)	3 (<0.1)	7 (<0.1)	3 (<0.1)	2 (<0.1)
Severe	233 (1.5)	258 (1.7)	152 (1.3)	177 (1.6)	81 (2.2)	81 (2.1)
Related to study vaccination						
All	1236 (8.2)	2067 (13.6)	945 (8.3)	1580 (13.8)	291 (7.8)	487 (12.9)
Serious	3 (<0.1)	8 (<0.1)	2 (<0.1)	6 (<0.1)	1 (<0.1)	2 (<0.1)
Fatal	0	0	0	0	0	0
Medically-attended	95 (0.6)	198 (1.3)	78 (0.7)	161 (1.4)	17 (0.5)	37 (1.0)
Leading to discontinuation from study vaccine*	14 (<0.1)	20 (0.1)	8 (<0.1)	17 (0.1)	6 (0.2)	3 (<0.1)
Leading to discontinuation from study†	0	1 (<0.1)	0	1 (<0.1)	0	0
Severe	31 (0.2)	83 (0.5)	20 (0.2)	59 (0.5)	11 (0.3)	24 (0.6)

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. Data-cutoff date: March 26, 2021.

Table S15. Summary Unsolicited AEs Reported by ≥1% of Participants in Any Treatment Group up to 28 Days After Any Injection, Safety Set

System Organ Class Preferred Term n (%)	Placebo (N=15162)	mRNA-1273 (N=15184)
Number of participants reporting unsolicited AEs	4338 (28.6)	4748 (31.3)
Number of unsolicited AEs	8599	9533
Nervous system disorders	881 (5.8)	1008 (6.6)
Headache	687(4.5)	744 (4.9)
Respiratory, thoracic and mediastinal disorders	667 (4.4)	603 (4.0)
Cough	165 (1.1)	177 (1.2)
Oropharyngeal pain	232 (1.5)	158 (1.0)
Nasal congestion	165 (1.1)	155 (1.0)
Musculoskeletal and connective tissue disorders	1017 (6.7	1007 (6.6)
Arthralgia	389 (2.6)	391 (2.6)
Myalgia	388 (2.6)	387 (2.5)
General disorders and administration site conditions	1065 (7.0)	1606 (10.6)
Fatigue	666 (4.4)	752 (5.0)
Injection site pain	118 (0.8)	258 (1.7)
Gastrointestinal disorders	567 (3.7)	599 (3.9)
Diarrhea	199 (1.3)	204 (1.3)
Nausea	164 (1.1)	162 (1.1)
Vascular disorders	204 (1.3)	198 (1.3)
Hypertension	161 (1.1)	153 (1.0)
Blood and lymphatic system disorders	148 (1.0)	292 (1.9)
Lymphadenopathy	127 (0.8)	264 (1.7)

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. Data-cutoff date: March 26, 2021.

Table S16. 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	233 (1.5)	258 (1.7)
Nervous system disorders		
Headache	11 (<0.1)	14 (<0.1)
Cardiac disorders		
Bradycardia	3 (<0.1)	4 (<0.1)
Atrial Fibrillation	3 (<0.1)	4 (<0.1)
Vascular disorders		
Hypertension	34 (0.2)	28 (0.2)
Systolic Hypertension	3 (<0.1)	3 (<0.1)
Gastrointestinal disorders		
Nausea	1 (<0.1)	5 (<0.1)
Abdominal pain	2 (<0.1)	4 (<0.1)
Musculoskeletal and connective tissue disorders		
Myalgia	4 (<0.1)	9 (<0.1)
Arthralgia	7 (<0.1)	7 (<0.1)
Back pain	7 (<0.1)	1 (<0.1)
General disorders and administration site conditions		
Fatigue	9 (<0.1)	20 (0.1)
Injection site erythema	0	8 (<0.1)
Injection site macule	0	6 (<0.1)
Injection site pain	1 (<0.1)	4 (<0.1)
Investigations		
Blood pressure increased	6 (<0.1)	10 (<0.1)
Blood pressure systolic increased	7 (<0.1)	7 (<0.1)
Infections and infestations		
Covid-19	7 (<0.1)	0

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. Data-cutoff date: March 26, 2021.

Table S17. Summary Unsolicited AEs Up to 28 Days After Any Injection by SARS-CoV-2 Baseline Status

Unsolicited TEAEs n (%)	SARS-CoV-2 Negative		SARS-CoV-2 Positive		SARS-CoV-2 Missing	
	Placebo N=14741	mRNA-1273 N=14750	Placebo N=337	mRNA-1273 N=347	Placebo N=84	mRNA-1273 N=87
Regardless of relationship to study vaccination						
All	4233 (28.7)	4652 (31.5)	92 (27.3)	77 (22.2)	13 (15.5)	23 (26.4)
Serious	101 (0.7)	96 (0.7)	3 (0.9)	1 (0.3)	0	1 (1.1)
Fatal	2 (<0.1)	2 (<0.1)	0	0	0	0
Medically-attended	1902 (12.9)	1782 (12.1)	35 (10.4)	25 (7.2)	3 (3.6)	12 (13.8)
Leading to discontinuation from study vaccine	84 (0.6)	54 (0.4)	8 (2.4)	6 (1.7)	0	1 (1.1)
Leading to discontinuation from study	6 (<0.1)	9 (<0.1)	0	0	0	0
Severe	225 (1.5)	256 (1.7)	7 (2.1)	1 (0.3)	1 (1.2)	1 (1.1)
Related to study vaccination						
All	1201 (8.1)	2032 (13.8)	30 (8.9)	30 (8.6)	5 (6.0)	5 (5.7)
Serious	3 (<0.1)	8 (<0.1)	0	0	0	0
Fatal	0	0	0	0	0	0
Medically-attended	90 (0.6)	197 (1.3)	5 (1.5)	1 (0.3)	0	0
Leading to discontinuation from study vaccine	14 (<0.1)	20 (0.1)	0	0	0	0
Leading to discontinuation from study	0	1 (<0.1)	0	0	0	0
Severe	30 (0.2)	83 (0.6)	1 (0.3)	0	0	0

Treatment-emergent adverse event (TEAE) 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 safety set. Missing data: *n=45 (19.1%), n=60 (20.8%); n=105 (20.1%) and †n=8 (3.4%), n=11 (3.8%) and 19 (3.6%). Data-cutoff date: March 26, 2021.

Table S18. Summary of Unsolicited AEs by Severe Covid-19 Risk Up to 28 Days After Any Injection, Safety Set

n (%)	Not at Risk		At Risk	
	Placebo N=11705	mRNA-1273 N=11736	Placebo N=3457	mRNA-1273 N=3448
Regardless of relationship to study vaccination				
All	3265 (27.9)	3564 (30.4)	1073 (31.0)	1188 (34.5)
Serious	55 (0.5)	62 (0.5)	49 (1.4)	36 (1.0)
Fatal	2 (<0.1)	2 (<0.1)	0	0
Medically-attended	1424 (12.2)	1325 (11.3)	516 (14.9)	494 (14.3)
Leading to discontinuation from study vaccine	65 (0.6)	47 (0.4)	27 (0.8)	14 (0.4)
Leading to discontinuation from study	4 (<0.1)	8 (<0.1)	2 (<0.1)	1 (<0.1)
Severe	148 (1.3)	199 (1.7)	85 (2.5)	59 (1.7)
Related to study vaccination				
All	909 (7.8)	1545 (13.2)	327 (9.5)	522 (15.1)
Serious	1 (<0.1)	6 (<0.1)	2 (<0.1)	2 (<0.1)
Fatal	0	0	0	0
Medically-attended	74 (0.6)	137 (1.2)	21 (0.6)	61 (1.8)
Leading to discontinuation from study vaccine	11 (<0.1)	15 (0.1)	3 (<0.1)	5 (0.1)
Leading to discontinuation from study	0	1 (<0.1)	0	0
Severe	17 (0.1)	64 (0.5)	14 (0.4)	19 (0.6)

A treatment-emergent adverse event (TEAE) 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 safety set. At risk includes those ≥65 years and those <65 years who were considered at increased risk for severe Covid-19 illness having at least 1 of the following CDC-defined risk factors at screening: chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis, and cystic fibrosis) or moderate to severe asthma, significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension), severe obesity (body mass index ≥ 40 kg/m2), diabetes (Type 1, Type 2 or gestational), liver disease, Human Immunodeficiency Virus (HIV) infection. Not at risk includes those <65 years without risk factors. Data-cutoff date: March 26, 2021.

Table S19. Summary Unsolicited AEs Overall and Age Groups After Any Injection During Overall Study, Safety Set

	Overall Safety Set		≥18-<65 years		≥65 years	
n (%)	Placebo N=15162	mRNA-1273 N=15184	Placebo N=11411	mRNA-1273 N=11415	Placebo N=3751	mRNA-1273 N=3769
Regardless of relationship to study vaccination						
All	6513 (43.0)	6310 (41.6)	4909 (43.0)	4639 (40.6)	1604 (42.8)	1671 (44.3)
Serious	292 (1.9)	268 (1.8)	168 (1.5)	150 (1.3)	124 (3.3)	118 (3.1)
Fatal	16 (0.1)	17* (0.1)	10 (<0.1)	8 (<0.1)	6 (0.2)	9* (0.2)
Medically-attended	4131 (27.2)	3468 (22.8)	3089 (27.1)	2457 (21.5)	1042 (27.8)	1011 (26.8)
Leading to discontinuation from study vaccine*	109 (0.7)	74 (0.5)	82 (0.7)	59 (0.5)	27 (0.7)	15 (0.4)
Leading to discontinuation from study†	23 (0.2)	26 (0.2)	15 (0.1)	15 (0.1)	8 (0.2)	11 (0.3)
Severe	486 (3.2)	461 (3.0)	319 (2.8)	304 (2.7)	167 (4.5)	157 (4.2)
Related to study vaccination						
All	1288 (8.5)	2107 (13.9)	986 (8.6)	1610 (14.1)	302 (8.1)	497 (13.2)
Serious	4 (<0.1)	12 (<0.1)	2 (<0.1)	9 (<0.1)	2 (<0.1)	3 (<0.1)
Fatal	0	0	0	0	0	0
Medically-attended	109 (0.7)	213 (1.4)	89 (0.8)	172 (1.5)	20 (0.5)	41 (1.1)
Leading to discontinuation from study vaccine*	15 (<0.1)	20 (0.1)	8 (<0.1)	17 (0.1)	7 (0.2)	3 (<0.1)
Leading to discontinuation from study†	0	1 (<0.1)	0	1 (<0.1)	0	0
Severe	34 (0.2)	88 (0.6)	23 (0.2)	62 (0.5)	11 (0.3)	26 (0.7)

A treatment-emergent adverse event (TEAE) 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. *One participant had an AE in the blinded phase and ended in death in the unblinded phase, and thus is included in the fatal category for AEs. Percentages are based on the number of safety subjects. Data-cutoff date: March 26, 2021.

