



PRIMARY ANALYSIS CLINICAL STUDY REPORT

A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

PROTOCOL NUMBER mRNA-1273-P201

Name of Test Product: mRNA-1273
Indication: COVID-19
ClinicalTrials.gov Identifier: NCT04405076

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Drug Development Phase: 2a
Study Initiation Date: First participant, first visit: 22 May 2020
Primary Analysis Cutoff: Through Day 57 (database lock 05 Nov 2020)
Sponsor Medical Officer: Roderick McPhee, MD, PhD
Date of Report: 23 February 2021

The study was conducted according to the International Council for Harmonisation
harmonised tripartite guideline E6(R2): Good Clinical Practice.

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Synopsis

Title of Study: A Phase 2a, Randomized, Observer-Blind, Placebo-Controlled, Dose-Confirmation Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of mRNA-1273 SARS-CoV-2 Vaccine in Adults Aged 18 Years and Older

Investigators: This was a multicenter study.

Study Centers: This study was conducted at 8 study sites in the United States.

Publication (Reference): Chu L, McPhee R, Huang W, Bennett H, Pajon R, Nestorova B, Leav B on behalf of the mRNA-1273 Study Group. A preliminary report of a randomized controlled phase 2 trial of the safety and immunogenicity of mRNA-1273 SARS-CoV-2 vaccine. Vaccine 2021. DOI: 10.1016/j.vaccine.2021.02.007.

Study Period: 22 May 2020 (first participant, first visit) to 05 Nov 2020 (database lock).

Drug Development Phase: 2a

Objectives and Endpoints:

Objectives	Endpoints
Primary safety To evaluate the safety and reactogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart	- Solicited local and systemic ARs through 7 days after each injection - Unsolicited AEs through 28 days after each injection - MAAEs through the entire study period - SAEs throughout the entire study period - Safety laboratory abnormalities at Day 29 and Day 57 (Cohort 2 only) - Vital sign measurements and physical examination findings
Primary immunogenicity To evaluate the immunogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, as assessed by the level of specific bAb	Level of SARS-CoV-2-specific bAb measured by ELISA on Day 1, Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13)

Objectives	Endpoints
Secondary	
To evaluate the immunogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, as assessed by the titer of nAb	- Titer of SARS-CoV-2-specific nAb on Day 1, Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13) - Seroconversion on Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13) as measured by an increase of SARS-CoV-2-specific nAb titer either from below the LLOQ to equal to or above LLOQ, or a 4-times higher titer in participants with pre-existing nAb titers
Exploratory	
- To profile S protein-specific serum Ig class and subclass and nAb in serum - To describe the ratio or profile of specific bAb relative to nAb in serum - To describe initial immunogenicity responses following the first dose (Day 1) and prior to the second dose (Day 29) - To characterize the clinical profile and immune response of participants infected by SARS-CoV-2 - To evaluate the effect of the mRNA-1273 vaccine on the incidence of SARS-CoV-2 infection	- Serum titers of S protein-specific binding Ig assessed by class and subclass and nAb in serum - Relative amounts or profiles of S protein-specific bAb and specific nAb levels/titers in serum - Clinical severity and immune response of participants infected by SARS-CoV-2 - Number of cases and incidence of confirmed SARS-CoV-2 infection using an assay designed to detect nonvaccine antigens of SARS-CoV-2

Abbreviations: AE=adverse event; AR=adverse reaction; bAb=binding antibody; ELISA=enzyme-linked immunoabsorbent assay; Ig=immunoglobulin; LLOQ=lower limit of quantification; M=month; MAAE=medically attended adverse event; nAb=neutralizing antibody; S=spike; SAE=serious adverse event; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

Methodology: The mRNA-1273-P201 was a randomized, observer-blind, and placebo-controlled study, with adult participants at least 18 years of age.

This primary analysis clinical study report (CSR) provides the primary analysis of safety and immunogenicity data through Day 57 (data cutoff date of 05 Nov 2020). The end-of-study (EOS) CSR will include final analysis of all endpoints and will be completed after all participants have completed the Month 13 study procedures and the database is cleaned and locked.