Table S20. Serious AEs Reported by Preferred Term in Any Treatment Group, Overall Safety Set

System Organ Class Preferred Term n (%)	Placebo (N=15162)	mRNA-1273 N=15184	Rate ratio (95% CI)
Number of participants reporting serious AEs	292 (1.9)	268 (1.8)	
Number of serious AEs	439	401	
Infections and infestations	77 (0.5)	48 (0.3)	
Pneumonia	11 (<0.1)	9 (<0.1)	0.82 (0.35, 1.92)
Appendicitis	5 (<0.1)	4 (<0.1)	
Sepsis	3 (<0.1)	4 (<0.1)	
Cellulitis	0	3 (<0.1)	
Bronchitis	0	2 (<0.1)	
Covid-19	40 (0.3)	2 (<0.1)	0.05 (0.01, 0.19)
Peritonitis	0	2 (<0.1)	
Postoperative abscess	0	2 (<0.1)	
Urosepsis	0	2 (<0.1)	
Abscess limb	0	1 (<0.1)	
Appendicitis perforated	1 (<0.1)	1 (<0.1)	
Clostridium difficile infection	0	1 (<0.1)	
Diabetic foot infection	0	1 (<0.1)	
Diverticulitis	3 (<0.1)	1 (<0.1)	
Gastroenteritis viral	0	1 (<0.1)	
Giardiasis	0	1 (<0.1)	
Hepatitis A	0	1 (<0.1)	
Liver abscess	0	1 (<0.1)	
Lung abscess	0	1 (<0.1)	
Pneumonia mycoplasmal	0	1 (<0.1)	
Pneumonia staphylococcal	0	1 (<0.1)	
Post procedural infection	0	1 (<0.1)	
Postoperative wound infection	0	1 (<0.1)	
Pyelonephritis acute	1 (<0.1)	1 (<0.1)	
Salpingitis	0	1 (<0.1)	
Septic shock	3 (<0.1)	1 (<0.1)	
Spinal cord abscess	0	1 (<0.1)	
Toxic shock syndrome	0	1 (<0.1)	
Upper respiratory tract infection	0	1 (<0.1)	
Urinary tract infection	5 (<0.1)	1 (<0.1)	
Viral infection	0	1 (<0.1)	
Viral pharyngitis	0	1 (<0.1)	
Wound infection	0	1 (<0.1)	
Covid-19 pneumonia	8 (<0.1)	0	
Clostridium difficile colitis	1 (<0.1)	0	
Coccidioidomycosis	1 (<0.1)	0	
Enterococcal bacteraemia	1 (<0.1)	0	
Localised infection	1 (<0.1)	0	
Meningitis aseptic	1 (<0.1)	0	
Osteomyelitis	1 (<0.1)	0	
Perirectal abscess	1 (<0.1)	0	
Pharyngitis streptococcal	1 (<0.1)	0	
Pneumonia bacterial	1 (<0.1)	0	
Pneumonia klebsiella	1 (<0.1)	0	
Pyelonephritis	2 (<0.1)	0	
Streptococcal sepsis	1 (<0.1)	0	
Tooth abscess	1 (<0.1)	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)	
Prostate cancer	4 (<0.1)	5 (<0.1)	
Hepatocellular carcinoma	0	2 (<0.1)	
B-cell small lymphocytic lymphoma	0	1 (<0.1)	

Benign lung neoplasm	0	1 (<0.1)	
Cancer pain	0	1 (<0.1)	
Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)	
Colorectal cancer	0	1 (<0.1)	
Gastric cancer	0	1 (<0.1)	
Gastrointestinal stromal tumour	0	1 (<0.1)	
Invasive lobular breast carcinoma	0	1 (<0.1)	
Liposarcoma	0	1 (<0.1)	
Malignant melanoma	0	1 (<0.1)	
Meningioma	0	1 (<0.1)	
Metastases to bone	0	1 (<0.1)	
Metastases to lung	0	1 (<0.1)	
Metastatic neoplasm	0	1 (<0.1)	
Non-Hodgkin's lymphoma	0	1 (<0.1)	
Oesophageal carcinoma	0	1 (<0.1)	
Papillary thyroid cancer	1 (<0.1)	1 (<0.1)	
Pelvic neoplasm	0	1 (<0.1)	
Plasma cell myeloma	0	1 (<0.1)	
Renal cell carcinoma	1 (<0.1)	1 (<0.1)	
Splenic marginal zone lymphoma	0	1 (<0.1)	
Throat cancer	0	1 (<0.1)	
Thymoma malignant	0	1 (<0.1)	
Thyroid cancer metastatic	0	1 (<0.1)	
Adenocarcinoma gastric	1 (<0.1)	0	
Breast cancer stage I	1 (<0.1)	0	
Colon cancer stage III	1 (<0.1)	0	
Endometrial cancer	3 (<0.1)	0	
Intraductal proliferative breast lesion	3 (<0.1)	0	
Invasive ductal breast carcinoma	1 (<0.1)	0	
Leiomyosarcoma metastatic	1 (<0.1)	0	
Lung adenocarcinoma	1 (<0.1)	0	
Non-small cell lung cancer	1 (<0.1)	0	
Pancreatic carcinoma stage IV	1 (<0.1)	0	
Prostate cancer metastatic	1 (<0.1)	0	
Thyroid cancer	1 (<0.1)	0	
Uterine leiomyoma	1 (<0.1)	0	
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)	
Anaemia	2 (<0.1)	2 (<0.1)	
Blood loss anaemia	1 (<0.1)	1 (<0.1)	
Thrombocytopenia	1 (<0.1)	1 (<0.1)	
Anaemia macrocytic	1 (<0.1)	0	
Iron deficiency anaemia	1 (<0.1)	0	
Thrombocytosis	1 (<0.1)	0	
Immune system disorders	2 (<0.1)	0	
Anaphylactic reaction	1 (<0.1)	0	
Cytokine storm	1 (<0.1)	0	
Endocrine disorders	0	1 (<0.1)	
Basedow's disease	0	1 (<0.1)	
Metabolism and nutrition disorders	15 (<0.1)	17 (0.1)	
Dehydration	4 (<0.1)	4 (<0.1)	
Diabetic ketoacidosis	3 (<0.1)	3 (<0.1)	
Hyponatraemia	1 (<0.1)	3 (<0.1)	
Hypoglycaemia	1 (<0.1)	2 (<0.1)	
Type 2 diabetes mellitus	1 (<0.1)	2 (<0.1)	
Diabetic complication	0	1 (<0.1)	
Failure to thrive	0	1 (<0.1)	
Gout	1 (<0.1)	1 (<0.1)	
Hyperkalaemia	0	1 (<0.1)	
Hypokalaemia	1 (<0.1)	1 (<0.1)	

Obesity	0	1 (<0.1)	
Diabetes mellitus	1 (<0.1)	0	
Diabetes mellitus inadequate control	1 (<0.1)	0	
Hypomagnesaemia	1 (<0.1)	0	
Metabolic acidosis	1 (<0.1)	0	
Psychiatric disorders	13 (<0.1)	13 (<0.1)	
Depression	2 (<0.1)	3 (<0.1)	
Alcohol withdrawal syndrome	1 (<0.1)	2 (<0.1)	
Alcohol abuse	0	1 (<0.1)	
Completed suicide	1 (<0.1)	1 (<0.1)	
Drug abuse	0	1 (<0.1)	
Intentional self-injury	0	1 (<0.1)	
Mental status changes	1 (<0.1)	1 (<0.1)	
Schizoaffective disorder	1 (<0.1)	1 (<0.1)	
Substance-induced mood disorder	0	1 (<0.1)	
Substance-induced psychotic disorder	0	1 (<0.1)	
Suicidal ideation	0	1 (<0.1)	
Suicide attempt	0	1 (<0.1)	
Alcoholism	1 (<0.1)	0	
Anxiety	1 (<0.1)	0	
Anxiety disorder	1 (<0.1)	0	
Confusional state	1 (<0.1)	0	
Depression suicidal	1 (<0.1)	0	
Major depression	2 (<0.1)	0	
Mania	1 (<0.1)	0	
Schizophrenia	1 (<0.1)	0	
Nervous system disorders	27 (0.2)	31 (0.2)	
Cerebrovascular accident	4 (<0.1)	6 (<0.1)	
Syncope	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)
Seizure	1 (<0.1)	3 (<0.1)	
Subarachnoid haemorrhage	0	3 (<0.1)	
Embolic stroke	0	2 (<0.1)	
Transient ischaemic attack	2 (<0.1)	2 (<0.1)	
Aphasia	0	1 (<0.1)	
Autonomic nervous system imbalance	0	1 (<0.1)	
Carotid artery stenosis	0	1 (<0.1)	
Carotid artery thrombosis	0	1 (<0.1)	
Cauda equina syndrome	0	1 (<0.1)	
Cervical radiculopathy	0	1 (<0.1)	
Dizziness	1 (<0.1)	1 (<0.1)	
Facial paralysis	0	1 (<0.1)	
Hemiparesis	0	1 (<0.1)	
Lumbar radiculopathy	0	1 (<0.1)	
Multiple sclerosis	1 (<0.1)	1 (<0.1)	
Optic neuritis	0	1 (<0.1)	
Spinal cord compression	0	1 (<0.1)	
Amyotrophic lateral sclerosis	1 (<0.1)	0	
Arachnoid cyst	1 (<0.1)	0	
Basal ganglia haemorrhage	1 (<0.1)	0	
Encephalopathy	2 (<0.1)	0	
Hydrocephalus	1 (<0.1)	0	
Ischaemic stroke	1 (<0.1)	0	
Loss of consciousness	1 (<0.1)	0	
Migraine	1 (<0.1)	0	
Nerve compression	1 (<0.1)	0	
Paraesthesia	1 (<0.1)	0	
Speech disorder	1 (<0.1)	0	
Eye disorders	1 (<0.1)	0	
Retinal detachment	1 (<0.1)	0	
Retinal tear	1 (<0.1)	0	

Cardiac disorders	43 (0.3)	36 (0.2)	
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.30, 2.01)
Atrial fibrillation	10 (<0.1)	6 (<0.1)	0.60 (0.23, 1.59)
Cardiac failure congestive	3 (<0.1)	4 (<0.1)	
Acute coronary syndrome	0	3 (<0.1)	
Acute myocardial infarction	6 (<0.1)	3 (<0.1)	
Coronary artery disease	3 (<0.1)	3 (<0.1)	
Atrial flutter	2 (<0.1)	2 (<0.1)	
Cardio-respiratory arrest	1 (<0.1)	2 (<0.1)	
Pericarditis*	2 (<0.1)	2 (<0.1)	
Acute left ventricular failure	2 (<0.1)	1 (<0.1)	
Angina unstable	0	1 (<0.1)	
Bradycardia	0	1 (<0.1)	
Cardiac arrest	0	1 (<0.1)	
Cardiac failure	2 (<0.1)	1 (<0.1)	
Cardiac failure acute	1 (<0.1)	1 (<0.1)	
Coronary artery occlusion	0	1 (<0.1)	
Pericardial effusion	1 (<0.1)	1 (<0.1)	
Stress cardiomyopathy	0	1 (<0.1)	
Supraventricular tachycardia	0	1 (<0.1)	
Ventricular extrasystoles	0	1 (<0.1)	
Angina pectoris	1 (<0.1)	0	
Arrhythmia	1 (<0.1)	0	
Atrioventricular block complete	1 (<0.1)	0	
Atrioventricular block second degree	1 (<0.1)	0	
Paroxysmal arrhythmia	1 (<0.1)	0	
Sinus tachycardia	2 (<0.1)	0	
Vascular disorders	15 (<0.1)	15 (<0.1)	
Deep vein thrombosis	1 (<0.1)	4 (<0.1)	
Haematoma	0	2 (<0.1)	
Hypertension	2 (<0.1)	2 (<0.1)	
Hypertensive urgency	1 (<0.1)	2 (<0.1)	
Aortic aneurysm	1 (<0.1)	1 (<0.1)	
Arteriosclerosis	0	1 (<0.1)	
Axillary vein thrombosis	0	1 (<0.1)	
Embolism venous	0	1 (<0.1)	
Hypotension	2 (<0.1)	1 (<0.1)	
Polyarteritis nodosa	0	1 (<0.1)	
Venous thrombosis limb	0	1 (<0.1)	
Aortic stenosis	1 (<0.1)	0	
Arterial haemorrhage	1 (<0.1)	0	
Fibromuscular dysplasia	1 (<0.1)	0	
Hypertensive emergency	2 (<0.1)	0	
Peripheral artery aneurysm	1 (<0.1)	0	
Peripheral artery occlusion	1 (<0.1)	0	
Thrombophlebitis superficial	1 (<0.1)	0	
Respiratory, thoracic and mediastinal disorders	35 (0.2)	25 (0.2)	
Acute respiratory failure	10 (<0.1)	7 (<0.1)	0.70 (0.28, 1.77)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.30, 2.43)
Dyspnoea	0	5 (<0.1)	
Pleural effusion	2 (<0.1)	2 (<0.1)	
Respiratory failure	1 (<0.1)	2 (<0.1)	
Atelectasis	0	1 (<0.1)	
Chronic obstructive pulmonary disease	8 (<0.1)	1 (<0.1)	0.12 (0.02, 0.77)
Emphysema	1 (<0.1)	1 (<0.1)	
Pneumothorax	2 (<0.1)	1 (<0.1)	
Pulmonary mass	0	1 (<0.1)	
Acute respiratory distress syndrome	1 (<0.1)	0	
Asthma	1 (<0.1)	0	
Epistaxis	1 (<0.1)	0	

Hypoxia	3 (<0.1)	0	
Laryngeal oedema	1 (<0.1)	0	
Organising pneumonia	1 (<0.1)	0	
Pleuritic pain	1 (<0.1)	0	
Pneumonia aspiration	1 (<0.1)	0	
Pulmonary fibrosis	1 (<0.1)	0	
Pulmonary infarction	1 (<0.1)	0	
Gastrointestinal disorders	25 (0.2)	36 (0.2)	
Colitis	4 (<0.1)	3 (<0.1)	
Gastrointestinal haemorrhage	2 (<0.1)	3 (<0.1)	
Nausea	3 (<0.1)	3 (<0.1)	
Small intestinal obstruction	3 (<0.1)	3 (<0.1)	
Abdominal pain	2 (<0.1)	2 (<0.1)	
Abdominal pain upper	0	2 (<0.1)	
Diarrhoea	1 (<0.1)	2 (<0.1)	
Duodenal ulcer perforation	0	2 (<0.1)	
Hiatus hernia	1 (<0.1)	2 (<0.1)	
Intestinal obstruction	0	2 (<0.1)	
Vomiting	2 (<0.1)	2 (<0.1)	
Crohn's disease	0	1 (<0.1)	
Diverticular perforation	0	1 (<0.1)	
Duodenal ulcer	0	1 (<0.1)	
Gastritis	2 (<0.1)	1 (<0.1)	
Gastrooesophageal reflux disease	0	1 (<0.1)	
Inguinal hernia	0	1 (<0.1)	
Intra-abdominal fluid collection	0	1 (<0.1)	
Large intestine perforation	0	1 (<0.1)	
Oesophageal rupture	0	1 (<0.1)	
Oesophageal spasm	0	1 (<0.1)	
Pancreatitis	2 (<0.1)	1 (<0.1)	
Pancreatitis acute	0	1 (<0.1)	
Rectal prolapse	0	1 (<0.1)	
Retroperitoneal haemorrhage	0	1 (<0.1)	
Abdominal hernia	1 (<0.1)	0	
Abdominal pain lower	2 (<0.1)	0	
Duodenal ulcer haemorrhage	1 (<0.1)	0	
Gastric perforation	1 (<0.1)	0	
Gastric ulcer haemorrhage	1 (<0.1)	0	
Tooth socket haemorrhage	1 (<0.1)	0	
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)	
Cholecystitis	3 (<0.1)	3 (<0.1)	
Bile duct stone	0	2 (<0.1)	
Cholelithiasis	0	1 (<0.1)	
Biliary dyskinesia	1 (<0.1)	0	
Cholecystitis acute	1 (<0.1)	0	
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)	
Alopecia areata	0	1 (<0.1)	
Angioedema	1 (<0.1)	1 (<0.1)	
Rash	0	1 (<0.1)	
Rash vesicular	0	1 (<0.1)	
Dermatitis bullous	1 (<0.1)	0	
Musculoskeletal and connective tissue disorders	28 (0.2)	24 (0.2)	
Osteoarthritis	12 (<0.1)	8 (<0.1)	0.67 (0.28, 1.58)
Intervertebral disc protrusion	2 (<0.1)	3 (<0.1)	
Back pain	0	2 (<0.1)	
Spinal stenosis	2 (<0.1)	2 (<0.1)	
Flank pain	1 (<0.1)	1 (<0.1)	
Fracture nonunion	0	1 (<0.1)	
Muscular weakness	1 (<0.1)	1 (<0.1)	
Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)	