Two dose levels of mRNA-1273, 50 µg and 100 µg, were evaluated in this study, based in part on initial safety data from the Phase 1 Division of Microbiology and Infectious Diseases study of mRNA-1273. The study included 2 age cohorts: Cohort 1 ≥ 18 to < 55 years old (300 participants planned) and Cohort 2 ≥ 55 years old (300 participants planned). Eligible participants (approximately 600 planned) received either mRNA-1273 or saline placebo control according to a 1:1:1 randomization ratio; ie, within each age cohort, 100 participants received mRNA-1273 50 µg, 100 participants received mRNA-1273 100 µg, and 100 participants received saline placebo.

The study was initiated with a parallel enrollment of all 300 participants in Cohort 1 (≥ 18 to < 55 years old) and a sentinel group of 50 participants in Cohort 2 (≥ 55 years old) receiving study treatment. Before initiating study treatment of the remaining participants in Cohort 2, safety data through Day 7 from the sentinel group of Cohort 2 and all available data from Cohort 1 were reviewed by the Safety Monitoring Committee (SMC). No safety concerns were found, and Cohort 2 enrollment continued.

The full study comprised 10 scheduled study site visits: Screening, Day 1, Day 8, Day 15, Day 29 (Month 1), Day 36, Day 43, Day 57 (Month 2), Day 209 (Month 7), and Day 394 (Month 13). Scheduled participant contact continued approximately every 2 weeks after Day 57 to collect medically attended adverse events (MAAEs), adverse events (AEs) leading to withdrawal, serious AEs (SAEs), concomitant medications associated with these events, receipt of nonstudy vaccinations, exposure to someone with known coronavirus disease 2019 (COVID-19) or severe acute respiratory syndrome coronavirus that causes COVID-19 (SARS-CoV-2) infection, and participant experience of COVID-19 symptoms as indicated in the Schedule of Events. Every 4 weeks from Day 71 through Day 183 and from Day 223 through Day 363, each participant completed a questionnaire in an electronic diary (eDiary) that was reviewed by study site personnel. Safety telephone calls occurred every 4 weeks from Day 85 through Day 197 and from Day 237 through Day 377. At study completion, the study duration for each participant will be approximately 14 months: a screening period of up to 1 month and a study period of 13 months, which includes the first dose of investigational product (IP) on Day 1 and the second dose on Day 29. A participant's final visit will be Day 394 (Month 13), 12 months after the second dose of the IP on Day 29 (Month 1).

To test for the presence of SARS-CoV-2, nasopharyngeal swab samples were collected at Day 1, Day 29, and Day 57. During the course of the study, participants meeting prespecified disease criteria that suggested possible SARS-CoV-2 infection were asked to contact the study site to arrange for a prompt, thorough, and careful assessment.

Each participant received 2 injections of mRNA-1273 or placebo by 0.5 mL intramuscular (IM) injection on Day 1 and Day 29. Investigational product accountability, dose preparation, and administration were performed by unblinded pharmacy personnel who did not participate in any other aspects of the study. The remainder of the study staff, all participants, and Sponsor personnel (or its designees) remained blinded to dosing assignment.

All participants were followed for safety and reactogenicity and provided pre- and postinjection blood specimens for immunogenicity through 12 months after the last dose of IP. An SMC met

on a regular basis to assess safety throughout the study conduct and could have convened on an ad hoc basis if study pause rules were met.

The EOS was defined as the release of the last testing result of samples collected at Visit 9 or the completion of the last participant's last visit, whichever occurred later. Participants will be considered to have completed the study if they completed the final visit on Day 394 (Month 13), 12 months after the second injection on Day 29 (Month 1).

At each dosing visit, participants were instructed (Day 1) or reminded (Day 29) how to document and report solicited adverse reactions (ARs) within an eDiary application and/or device provided to them. Solicited ARs were assessed for 7 days (the day of injection and the following 6 days) after each injection and unsolicited AEs were assessed for 28 days after each injection; SAEs and MAAEs were assessed throughout the study.

Participants provided blood samples for the assessment of safety and immunogenicity at scheduled study visits. Blood samples were drawn from participants in case of any medical concerns according to the investigator's judgment. In addition, participants provided blood samples at unscheduled visits for acute respiratory symptoms.

Number of Participants (Planned and Analyzed): Approximately 600 participants were planned and were enrolled in this study: 400 participants were planned and received mRNA-1273, 200 participants in each dose level, or 100 participants in each age cohort and dose level; and 200 participants were planned and received placebo, with 100 participants in each age cohort.