Neck pain	0	1 (<0.1)	
Rheumatoid arthritis	0	1 (<0.1)	
Spinal osteoarthritis	3 (<0.1)	1 (<0.1)	
Spondylolisthesis	0	1 (<0.1)	
Vertebral foraminal stenosis	0	1 (<0.1)	
Arthritis	1 (<0.1)	0	
Cervical spinal stenosis	1 (<0.1)	0	
Joint stiffness	1 (<0.1)	0	
Osteonecrosis	1 (<0.1)	0	
Polymyalgia rheumatica	1 (<0.1)	0	
Rhabdomyolysis	1 (<0.1)	0	
Renal and urinary disorders	11 (<0.1)	10 (<0.1)	
Acute kidney injury	6 (<0.1)	5 (<0.1)	
Nephrolithiasis	1 (<0.1)	5 (<0.1)	
Chronic kidney disease	2 (<0.1)	1 (<0.1)	
Renal impairment	1 (<0.1)	0	
Urinary retention	1 (<0.1)	0	
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)	
Abortion spontaneous	1 (<0.1)	1 (<0.1)	
Ectopic pregnancy	1 (<0.1)	0	
Reproductive system and breast disorders	6 (<0.1)	6 (<0.1)	
Pelvic pain	0	2 (<0.1)	
Benign prostatic hyperplasia	1 (<0.1)	1 (<0.1)	
Dysfunctional uterine bleeding	0	1 (<0.1)	
Ovarian cyst	2 (<0.1)	1 (<0.1)	
Uterine haemorrhage	0	1 (<0.1)	
Breast pain	1 (<0.1)	0	
Endometrial hyperplasia	1 (<0.1)	0	
Pelvic prolapse	1 (<0.1)	0	
Congenital, familial and genetic disorders	1 (<0.1)	0	
Talipes	1 (<0.1)	0	
General disorders and administration site conditions	12 (<0.1)	15 (<0.1)	
Death	2 (<0.1)	4 (<0.1)	
Non-cardiac chest pain	2 (<0.1)	3 (<0.1)	
Chest pain	2 (<0.1)	2 (<0.1)	
Swelling face	1 (<0.1)	2 (<0.1)	
Asthenia	0	1 (<0.1)	
Drug withdrawal syndrome	0	1 (<0.1)	
Generalised oedema	0	1 (<0.1)	
Multiple organ dysfunction syndrome	0	1 (<0.1)	
Oedema peripheral	0	1 (<0.1)	
Feeling hot	1 (<0.1)	0	
Incarcerated hernia	2 (<0.1)	0	
Pyrexia	1 (<0.1)	0	
Systemic inflammatory response syndrome	2 (<0.1)	0	
Investigations	1 (<0.1)	3 (<0.1)	
Hepatic enzyme increased	0	2 (<0.1)	
Heart rate irregular	0	1 (<0.1)	
Transaminases increased	1 (<0.1)	0	
Injury, poisoning and procedural complications	29 (0.2)	27 (0.2)	
Hip fracture	3 (<0.1)	3 (<0.1)	
Cervical vertebral fracture	0	2 (<0.1)	
Craniocerebral injury	0	2 (<0.1)	
Fall	5 (<0.1)	2 (<0.1)	
Road traffic accident	1 (<0.1)	2 (<0.1)	
Subdural haematoma	0	2 (<0.1)	
Back injury	0	1 (<0.1)	
Concussion	0	1 (<0.1)	

Facial bones fracture	0	1 (<0.1)	
Femoral neck fracture	0	1 (<0.1)	
Femur fracture	2 (<0.1)	1 (<0.1)	
Gastrointestinal procedural complication	0	1 (<0.1)	
Head injury	0	1 (<0.1)	
Humerus fracture	0	1 (<0.1)	
Incarcerated incisional hernia	0	1 (<0.1)	
Incision site pain	0	1 (<0.1)	
Joint injury	1 (<0.1)	1 (<0.1)	
Overdose	0	1 (<0.1)	
Post procedural haemorrhage	1 (<0.1)	1 (<0.1)	
Procedural haemorrhage	1 (<0.1)	1 (<0.1)	
Rib fracture	3 (<0.1)	1 (<0.1)	
Skin laceration	1 (<0.1)	1 (<0.1)	
Superficial injury of eye	0	1 (<0.1)	
Tendon rupture	1 (<0.1)	1 (<0.1)	
Traumatic liver injury	0	1 (<0.1)	
Upper limb fracture	0	1 (<0.1)	
Wound dehiscence	0	1 (<0.1)	
Wrist fracture	0	1 (<0.1)	
Ankle fracture	1 (<0.1)	0	
Cartilage injury	1 (<0.1)	0	
Gun shot wound	1 (<0.1)	0	
Immunisation anxiety related reaction	1 (<0.1)	0	
Pelvic fracture	1 (<0.1)	0	
Post procedural fever	1 (<0.1)	0	
Post procedural haematoma	1 (<0.1)	0	
Post-traumatic pain	1 (<0.1)	0	
Sternal fracture	1 (<0.1)	0	
Thoracic vertebral fracture	1 (<0.1)	0	
Tracheal haemorrhage	1 (<0.1)	0	
Traumatic haemothorax	2 (<0.1)	0	
Social circumstances	1 (<0.1)	0	
Sexual abuse	1 (<0.1)	0	
Product issues	1 (<0.1)	0	
Lead dislodgement	1 (<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. *Onset post-dose 2 at 68 days (moderate pericarditis and grade 4 pericardial effusion) and at 73 days (grade 4 pericarditis) in mRNA-1273 participants. Data-cutoff date: March 26, 2021.

Table S21. Serious and Severe Treatment-related AEs after Any Injection in Overall and Age Groups Safety Set

Adverse events n (%)	Overall		≥18-<65 yrs		≥65 yrs	
	Placebo	mRNA-1273	Placebo	mRNA-1273	Placebo	mRNA-1273
	N=15162	N=15184	N=11411	N=11415	N=3751	N=3769
Serious AEs (study observation period)						
Incidence of unsolicited AEs	4 (<0.1)	12 (<0.1)	2 (<0.1)	9 (<0.1)	2 (<0.1)	3 (<0.1)
B-cell small lymphocytic lymphoma	0	1 (<0.1)	-	-	0	1 (<0.1)
Basedow's disease	0	1 (<0.1)	-	-	0	1 (<0.1)
Hypomagnesaemia	1 (<0.1)	0	-	-	1 (<0.1)	0
Autonomic nervous system imbalance	0	1 (<0.1)	0	1 (<0.1)	-	-
Cerebrovascular accident	0	1 (<0.1)	0	1 (<0.1)	-	-
Multiple sclerosis	0	1 (<0.1)	0	1 (<0.1)	-	-
Paraesthesia	1 (<0.1)	0	1 (<0.1)	0	-	-
Pericardial effusion	0	1 (<0.1)	0	1 (<0.1)	-	-
Pericarditis	0	1 (<0.1)*	0	1 (<0.1)	-	-
Acute myocardial infarction	1 (<0.1)	0	-	-	1 (<0.1)	0
Atrial fibrillation	1 (<0.1)	0	-	-	1 (<0.1)	0
Pleural effusion	0	1 (<0.1)	0	1 (<0.1)		
Organising pneumonia	1 (<0.1)	0	-	-	1 (<0.1)	0
Respiratory failure	1 (<0.1)	0	-	-	1 (<0.1)	0
Nausea	0	1 (<0.1)	-	-	0	1 (<0.1)
Vomiting	0	1 (<0.1)	-	-	0	1 (<0.1)
Alopecia areata	0	1 (<0.1)	0	1 (<0.1)	-	-
Angioedema	0	1 (<0.1)	0	1 (<0.1)	-	-
Rheumatoid arthritis	0	1 (<0.1)	0	1 (<0.1)	-	-
Polymyalgia rheumatica	1 (<0.1)	0	-	-	1 (<0.1)	0
Acute kidney injury	1 (<0.1)	0	-	-	1 (<0.1)	0
Swelling face	1 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	-	-
Feeling hot	1 (<0.1)	0	1 (<0.1)	0	-	-
Immunisation anxiety-related reaction	1 (<0.1)	0	1 (<0.1)	0	-	-
Procedural haemorrhage	1 (<0.1)	0	1 (<0.1)	0	-	-
Severe AEs (≤28 days after any injection)						
Incidence of unsolicited severe AEs	31 (0.2)	83 (0.5)	20 (0.2)	59 (0.5)	11 (0.3)	24 (0.6)
Lymph node pain	0	1 (<0.1)	0	1 (<0.1)	-	-
Lymphadenopathy	0	1 (<0.1)	0	1 (<0.1)	-	-
Type IV hypersensitivity reaction	0	1 (<0.1)	-	-	0	1 (<0.1)
Headache	7 (<0.1)	7 (<0.1)	6 (<0.1)	6 (<0.1)	1 (<0.1)	1 (<0.1)
Migraine	0	2 (<0.1)	0	2 (<0.1)	-	-
Dizziness	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	-	-
Migraine with aura	0	1 (<0.1)	-	-	-	-
Movement disorder	0	1 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Syncope	0	1 (<0.1)	0	1 (<0.1)	-	-
Vertigo	0	1 (<0.1)	0	1 (<0.1)	-	-
Hypertension	9 (<0.1)	6 (<0.1)	1 (<0.1)	3 (<0.1)	8 (0.2)	3 (<0.1)
Tachypnoea	0	1 (<0.1)	0	1 (<0.1)	-	-
Nausea	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Dyspepsia	0	1 (<0.1)	0	1 (<0.1)	-	-
Dermatitis	0	1 (<0.1)	-	-	0	1 (<0.1)
Pruritus	0	1 (<0.1)	0	1 (<0.1)	-	-
Rash	0	1 (<0.1)	0	1 (<0.1)	-	-
Rash macular	0	1 (<0.1)	-	-	0	1 (<0.1)
Urticaria	0	1 (<0.1)	0	1 (<0.1)	-	-
Myalgia	2 (<0.1)	8 (<0.1)	2 (<0.1)	6 (<0.1)	0	2 (<0.1)
Arthralgia	5 (<0.1)	3 (<0.1)	5 (<0.1)	3 (<0.1)	-	-
Muscle spasms	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Pain in extremity	0	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)
Neck pain	0	1 (<0.1)	0	1 (<0.1)	-	-
Temporomandibular joint syndrome	0	1 (<0.1)	0	1 (<0.1)	-	-
Back pain	1 (<0.1)	0	1 (<0.1)	0	-	-
Polymyalgia rheumatica	1 (<0.1)	0	-	-	1 (<0.1)	0
Fatigue	6 (<0.1)	16 (0.1)	4 (<0.1)	13 (0.1)	2 (<0.1)	3 (<0.1)
Injection site erythema	0	8 (<0.1)	0	5 (<0.1)	0	3 (<0.1)

Injection site macule	0	6 (<0.1)	0	3 (<0.1)	0	3 (<0.1)
Injection site pain	1 (<0.1)	3 (<0.1)	1 (<0.1)	3 (<0.1)	-	-
Injection site swelling	0	3 (<0.1)	0	2 (<0.1)	0	1 (<0.1)
Chills	0	2 (<0.1)	0	2 (<0.1)	-	-
Injection site lymphadenopathy	1 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	-	-
Injection site urticaria	0	2 (<0.1)	-	-	0	2 (<0.1)
Injection site induration	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	-	-
Injection site rash	0	1 (<0.1)	0	1 (<0.1)	-	-
Malaise	0	1 (<0.1)	0	1 (<0.1)	-	-
Pyrexia	0	1 (<0.1)	-	-	0	1 (<0.1)
Swelling face	0	1 (<0.1)	0	1 (<0.1)	-	-
Asthenia	1 (<0.1)	0	1 (<0.1)	0	-	-
Blood pressure increased	1 (<0.1)	3 (<0.1)	1 (<0.1)	2 (<0.1)	0	1 (<0.1)
Blood pressure diastolic increased	0	1 (<0.1)	-	-	0	1 (<0.1)
Blood pressure systolic increased	0	1 (<0.1)	0	1 (<0.1)		

Treatment-emergent adverse event (TEAE) 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 subjects. The 95% CI was calculated using the Miettinen and Nurminen method. *Occurred 28 days post-dose 2.
MedDRA version 23.0. Data-cutoff date: March 26, 2021.