All 600 participants in the Randomized Set received IP and were included in the Safety Set and the Solicited Safety Set. The majority of participants who received mRNA-1273 or placebo were included in the Per-Protocol (PP) Set for SARS-CoV-2-specific binding antibody (bAb) (374/400 [93.5%] and 186/200 [93.0%], respectively), with no notable differences observed for the Day 29 and Day 57 analyses. Similarly, the majority of participants who received mRNA-1273 or placebo were included in the PP Set for SARS-CoV-2-specific neutralizing antibody (nAb) from the First Lot (365/400 [91.3%] and 181/200 [90.5%], respectively), with no notable differences observed for the Day 29 and Day 57 analyses.

Diagnosis and Main Criteria for Inclusion and Exclusion: Participants eligible for enrollment in this study included males or females (those of nonchildbearing and childbearing potential) 18 years of age or older at the time of consent who were in good general health with a body mass index of 18 kg/m² to 30 kg/m² (inclusive); male participants and female participants of

childbearing potential agreed to comply with protocol-defined contraception requirements. Participants were excluded if they had a known history of SARS-CoV-2 infection or known exposure to someone with SARS-CoV-2 infection or COVID-19, had traveled outside of the United States in the 28 days prior to the Screening Visit, were a healthcare worker or member of emergency response team, resided in a nursing home, or had any exclusionary pre-existing condition or test result.

Test Product, Dose and Mode of Administration, Batch Number(s): mRNA-1273 was administered as an 0.5 mL IM injection containing 50 or 100 µg of mRNA-1273 (Lot Numbers: 8520100102 and 8520100103) into the deltoid muscle (preferably the nondominant arm) on a 2-dose injection schedule on Day 1 and Day 29. The second dose of IP should have been administered in the same arm as the first dose.

Control Product, Dose and Mode of Administration, Batch Number(s): Placebo (0.9% sodium chloride) administered as an 0.5 mL IM injection into the deltoid muscle on an identical schedule as mRNA-1273.

Duration of Treatment: Participants received the randomly assigned IP of mRNA-1273 or placebo as 2 injections administered 28 days apart (Day 1 and Day 29).

Statistical Methods:

Safety

All safety analyses were conducted on the Safety Set, except summaries of solicited ARs, which were based on the Solicited Safety Set. Unsolicited AEs and medical history were coded by system organ class (SOC) and preferred term (PT) according to the Medical Dictionary for Regulatory Activities (MedDRA) version 23.0.

All solicited ARs (local and systemic) were considered causally related to injection.

All solicited ARs analyses were summarized by overall treatment group and by age cohort for the first injection, second injection, and any injection, unless otherwise specified. The following summary tables were provided:

- The number and percentage of participants who reported each individual solicited local AR (severity $\geq$ grade 1) and solicited systemic AR (severity $\geq$ grade 1) during the 7-day follow-up period after each injection were summarized by severity grade.

- The number and percentage of participants who reported each individual solicited AR were summarized by severity grade and day of reporting, within this summary the number and percentage of participants experiencing fever ($\geq 38.9^{\circ}\text{C}/102.1^{\circ}\text{F}$; oral, axillary, or tympanic route) were summarized by severity grade.
- The number and percentage of participants with onset of individual solicited AR were summarized by study day relative to the corresponding injection (Day 1 through Day 7), where onset of individual solicited AR was defined as the time point after each injection at which the respective solicited AR first occurred.
- The number of days reporting each solicited AR was summarized descriptively and summarized by the following time windows: 1 to 2 days, 3 to 4 days, 5 to 6 days, and ≥ 7 days.
- The number and percentage of participants who reported solicited rash and lymphadenopathy, as assessed by healthcare provider (HCP), were summarized by severity grade.

In the summary by severity grade and summary by severity grade and day of reporting, a 2-sided 95% exact confidence interval (CI) using the Clopper-Pearson method was provided for the percentage of participants who reported any solicited local AR, solicited systemic AR, or any solicited AR. Within each summary of systemic ARs, the number and percentage of participants experiencing fever ($\geq 38.9^{\circ}\text{C}/102.1^{\circ}\text{F}$; oral, axillary, or tympanic route) were summarized by severity grade.

All summary tables for unsolicited treatment-emergent AEs (TEAEs; except for the overall summary of TEAEs) were presented by SOC and PT for TEAEs with counts of participants included. All safety analyses were summarized by overall treatment group and by age cohort, unless otherwise specified. Unsolicited TEAEs were summarized separately by stage (28 days after any vaccination stage and overall stage [Day 1 to Day 57 for this primary analysis; the EOS CSR will provide overall stage Day 1 to Day 394]). Participants with multiple occurrences of the same AE or a continuing AE were counted once in summaries within each SOC and PT. Participants who reported multiple events under the same SOC and/or PT were presented in summaries according to the highest severity (the strongest relationship).

The following summaries of unsolicited TEAEs (number and percentage) for each stage were included: overview summary of TEAEs, all unsolicited TEAEs, all unsolicited treatment-related TEAEs, all serious TEAEs, all treatment-related serious TEAEs, all unsolicited TEAEs leading to discontinuation from participation in the study, all unsolicited severe TEAEs, all unsolicited treatment-related TEAEs, all unsolicited TEAEs that were MAAEs. A summary of TEAEs by

SOC, PT, and severity (mild, moderate, and severe) using frequency counts and percentages was provided for all unsolicited TEAEs and all unsolicited treatment-related TEAEs.

For continuous hematology, serum chemistry, and coagulation measurements, the observed values and changes from baseline were summarized at each visit by treatment group for Cohort 2. The number and percentage who had any abnormal result based on toxicity grades in hematology, serum chemistry, or coagulation measurements also were summarized by visit and treatment group for Cohort 2. Shift from baseline in the toxicity grades to the worst postbaseline result in the vaccination stage was summarized by treatment group for Cohort 2.

Observed values and changes from baseline for all vital sign measurements were summarized at each visit by overall treatment group and by age cohort. Shift from baseline in the toxicity grades at each visit and shift from baseline in the toxicity grades to the worst postbaseline result also were summarized by overall treatment group and by age cohort.

Immunogenicity

The analyses of immunogenicity were based on the PP Set and were performed by treatment group for each age cohort separately. For each analysis listed below, the 95% CIs were calculated based on the t-distribution of the log-transformed values then back transformed to the original scale for presentation and descriptive statistics at each time point were the number of participants, median, minimum, and maximum (unless otherwise specified). For each group, the following evaluations were performed at each time point at which blood samples were collected for immunogenicity (unless otherwise specified):

- The geometric mean (GM) level of SARS-CoV-2-specific bAb levels with corresponding 95% CI were provided at each time point. The GM level and corresponding 95% CI were plotted at each time point.
- The GM fold-rise (GMFR) of SARS-CoV-2-specific bAb levels with corresponding 95% CI were provided at each postbaseline time point over pre-injection baseline at Day 1. The GMFR and corresponding 95% CI were plotted at each time point.
- The GM titer of SARS-CoV-2-specific nAb titers with corresponding 95% CI were provided at each time point.
- The GMFR of SARS-CoV-2-specific nAb titers with corresponding 95% CI were provided at each postbaseline time point over pre-injection baseline at Day 1. The proportion of participants with fold-rise ≥ 2 , fold-rise ≥ 3 , and fold-rise ≥ 4 of serum SARS-CoV-2-specific nAb titers from Day 1 (baseline) at each postinjection time points were tabulated with 2-sided 95% Clopper-Pearson CIs.

- The proportion of participants with seroconversion were tabulated with 2-sided 95% Clopper-Pearson CIs at each postbaseline time point. Seroconversion at a participant level was defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively) or a 4-times higher titer ratio in participants with pre-existing nAb titers.
- The GM level, GM titer, and GMFR with corresponding 95% CI were also evaluated using an analysis of covariance model with baseline level/titer as a covariate and age cohort as a factor in the analysis in the overall group. The model was conducted based on the log-transformed values then back transformed to the original scale for presentation.
- Additional sensitivity analysis of immunogenicity data was conducted for the above endpoints using the “adjusted” PP Set based on the more rigid visit window, -3/+7 for the Day 29 visit, as appropriate.