Table S22. Unsolicited Adverse Events of Hypersensitivity, Overall Safety Set

Preferred term n (%)	Overall		≥18 and <65 Years		≥65 years	
	Placebo N=15162	mRNA-1273 N=15184	Placebo N=11411	mRNA-1273 N=11415	Placebo N=3751	mRNA-1273 N=3769
Participants reporting hypersensitivity	278 (1.8)	336 (2.2)	217 (1.9)	248 (2.2)	61 (1.6)	88 (2.3)
Allergic cough	0	2 (<0.1)	0	2 (<0.1)	-	-
Allergic sinusitis	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	-	-
Anaphylactic reaction	2 (<0.1)	2 (<0.1)	2 (<0.1)	2 (<0.1)	-	-
Angioedema	3 (<0.1)	3 (<0.1)	2 (<0.1)	3 (<0.1)	1 (<0.1)	0
Bronchospasm	1 (<0.1)	3 (<0.1)	1 (<0.1)	1 (<0.1)	0	2 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Dermatitis	14 (<0.1)	10 (<0.1)	11 (<0.1)	7 (<0.1)	3 (<0.1)	3 (<0.1)
Dermatitis allergic	5 (<0.1)	3 (<0.1)	5 (<0.1)	3 (<0.1)	-	-
Dermatitis atopic	9 (<0.1)	6 (<0.1)	9 (<0.1)	3 (<0.1)	0	3 (<0.1)
Dermatitis bullous	2 (<0.1)	0	1 (<0.1)	0	1 (<0.1)	0
Dermatitis contact	41 (0.3)	34 (0.2)	28 (0.2)	26 (0.2)	13 (0.3)	8 (0.2)
Drug hypersensitivity	8 (<0.1)	12 (<0.1)	6 (<0.1)	8 (<0.1)	2 (<0.1)	4 (0.1)
Eczema	11 (<0.1)	18 (0.1)	8 (<0.1)	18 (0.2)	3 (<0.1)	0
Eczema nummular	1 (<0.1)	3 (<0.1)	0	2 (<0.1)	1 (<0.1)	1 (<0.1)
Exfoliative rash	0	1 (<0.1)	0	1 (<0.1)	-	-
Eye swelling	5 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Hand dermatitis	1 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	-	-
Hypersensitivity	9 (<0.1)	9 (<0.1)	7 (<0.1)	5 (<0.1)	2 (<0.1)	4 (0.1)
Idiopathic urticaria	1 (<0.1)	0	1 (<0.1)	0	-	-
Incision site rash	0	1 (<0.1)	0	1 (<0.1)	0	6 (0.2)
Injection related reaction	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	-	-
Injection site rash	1 (<0.1)	25 (0.2)	1 (<0.1)	19 (0.2)	-	-
Injection site urticaria	1 (<0.1)	38 (0.3)	0	27 (0.2)	1 (<0.1)	11 (0.3)
Laryngeal oedema	1 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)	-	-
Lip oedema	0	1 (<0.1)	0	1 (<0.1)	-	-
Lip swelling	2 (<0.1)	6 (<0.1)	1 (<0.1)	5 (<0.1)	1 (<0.1)	1 (<0.1)
Oropharyngeal blistering	0	1 (<0.1)	-	-	0	1 (<0.1)
Palatal oedema	1 (<0.1)	0	1 (<0.1)	0	-	-
Perioral dermatitis	3 (<0.1)	1 (<0.1)	3 (<0.1)	1 (<0.1)	-	-
Periorbital oedema	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Periorbital swelling	3 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0
Pharyngeal swelling	0	1 (<0.1)	-	-	0	1 (<0.1)
Rash	47 (0.3)	44 (0.3)	42 (0.4)	32 (0.3)	5 (0.1)	12 (0.3)
Rash erythematous	4 (<0.1)	3 (<0.1)	3 (<0.1)	3 (<0.1)	1 (<0.1)	0
Rash follicular	1 (<0.1)	0	1 (<0.1)	0	-	-
Rash macular	6 (<0.1)	8 (<0.1)	2 (<0.1)	3 (<0.1)	4 (0.1)	5 (0.1)
Rash maculo-papular	4 (<0.1)	9 (<0.1)	4 (<0.1)	7 (<0.1)	0	2 (<0.1)
Rash pruritic	11 (<0.1)	6 (<0.1)	10 (<0.1)	4 (<0.1)	1 (<0.1)	2 (<0.1)
Rash pustular	0	1 (<0.1)	0	1 (<0.1)	-	-
Rash vesicular	1 (<0.1)	2 (<0.1)	1 (<0.1)	2 (<0.1)	-	-
Rhinitis allergic	26 (0.2)	21 (0.1)	18 (0.2)	15 (0.1)	8 (0.2)	6 (0.2)
Serum sickness	1 (<0.1)	0	1 (<0.1)	0	-	-
Swelling face	4 (<0.1)	6 (<0.1)	3 (<0.1)	6 (<0.1)	1 (<0.1)	0
Swelling of eyelid	1 (<0.1)	4 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)
Swollen tongue	1 (<0.1)	2 (<0.1)	0	1 (<0.1)	1 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	0	1 (<0.1)	-	-	0	1 (<0.1)
Urticaria	46 (0.3)	55 (0.4)	37 (0.3)	40 (0.4)	9 (0.2)	15 (0.4)
Urticaria papular	5 (<0.1)	3 (<0.1)	4 (<0.1)	3 (<0.1)	1 (<0.1)	0
Vaccination site rash	0	2 (<0.1)	0	2 (<0.1)	-	-

Percentages are based on the number of safety subjects.MedDRA version 23.0. Hypersensitivity is identified through selected SMQ. Data-cutoff date: March 26, 2021.

Table S23. Incidence of Dermal Filler Reaction Post-Vaccination by Preferred Term by Age Group, Safety Set

Preferred term n (%)	Overall		≥18 and <65 Years		≥65 years	
	Placebo	mRNA-1273	Placebo	mRNA-1273	Placebo	mRNA-1273
	(N=15162)	(N=15184)	(N=11411)	(N=11415)	(N=3751	(N=3769)
Participants reporting dermal filler reaction	14 (<0.1)	20 (0.1)	9 (<0.1)	17 (0.1)	5 (0.1)	3 (<0.1)
Eye swelling	5 (<0.1)	2 (<0.1)	4 (<0.1)	1 (<0.1)	1 (<0.1)	1 (<0.1)
Lip oedema	0	1 (<0.1)	0	1 (<0.1)	-	-
Lip swelling	2 (<0.1)	6 (<0.1)	1 (<0.1)	5 (<0.1)	1 (<0.1)	1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)	0	1 (<0.1)	1 (<0.1)	0
Periorbital swelling	3 (<0.1)	0	2 (<0.1)	0	1 (<0.1)	0
Swelling face	4 (<0.1)	6 (<0.1)	3 (<0.1)	6 (<0.1)	1 (<0.1)	0)
Swelling of eyelid	1 (<0.1)	4 (<0.1)	1 (<0.1)	3 (<0.1)	0	1 (<0.1)

Percentages are based on the number of safety participants. .MedDRA version 23.0.
Data-cutoff date March 26, 2021.

Table S24. Bell's Palsy in Overall Safety Set and By Age Group

Adverse events n (%)	Placebo	mRNA-1273	Rate ratio	Total
Overall	**N=15162**	**N=15184**		**N=30346**
Facial paralysis	3 (<0.1)	8 (<0.1)	2.66 (0.77, 9.25)	11 (<0.1)
≥18-<65 yrs	**N=11411**	**N=11415**		**N=22826**
Facial paralysis	3 (<0.1)	5 (<0.1)*	-	8 (<0.1)
≥65 yrs	**N=3751**	**N=3769**		**N=7520**
Facial paralysis	0	3 (<0.1)†	-	3 (<0.1)
Serious				
Facial paralysis	0	1 (<0.1)		1 (<0.1)

Treatment-emergent adverse event (TEAE) defined as any event not present before exposure to study vaccination or any event already present that worsened in intensity or frequency after exposure. Percentages are based on the number of safety set participants. The rate ratio was calculated as the ratio of the percentage of participants who reported the event in mRNA-1273 divided by that in placebo; 95% CI was calculated using the Miettinen and Nurminen method.*1 AE severe (grade 3): male, 56 yrs, white, SARS-CoV-2 negative, not treatment-related, recovering/resolving, concomitant meds, follow-up time 2nd dose=179 days. †2 AE severe grade 3: 1) female, 67 yrs, white, SAE criteria, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days and 2) male, 73 yrs, white, not treatment-related, recovered/resolved, concomitant meds, follow-up time 2nd dose=172 days. MedDRA version 23.0. Data-cutoff date: March 26, 2021.

Table S25. Thromboembolic Events in the Overall Safety Set and by Age Group

	Overall			≥18-65 yrs		≥65 yrs	
Preferred term n (%)	Placebo N=15162	mRNA-1273 N=15184	Rate Ratio (95% CI)	Placebo N=11411	mRNA-1273 N=11415	Placebo N=3751	mRNA-1273 N=3769
Participants Reporting Embolic and Thrombotic Events*	43 (0.3)	47 (0.3)	-	28 (0.2)	26 (0.2)	15 (0.4)	21 (0.6)
Acute myocardial infarction	6 (<0.1)	4 (<0.1)	-	2 (<0.1)	2 (<0.1)	4 (0.1)	2 (<0.1)
Arterial occlusive disease	0	1 (<0.1)	-	-	-	0	1 (<0.1)
Axillary vein thrombosis	0	1 (<0.1)	-	-	-	0	1 (<0.1)
Blindness transient	0	1 (<0.1)	-	0	1 (<0.1)	-	-
Carotid artery thrombosis	0	1 (<0.1)	-	-	-	0	1 (<0.1)
Cerebrovascular accident	4 (<0.1)	7 (<0.1)	1.75 (0.6-5.6)	2 (<0.1)	4 (<0.1)	2 (<0.1)	3 (<0.1)
Coronary artery occlusion	0	2 (<0.1)	-	-	-	0	2 (<0.1)
Deep vein thrombosis	6 (<0.1)	8 (<0.1)	1.33 (0.5-3.7)	4 (<0.1)	4 (<0.1)	2 (<0.1)	4 (0.1)
Deep vein thrombosis postoperative	0	1 (<0.1)	-	0	1 (<0.1)	-	-
Embolic stroke	0	2 (<0.1)	-	-	-	0	2 (<0.1)
Embolism venous	0	1 (<0.1)	-	0	1 (<0.1)	-	-
Hemiparesis	0	1 (<0.1)	-	0	1 (<0.1)	-	-
Ischaemic stroke	1 (<0.1)	0	-	-	-	1 (<0.1)	0
Myocardial infarction	9 (<0.1)	7 (<0.1)	0.78 (0.3-2.0)	6 (<0.1)	4 (<0.1)	3 (<0.1)	3 (<0.1)
Peripheral arterial occlusive disease	0	1 (<0.1)		0	1 (<0.1)	0	1 (<0.1)
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)		1 (<0.1)	0	2 (<0.1)	2 (<0.1)
Pulmonary embolism	7 (<0.1)	6 (<0.1)	0.86 (0.3-2.4)	5 (<0.1)	4 (<0.1)	2 (<0.1)	2 (<0.1)
Pulmonary infarction	1 (<0.1)	0	-	1 (<0.1)	0	-	-
Retinal infarction	1 (<0.1)	0	-	0	1 (<0.1)	1 (<0.1)	0
Stress cardiomyopathy	0	1 (<0.1)	-	-	-	0	1 (<0.1)
Thrombophlebitis	0	1 (<0.1)	-	0	1 (<0.1)	-	-
Thrombophlebitis superficial	4 (<0.1)	2 (<0.1)	-	4 (<0.1)	2 (<0.1)	-	-
Transient ischaemic attack	4 (<0.1)	3 (<0.1)	-	4 (<0.1)	1 (<0.1)	0	2 (<0.1)
Venous thrombosis limb	0	1 (<0.1)	-	0	1 (<0.1)		
Vertebral artery occlusion	1 (<0.1)	0	-	-	-	1 (<0.1)	0

Percentages are based on the number of participants in the safety set. The rate ratio was calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo in the overall group. The 95% CI was calculated using the Miettinen and Nurminen method. *Embolic and Thrombotic Events were identified through selected Standardized MedDRA Query. Data-cutoff date March 26, 2021.

Table S26. Death summary in Blinded Phase

	Placebo N=15162	mRNA-1273 N=15184	Total N=30346
Number of Deaths Total, n (%)	16 (0.1)	16 (0.1)	32 (0.1)
Cause of death, n			
Symptomatic Covid-19	1	-	1
Covid-19//SARS-CoV-2	2	1†	3
Intra-abdominal perforation	1	--	1
Stage 4 pancreatic cancer	1	-	1
Complication of amyotrophic lateral sclerosis	1	-	1
Myocardial infarction	4	1	5
Cardiopulmonary arrest	1	2	3
Unknown death (details unknown, pending autopsy, unknown origin/cause)	2	3	5
Severe systemic inflammatory syndrome in the setting of CLL	1	-	1
Committed suicide	1	1	2
Seizure	1		1
End stage congestive heart failure	-	1	1
Cardiac arrest	-	1	1
Provisional diagnosis, sudden fatal event, likely myocardial infarction	-	1	1
Worsening metastatic hepatocellular carcinoma	-	1	1
Right lower lobe pulmonary nodule concerning for primary lung malignancy	-	1	1
GI bleed and multisystem organ failure and acute hypoxic respiratory failure	-	1	1
Head trauma	-	1	1
Death suspected due to coronary artery disease, probably to complications of diabetes mellitus	-	1	1

Percentages based on participants in the safety set. †Participant with a medical history of liver disease and human immunodeficiency virus, had a death attributed to Covid-19 that occurred 119 days post-dose 1; however, did not receive a second dose and was not included in the analysis of the secondary endpoint for prevention of Covid-19 death as only deaths due to Covid-19 14 days after 2nd dose were analyzed. Data-cutoff date March 26, 2021.

Table S27. Vaccine Efficacy for Primary and All Secondary Endpoints

Endpoint	Placebo N=14164	mRNA-1273 N=14287
Covid-19*, Adjudication Assessments Starting 14 Days After Second Injection		
Events (n)	744	55
Vaccine Efficacy (95% CI)*†		93.2 (91.0-94.8)
p-value‡		<.0001‡
Covid-19* Starting 14 Days After Second Injection		
Events (n)	751	55
Vaccine Efficacy (95% CI)†		93.2 (91.1-94.9)
Severe Covid-19* Adjudication Assessments Starting 14 Days After Second Injection		
Events (n)	106	2
Vaccine Efficacy (95% CI)†		98.2 (92.8-99.6)
Severe Covid-19* Starting 14 Days After Second Injection		
Events (n)	118	3
Vaccine Efficacy (95% CI)†		97.6 (92.4-99.2)
Secondary Definition of Covid-19* Starting 14 Days After Second Injection		
Events (n)	807	58
Vaccine Efficacy (95% CI)†		93.4 (91.4-94.9)
Covid-19* Based on Adjudication Committee Assessments Starting 14 Days After First Injection		
Events (n)	769	56
Vaccine Efficacy (95% CI)†		93.3 (91.1-94.9)
Covid-19* Starting 14 Days After First Injection		
Events (n)	782	58
Vaccine Efficacy (95% CI)†		93.1 (91.0-94.7)
Covid-19* Based on Adjudication Committee Assessments Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection		
Events, n/N¶	754/15166	58/15180
Vaccine Efficacy (95% CI)†		92.8 (90.6-94.5)
Covid-19* Starting 14 Days After Second Injection Regardless of Prior SARS-CoV-2 Infection		
Events, n/N¶	762/15166	58/15180
Vaccine Efficacy (95% CI)†		92.9 (90.7-94.6)
Death Caused by Covid-19 Starting 14 Days After Second Injection		
Events (n)	3	0
Vaccine Efficacy (95% CI)†		100.0 (NE-100.0)
SARS-CoV-2 Infection Regardless of Symptomatology and Severity Starting 14 Days After Second Injection		
Events (n)§	1339	280
Vaccine Efficacy (95% CI)†		82.0 (79.5-84.2)
Asymptomatic SARS-CoV-2 Infection Starting 14 Days After Second Injection		
Events (n)§	498	214
Vaccine Efficacy (95% CI)†		63.0 (56.6-68.5)

*With censoring rules for efficacy analyses. Covid-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If participant had positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participant was censored at the date with positive RT-PCR or Elecsys. †Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI were 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. For asymptomatic SARS-CoV-2 infection, VE and 95% CI were estimated using Fine and Gray's sub-distribution hazard model with disease cases as competing events and with the treatment group as a covariate, adjusting for stratification factor. ‡1-sided p-value from stratified Cox proportional hazard model to test the null hypothesis VE ≤0.3. §Includes participant decision visit data. ¶n and N are based on the number of participants in the Full Analysis Set. Data-cutoff date March 26, 2021.