Summary of Results:

Participant Disposition: In each treatment group, all participants received the first injection of IP and the majority of participants in both age cohorts (> 95%) received the second injection. Seven of 400 (1.8%) participants who received mRNA-1273 (5/200 [2.5%] and 2/200 [1.0%] in the mRNA-1273 50 and 100 µg groups, respectively) and 6 of 200 (3.0%) participants who received placebo discontinued the IP. Six and 4 participants in the mRNA-1273 overall group and placebo group, respectively, discontinued from the study.

The reasons for mRNA-1273 discontinuation were AEs (other), lost follow-up, and “other” reasons (each 2/400 [0.5%]) and withdrawal of consent (1/400 [0.3%]). The reasons for discontinuation of placebo were AE (COVID-19 infection; 1/200 [0.5%]), lost to follow-up (3/200 [1.5%]), and “other” reasons (2/200 [1.0%]; related to false-positive COVID-19 results).

Drug Exposure: A total of 600 participants (100%) received the first injection and 587 participants (97.8%) received the second injection.

Demography and Baseline Characteristics: The participants in the Safety Set were approximately two-thirds female (390/600 [65.0%] overall) and mostly White (569/600 [94.8%] overall) and not of Hispanic or Latino descent (552/600 [92.0%]), with a mean (standard deviation) age of 50.8 (15.85) years and an age range of 18 to 87 years. No apparent differences were observed in baseline demographics across treatment groups. Participant demographics for the Randomized Set and the primary analysis PP Sets for SARS-CoV-2-specific bAb and nAb were comparable to those observed for the Safety Set.

Safety: In this primary analysis, the mRNA-1273 vaccine, administered as 2 doses (50 µg or 100 µg) 28 days apart, demonstrated an acceptable safety profile in the participant population enrolled in this study in both age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).

The following are the key safety and reactogenicity findings supporting the safety conclusion:

Solicited Adverse Reactions

- More participants reported any solicited ARs within 7 days of any injection in the mRNA-1273 overall group (93.5%) than in the placebo group (51.5%).
- The incidence of solicited local ARs and systemic ARs within 7 days of any injection were both higher for participants who received mRNA-1273 (overall; 89.0% and 78.8%, respectively) than for those who received placebo (19.0% and 45.5%, respectively).
- The incidence of solicited local ARs within 7 days after injection was comparable after the first and second injections for the mRNA-1273 overall group (74.8% versus 83.0%). In the mRNA-1273 overall group, the incidence of solicited systemic ARs was numerically higher after the second injection than after the first injection (73.3% and 43.1%, respectively).
- Across all treatment groups, the majority of solicited ARs were grade 1 or grade 2; no grade 4 solicited ARs were reported. More grade 3 solicited ARs were reported in the mRNA-1273 overall group (14.3%) than in the placebo group (3.0%). In the mRNA-1273 overall group, most grade 3 solicited ARs occurred after the second injection and the most common solicited ARs were fatigue, myalgia, and headache.
- In the mRNA-1273 overall group, the most common solicited local AR was pain: 74.4% after the first injection and 82.4% after the second injection.
- The most common solicited systemic ARs in the mRNA-1273 overall group were headache (25.3%) and fatigue (24.6%) after the first injection and fatigue (59.0%), headache (50.9%), myalgia (47.1%), arthralgia (36.9%), and chills (32.3%) after the second injection.
- There was a dose-dependent increase in pain between the mRNA-1273 50 µg and 100 µg groups after the first injection (65.5% and 83.4%, respectively).
- Fever, fatigue, myalgia, arthralgia, nausea/vomiting, and chills showed a dose-dependent increase between the mRNA-1273 50 µg and 100 µg groups after the second injection but not after the first injection.