Table S28. Covid Case Summary Per-Protocol and mITT Definitions*

	Per-protocol population			Modified intent-to-treat population		
	Placebo N=14164	**mRNA-1273 N=14287**	**Estimated VE (95% CI)**	**Placebo N=14745**	**mRNA-1273 N=14746**	**Estimated VE (95% CI)**
Symptomatic infections, 14 days post-injection two, n (%)						
Covid-19 adjudicated cases	744 (5.3)	55 (0.4)	93.2 (91.0-94.8)	751 (5.1)	58 (0.4)	92.8 (90.6-94.5)
Covid-19 cases (adjudicated and any)	751 (5.3)	55 (0.4)	93.2 (91.1-94.9)	759 (5.1)	58 (0.4)	92.9 (90.7-94.6)
Secondary definition of Covid-19	807 (5.7)	58 (0.4)	93.4 (91.4-94.9)	816 (5.5)	61 (0.4)	93.1 (91.0-94.7)
Severe Covid-19 cases	106 (0.7)	2 (0)	97.6 (92.4-99.2)	107 (0.7)	2 (0)	98.2 (92.8-99.6)
Asymptomatic infection†	498 (3.5)	214 (1.5)	63.0 (56.6-68.5)	500 (3.4)	217 (1.5)	62.3 (55.7-67.8)
Asymptomatic infections (number of events) after randomization, n	**Placebo N=14164**	**mRNA-1273 N=14287**		**Placebo N=14745**	**mRNA-1273 N=14746**	
Asymptomatic infections total, n (%)	567 (4.0)‡	246 (1.7)	-	583 (4.0)‡	253 (1.7)	-
Infections detected at day 29	69	32	-	75	33	-
RT-PCR only	35	12	-	36	13	
Seroconversion only	26	17	-	27	17	
Both RT-PCR and seroconversion	8	3	-	12	3	-
Infections detected at day 57 (seroconversion)	31	13	-	34	14	-
Infections detected at day 209 (seroconversion)	2	0	-	2	0	-
Infections detected at PDV	463	201	-	470	206	-
RT-PCR only	157	153	-	158	156	-
Seroconversion only	191	41	-	193	43	-
Both RT-PCR and seroconversion	115	7	-	119	7	-

PDV=participant decision visit. Reverse transcriptase polymerase chain reaction (RT-PCR) test and Elecsys binding antibody (bAb) against SARS-CoV-2 nucleocapsid assay (seroconversion) results at post-baseline scheduled visits are considered in the case definition. *Only includes cases defined in the blinded phase and does not include cases defined in the open-label phase. Includes cases that occurred at the participant decision visit (PDV) before or on the efficacy data cutoff date of March 26, 2021. Asymptomatic SARS-CoV-2 infection (PP and mITT sets) was defined as absence of symptoms (no Covid-19 symptom for either primary efficacy Covid-19 end point, or secondary definition of Covid-19) and infections as detected by at least either seroconversion (bAb specific to SARS-CoV-2 nucleocapsid) at scheduled visits (months 1, 2, 7, 13 and 25 if applicable in Part A, participant decision visit and etc. in Part B) when blood samples for immunogenicity were collected, or by RT-PCR at scheduled visits such as pre-dose 2 at day 29 in Part A. Both RT-PCR test and bAb against SARS-CoV-2 nucleocapsid were considered, and the date of documented asymptomatic infection was the earlier date of seroconversion due to infection, or positive RT-PCR at scheduled visits, with the absence of symptoms. Participants who had a symptomatic infection (Covid-19 or secondary definition of Covid-19) prior to an asymptomatic infection were censored at the time of symptomatic infection for the analysis of asymptomatic infection. †For the primary analysis, documented asymptomatic infection was counted starting 14 days after the 2nd injection, which required seroconversion at months 2 (day 57, 209 or PDV). As disease cases (Covid-19 or secondary definition of Covid-19) are competing events for asymptomatic SARS-CoV-2 infections, competing risk method was used to estimate the vaccine efficacy of mRNA-1273, specifically, Fine and Gray's (FG) sub-distribution hazard model was used. ‡2 participants with data detected at unscheduled visit. Data cut-off date: March 26, 2021.

Table S29. Vaccine Efficacy to Prevent Covid-19* in Subgroups Assessed

Subgroup	n Events/N† Placebo N=14164	n Events/N† mRNA-1273 N=14287	Vaccine Efficacy % (95% CI)
Overall	744/14164	55 /14287	93.2 (91.0-94.8)
Age Years			
≥18 and <65	644/10569	46/10661	93.4 (91.1-95.1)
≥65	100/3595	9/3626	91.5 (83.2-.95.7)
≥65 and <75	81/2898	9/2990	89.7 (79.6-94.9)
≥75	19/697	0/636	100.0 (NE-100.0)
Sex			
Male	378/7494	30/7439	92.5 (89.1-94.8)
Female	366/6670	25/6848	93.8 (90.7-95.9)
Age and Health Risk for Severe Covid-19‡			
≥18 and <65 years and not at risk	501/8428	35/8464	93.5 (90.9-95.4)
≥18 and <65 years and at risk	143/ 2141	11/2197	93.0 (87.0-96.2)
≥65 years	100/3595	9/3626	91.5 (83.2-95.7)
At Risk for Severe Covid-19			
Yes	177/3212	16/3283	91.7 (86.2-95.0)
No	567/10952	39/11004	93.6 (91.2-95.4)
Race and Ethnicity			
Non-Hispanic White§	488/8998	39/9123	92.6 (89.8-94.7)
Communities of Color	256/5141	16/5139	94.2 (90.3-96.5)
Race			
White	631/11273	48/11391	93.0 (90.6-94.7)
Black or African American	41/1352	4/1,391	91.1 (75.2-96.8)
Asian	29/700	1/628	96.6 (74.2-99.5)
American Indian or Alaska Native	5/113	0/109	100.0 (NE-100.0)
Native Hawaiian or Other Pacific Islander	0/31	0/36	NE (NE-NE)
Other	19 /274	2 / 295	95.8 (68.6-99.4)
Multiple	8/304	1/282	88.1 (4.6-98.5)
Not Reported/Unknown	11/127	0/146	100.0 (NE-100.0)
Ethnicity			
Hispanic or Latino	177/2,787	10/2831	94.8 (90.2-97.3)
Not Hispanic or Latino	563/11,249	45/11,322	92.6 (90.0-94.5)
Not reported	2/76	0/99	100.0 (NE-100.0)
Unknown	2/52	0/35	100.0 (NE-100.0)
Comorbidities			
Chronic Lung Disease	30/692	4/675	87.2 (63.8-95.5)
Significant Cardiac Disease	30/696	4/726	88.0 (65.9-95.8)
Severe Obesity (>40 kg/m2)	75/980	7/1009	91.4 (81.4-96.0)
Diabetes	72/1363	3/1,402	96.2 (87.9-98.8)
Liver Disease	5/90	1/100	81.0 (-64.8-97.8)
HIV	4/82	0/85	100.0 (NE-100)
Occupational risk			
No Risk	72/2480	4/2541	94.8 (85.8-98.1)
Healthcare workers	209/3261	13/361	94.4 (90.3-96.8)
Emergency response	25/273	2/287	93.0 (70.6-98.4)
Retail and restaurant operations	58/875	5/870	92.0 (80.0-96.8)
Manufacturing and Production Operations	21/390	2/390	90.9 (61.0-97.9)
Warehouse Shipping and Fulfillment Centers	13/158	2/174	86.1 (38.4-96.9)
Transportation and Delivery Services	22/428	2/428	91.3 (62.8-97.9)
Border Protection and Military Personnel	3/66	0/64	100.0 (NE-100)
Personal Care and In-Home Services	29/413	2/417	93.5 (72.8-98.5)

Hospitality and Tourism Workers	10/200	3/214	74.1 (5.6-92.9)
Pastoral, Social or Public Health Workers	36/485	1/506	97.6 (82.2-99.7)
Educators and Students	77/1478	7/1476	91.3 (81.2-96.0)
Other	237/4506	23/4586	91.3 (81.2-96.0)

*With the censoring rules for efficacy analyses. Covid-19 case is based on eligible symptoms and positive RT-PCR within14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the subject is censored at the date with positive RT-PCR or Elecsys. Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI were 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 if applicable. †Based on the number of participants assessed in each subgroup. †Age and health risk for severe Covid-19 are derived from age and risk factor collected on case report form (CRF). ‡White is defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing. Data-cutoff date: March 26, 2021.

Table S30. Cases of Covid-19 and SARS-CoV-2 Infection Post-randomization by Time Periods, Per-Protocol Set

	Covid-19* adjudicated cases		Covid-19* cases		Severe Covid-19 adjudicated cases		SARS-CoV-2 infection regardless of symptomology/severity	
	Placebo	mRNA-1273	Placebo	mRNA-1273	Placebo	mRNA-1273	Placebo	mRNA-1273
Cases	**N=14164**	**N=14287**	**N=14164**	**N=14287**	**N=14164**	**N=14287**	**N=14164**	**N=14287**
n (%)	769 (5.4)	56 (0.4)	782 (5.5)	58 (0.4)	107 (0.8)	2 (<0.1)	1434 (10.1)	313 (2.2)
Events (n)								
Randomization up to 14 days after first injection	0	0	0	0	0	0	0	0
≥14 up to 21 days after first injection	0	0	0	0	0	0	1	0
≥21 days after first injection up to second injection	1	0	3	0	0	0	3	0
Second injection up to 7 days after second injection	11	1	12	3	0	0	78	33
≥7 up to 14 days after second injection	13	0	16	0	1	0	13	0
≥14 up to 28 days after second injection	49	4	48	4	7	0	63	9
≥28 up to 56 days after second injection	178	15	181	14	25	0	217	28
≥56 up to 84 days after second injection	228	12	229	13	33	2	290	28
≥84 up to 112 days after second injection	206	16	207	16	28	0	316	58
≥112 days after second injection	83	8	86	8	13	0	453	157

*With censoring rules for efficacy analyses. Covid-19 case was based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participant was censored at the date with positive RT-PCR or Elecsys. Data-cutoff date: March 26, 2021.