- After the first injection, the incidence of any solicited ARs and solicited local ARs was (88.0% and 84.0%, respectively) in the mRNA-1273 100 µg group and (71.0% and 65.5%, respectively) in mRNA-1273 50 µg group.
- In the mRNA-1273 overall group, the incidence of any solicited ARs, solicited local ARs, and solicited systemic ARs after the first injection were 85.0%, 80.0%, and 49.0%, respectively, in Cohort 1 (≥ 18 to < 55 years) and 74.0%, 69.5%, and 37.2%, respectively, in Cohort 2 (≥ 55 years).
- In the mRNA-1273 overall group, the incidence of any solicited ARs, solicited local ARs, and solicited systemic ARs after the second injection was 90.8%, 85.2%, and 75.0%, respectively, in Cohort 1 (≥ 18 to < 55 years) and 86.8%, 80.7%, and 71.6%, respectively, in Cohort 2 (≥ 55 years).
- In the mRNA-1273 overall and placebo groups, participants most often reported solicited local ARs and systemic ARs within the first 3 days after any injection, with an onset of each on Day 1 or Day 2 after any injection in both groups. The mean number of days solicited local ARs and systemic ARs were reported within the 7 days after any injection was 2.9 and 3.1 days, respectively, in the mRNA-1273 overall group and 2.0 and 2.4 days, respectively, in the placebo group.
- The incidence of solicited ARs that were ongoing 7 days after any injection and reported as TEAEs in the mRNA-1273 overall group was 28/400 (7.0%) and that in the placebo group was 8/200 (4.0%); no solicited AR met the SAE criteria. In the mRNA-1273 overall group or placebo group, the highest incidence ($> 1.0\%$) of solicited ARs ongoing 7 day after any injection and reported as TEAEs (by decreasing incidence in the mRNA-1273 overall group) were fatigue (3.5% and 2.5%, respectively), headache (2.8% and 0.5%, respectively), and arthralgia and myalgia (both 1.8% and 1.0%, respectively).
- One participant in the mRNA-1273 100 µg group discontinued vaccination due to three grade 3 solicited ARs (fatigue, myalgia, and arthralgia).
- Ad hoc analysis of medication use for pain or fever, which was based on patient-reported use in Diary entries (after any, first, or second injection), demonstrated that more participants reported medication use in the mRNA-1273 groups (50 µg, 100 µg) than the placebo group (39.5%, 51.5%, and 14.5%, respectively) after any injection.

Unsolicited TEAEs

- The incidence of unsolicited TEAEs up to 28 days after any IP administration was comparable between the mRNA-1273 overall group (28.3%) and the placebo group (25.5%), with no dose-dependent increase with mRNA-1273 dose (50 and 100 µg both approximately 28%).
- The incidence of the most common unsolicited TEAEs was comparable between the mRNA-1273 overall group and placebo group. The common TEAEs with the highest incidence ($\geq 2\%$) in the mRNA-1273 overall group or placebo group (by decreasing incidence in the mRNA-1273 overall group) were headache (3.8% and 2.5%, respectively), fatigue (3.5% and 3.0%, respectively), arthralgia (2.3% and 2.0%, respectively), and myalgia (2.0% and 1.5%, respectively).
- Most unsolicited TEAEs reported up to 28 days after any injection in both the mRNA-1273 overall and placebo groups were mild or moderate in severity. Few participants reported severe unsolicited TEAEs: 3.0% in the mRNA-1273 overall group and 2.0% in the placebo group, and approximately half of the reported severe unsolicited TEAEs in the each treatment group were considered related to IP.
- More participants reported treatment-related unsolicited TEAEs in the mRNA-1273 overall group (10.8%) than in the placebo group (6.5%). The treatment-related TEAEs with the highest incidence ($> 1\%$) in mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were fatigue (3.3% and 3.0%, respectively), headache (2.8% and 0.5%, respectively), arthralgia (1.8% and 2.0%, respectively), myalgia (1.8% and 1.0%, respectively), and injection site pain (1.3% and 0.5%, respectively). No treatment-related SAEs were reported through Day 57.
- Of the 7 participants with confirmed SARS CoV 2 infection, 3 participants were symptomatic (2 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group) and 4 participants remained asymptomatic (3 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group). No cases of asymptomatic SARS-CoV-2 infection or symptomatic COVID-19 were reported in the 100-µg group. All participants with SARS-CoV-2 infection or COVID-19 reported TEAEs of COVID-19; none were severe, all resolved, and none were considered related to the IP.
- No deaths occurred up to the data cutoff for this primary analysis and one participant (mRNA-1273 50 µg) had a serious TEAE (pneumonia), which occurred > 28 days after any IP administration and was considered not related to IP.
- Due to positive COVID-19 on Day 6, one participant in the mRNA-1273 50 µg group discontinued IP administration. One participant each in the mRNA-1273 50 µg and

placebo groups had a TEAE that led to IP discontinuation that occurred > 28 days after any IP administration; both TEAE were considered not related to IP.