Table S31. Covid-19 Symptoms and Severity in Adjudicated Covid-19 and Severe Covid-19 Cases, Per-protocol Set

	All Covid-19 cases*		Severe Covid-19 cases	
Covid-19 n (%)	Placebo N=744	mRNA-1273 N=55*	Placebo N=106	mRNA-1273 N=2
Respiratory symptom				
Clinical evidence of pneumonia	18 (2.4)	0	16 (15.1)	0
Cough	632 (84.9)	35 (63.6)	100 (94.3)	2 (100)
Difficulty breathing	185 (24.9)	10 (18.2)	49 (46.2)	2 (100)
Radiographical evidence of pneumonia	16 (2.2)	0	14 (13.2)	0
Shortness of breath	275 (37.0)	19 (34.5)	74 (69.8)	1 (50.0)
Systemic symptom				
Body aches	464 (62.4)	24 (43.6)	83 (78.3)	1 (50.0)
Chills	378 (50.8)	17 (30.9)	65 (61.3)	1 (50.0)
Diarrhea	282 (37.9)	16 (29.1)	55 (51.9)	2 (100)
Fatigue	620 (83.3)	39 (70.9)	96 (90.6)	1 (50.0)
Fever†	175 (23.5)	5 (9.1)	45 (42.5)	0
Headache	583 (78.4)	47 (85.5)	92 (86.8)	1 (50.0)
Muscle aches (myalgia)	409 (55.0)	23 (41.8)	76 (71.7)	1 (50.0)
Nasal congestion	591 (79.4)	43 (78.2)	79 (74.5)	2 (100)
Nausea	272 (36.6)	15 (27.3)	49 (46.2)	2 (100)
New loss of smell	445 (59.8)	18 (32.7)	57 (53.8)	0
New loss of taste	416 (55.9)	14 (25.5)	58 (54.7)	0
Runny nose (rhinorrhea)	489 (65.7)	39 (70.9)	72 (67.9)	2 (100)
Sore throat	386 (51.9)	34 (61.8)	52 (49.1)	2 (100)
Vomiting	79 (10.6)	3 (5.5)	23 (21.7)	1 (50.0)
Number of participants with any severe symptom	112 (15.1)	3 (5.5)	103 (97.2)	(100)
Acute renal dysfunction	2 (0.3)	0	2 (1.9)	0
Acute Respiratory Distress Syndrome	2 (0.3)	0	2 (1.9)	0
ECMO	1 (0.1)	0	1 (0.9)	0
High-flow oxygen	6 (0.8)	1 (1.8)	6 (5.7)	1 (50.0)
Mechanical ventilation	2 (0.3)	0	2 (1.9)	0
Non-Invasive ventilation	2 (0.3)	0	2 (1.9)	0
Admission to an intensive care unit due to SARS-CoV-2	4 (0.5)	0	5 (4.7)	0
Hospitalization due to SARS-CoV-2	27 (3.6)	1 (1.8)	22 (20.8)	1 (50.0)
Heart Rate ≥125 beats per minute	5 (0.7)	0	5 (4.7)	0
Hepatic dysfunction	0	0	0	0
Neurologic dysfunction	2 (0.3)	0	2 (1.9)	0
Oxygen saturation ≤93‡	97 (13.0)	3 (5.5)	94 (88.7)	2 (100)
Oxygen saturation SpO2 ≤93% on room air at sea level	98 (13.2)	3 (5.5)	94 (88.7)	2 (100)
PaO2/FIO2 ratio <300 mmHg	1 (0.1)	0	1 (0.9)	0
Respiratory failure	4 (0.5)	1 (1.8)	5 (4.7)	1 (50.0)
Respiratory rate ≥30 per minute	4 (0.5)	0	3 (2.8)	0
Systolic blood pressure <90 mmHg, diastolic blood Pressure <60 mmHg	14 (1.9)	0	9 (8.5)	0
Vasopressors required	0	0	0	0
Deaths	4 (0.5)	0	2 (1.9)	0

* Adjudicated cases with the censoring rules for efficacy analyses. Covid-19 case based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participant was censored at the date with positive RT-PCR or Elecsys. All symptoms reported are included, regardless of relationship with the positive RT-PCR test used to define the COVID-19 case. 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. †Derived based on temperature collected on case report form (CRF) symptoms. ‡Derived based on oxygen saturation collected on CRF symptom log page. Data-cutoff date: March 26, 2021.

Table S32. Baseline Characteristics of Participants with Covid-19* Based on Adjudicated Cases, Per-protocol Set

Characteristics n (%)	All Covid-19 cases*		Severe Covid-19* cases	
	Placebo N=744	mRNA-1273 N=55	Placebo N=106	mRNA-1273 N=2
Age, years				
Mean (range)	48 (18-87)	49 (24-74)	53 (22-85)	63 (53-72)
18-65	44 (18-64)	45 (24 -64)	47 (22-63)	53 (53-53)
≥65 ys	71 (65-87)	70 (66-74)	71 (65-85)	72 (72-72)
Sex, n (%)				
Male	378 (50.8)	30 (54.5)	50 (47.2)	1 (50.0)
Female	366 (49.2)	25 (45.5)	56 (52.8)	1 (50.0)
Age and Health Risk for Severe Covid-19†				
≥18 and <65 Years and Not at Risk	482 (64.8)	34 (61.8)	43 (40.6)	1 (50.0)
≥18 and <65 Years and at Risk	162 (21.8)	12 (21.8)	33 (31.1)	0
≥65 Years	100 (13.4)	9 (16.4)	30 (28.3)	1 (50.0)
Risk Factor for Severe Covid-19 at Screening‡				
Chronic Lung Disease	30 (4.0)	4 (7.3)	9 (8.5)	1 (50.0)
Significant Cardiac Disease	30 (4.0)	4 (7.3)	9 (8.5)	0
Severe Obesity	75 (10.1)	7 (12.7)	15 (14.2)	0
Diabetes	72 (9.7)	3 (5.5)	22 (20.8)	0
Liver Disease	5 (0.7)	1 (1.8)	1 (0.9)	0
Human Immunodeficiency Virus Infection	4 (0.5)	0	1 (0.9)	0
At Risk for Severe Covid-19 at Screening, n (%)				
Yes	177 (23.8)	16 (29.1)	44 (41.5)	1 (50.0)
One Risk Factor for Severe Covid-19	143 (19.2)	14 (25.5)	32 (30.2)	1 (50.0)
Two or More Risk Factors for Severe Covid-19	34 (4.6)	2 (3.6)	12 (11.3)	0
No	567 (76.2)	39 (70.9)	62 (58.5)	1 (50.0)
Age and Risk for Severe Covid-19, n (%)§				
≥18 and <65 Years and Not at Risk	501 (67.3)	35 (63.6)	46 (43.4)	1 (50.0)
≥18 and <65 Years and at Risk	143 (19.2)	11 (20.0)	30 (28.3)	0
≥65 Years and Not at Risk	66 (8.9)	4 (7.3)	16 (15.1)	0
≥65 Years and at Risk	34 (4.6)	5 (9.1)	14 (13.2)	1 (50.0)
Race, n (%)				
White	631 (84.8)	48 (87.3)	86 (81.1)	2 (100)
Black or African American	41 (5.5)	4 (7.3)	6 (5.7)	0
Asian	29 (3.9)	1 (1.8)	4 (3.8)	0
American Indian or Alaska Native	5 (0.7)	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Multiracial	8 (1.1)	1 (1.8)	3 (2.8)	0
Other	19 (2.6)	1 (1.8)	4 (3.8)	0
Not Reported	5 (0.7)	0	2 (1.9)	0
Unknown	6 (0.8)	0	1 (0.9)	0

Ethnicity, n (%)				
Hispanic or Latino	177 (23.8)	10 (18.2)	21 (19.8)	1 (50.0)
Not Hispanic or Latino	563 (75.7)	45 (81.8)	84 (79.2)	1 (50.0)
Not Reported	2 (0.3)	0	0	0
Unknown	2 (0.3)	0	1 (0.9)	0
Race and Ethnicity Group, n (%)‖				
Minority	220 (29.6)	14 (25.5)	27 (25.5)	1 (50.0)
Non-minority	524 (70.4)	41 (74.5)	79 (74.5)	1 (50.0)
Race and Ethnicity Group, n (%)**				
White	488 (65.6)	39 (70.9)	72 (67.9)	1 (50.0)
Communities of Color	256 (34.4)	16 (29.1)	34 (32.1)	1 (50.0)
Body Mass Index (kg/m^2)				
n	741	55	105	2
Mean (SD)	30.5 (7.0)	31.8 (6.9)	32.0 (7.2)	31.9 (3.1)

*With the censoring rules for efficacy analyses. Covid-19 case based on eligible symptoms and positive RT-PCR within 14 days. If a participant had a positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participants was censored at the date with positive RT-PCR or Elecsys. Percentages are based on the number of participants in per-protocol set with Covid-19 based on adjudication committee assessments starting 14 days after second injection. †Based on stratification factor from IRT, participants <65 years old were categorized as at risk for severe Covid-19 illness if they have at least 1 of the risk factors specified in the study protocol at screening. ‡ Participants could be under one or more categories and are counted once at each category. §Age and health risk for severe Covid-19 were derived from age and risk factors collected on case report forms. ¶Baseline SARS-CoV-2 Status defined as positive if there was immunologic or virologic evidence of prior Covid-19 (positive RT-PCR test or positive Elecsys result at day 1) and negative defined as negative RT-PCR test and negative Elecsys result at day 1. ‖Minority defined as Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians, and other Pacific Islanders, and Non-Minority includes all the others whose race or ethnicity is not unknown, unreported or missing. **White defined as White and non-Hispanic, and Communities of Color includes all the others whose race or ethnicity is not unknown, unreported or missing. Data-cutoff date: March 26, 2021.

Table S33. Exploratory Analysis in Participants with One Injection 14 days First Injection, mITT

Covid-19 cases	Placebo N=425	mRNA-1273 N=334
Covid-19*, adjudicated cases n (%)	45 (10.6)	4 (1.2)
Incidence rate per 1000 person-year (95% CI)	471.1 (343.6-630.4)	49.6 (13.5-127.1)
Severe Covid-19 n (%)	6 (1.4)	1 (0.3)
Incidence rate per 1000 person-year (95% CI)	54.4 (19.9-118.4)	12.0 (0.3-67.0)

*With the censoring rules for efficacy analyses. Covid-19 case based on eligible symptoms and positive RT-PCR within 14 days. If a participant had a positive RT-PCR at pre-dose 2 visit (day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a Covid-19 case, the participant was censored at the date of positive RT-PCR or Elecsys. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are 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. Person-years defined as the total years from randomization date to the date of Covid-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Data-cutoff date: March 26, 2021.