- No unsolicited TEAE led to study discontinuation from Day 1 through Day 57.
- The incidence of MAAEs up to 28 days after any injection was comparable in the mRNA-1273 overall group (9.8%) and placebo group (8.5%). Few participants in any treatment group had MAAEs considered related to IP.
- As identified from ad hoc analysis based on a Standardized MedDRA Query (SMQ) search of the database, the incidence of hypersensitivity was comparable between the mRNA-1273 overall group (2.8%) and placebo group (3.0%). No participants had AEs of special interest in the SMQs of vasculitis, peripheral neuropathy, demyelination, or convulsions. One participant in the mRNA-1273 100 µg group had an AE of special interest in the arthritis SMQ (gout).
- No treatment-related, dose-related, or clinically relevant trends in changes from baseline from Day 1 through Day 57 were observed for the hematology, coagulation, and chemistry laboratory test results of participants in Cohort 2.
- Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed from Day 1 and through Day 57 were similar to those observed at baseline, with no notable trends or differences between any of the treatment groups.
- The only notable difference by age cohorts was for treatment-related TEAEs in the mRNA-1273 100 µg group, with a higher incidence in Cohort 1 (18.0%) than in Cohort 2 (9.0%). In addition, in Cohort 1, more participants in the mRNA-1273 100 µg group reported treatment-related unsolicited TEAEs than participants in the mRNA-1273 50 µg and placebo groups (18.0%, 7.0%, and 6.0%, respectively).

Immunogenicity: In this primary analysis, mRNA-1273 50 µg and 100 µg both induced anti-SARS-CoV-2 spike bAbs and nAbs at Day 29 (28 days after the first injection) that peaked at Day 43 and persisted through Day 57 (14 and 28 days, respectively, after the second injection), with generally comparable immunogenicity demonstrated in each age cohort.

The following are the key findings supporting the immunogenicity conclusions:

- The GMFRs (95% CI) of VAC58 spike immunoglobulin G (IgG) antibodies at Day 29 were 4.29 (3.87, 4.76) in the mRNA-1273 100 µg group and 3.36 (3.05, 3.69) in the mRNA-1273 50 µg group, and were 33.51 (30.37, 36.96) in the mRNA-1273 100 µg group compared with 27.46 (24.86, 30.33) in the mRNA-1273 50 µg group at Day 43.

- In both mRNA-1273 50 and 100 µg groups, the GMFR in VAC58 spike IgG antibody levels were > 27 at Day 43 and > 20 at Day 57.
- The GMFRs (95% CI) of VAC58 spike IgG antibodies trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (4.29 [3.87, 4.76] and 3.36 [3.05, 3.69], respectively), Day 43 (33.51 [30.37, 36.96] and 27.46 [24.86, 30.33, respectively) and Day 57 (25.04 [22.51, 27.86] and 20.39 [18.31, 22.70], respectively). In Cohort 1, the GMFRs (95% CI) were generally higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (5.26 [4.57, 6.06] and 3.65 [3.20, 4.16], respectively), Day 43 (38.47 [34.54, 42.85] and 26.82 [23.46, 30.67], respectively), and Day 57 (29.13 [25.68, 33.03] and 20.70 [17.92, 23.90], respectively). No apparent trend was observed between the two mRNA-1273 doses in Cohort 2.
- Both mRNA-1273 doses induced nAb responses, assessed by microneutralization (MN) endpoint titers and MN₅₀ at each postbaseline visit. While no formal statistical testing was done, nAb responses were generally comparable in participants who received the mRNA-1273 100 µg and the 50 µg dose at all time points.
- At Day 29 (28 days after the first injection), the MN endpoint GMFRs (95% CI) were 5.59 (4.65, 6.71) in the mRNA-1273 50 µg group and 7.46 (6.32, 8.81) in the mRNA-1273 100 µg group. At both Day 43 and Day 57, the GMFR was > 53 in each mRNA-1273 dose group.
- At Day 29 (28 days after the first injection), the MN₅₀ GMFRs (95% CI) were 3.75 (3.16, 4.45) in the mRNA-1273 50 µg group and 4.97 (4.23, 5.85) in the mRNA-1273 100 µg group. At both Day 43 and Day 57, the GMFR was > 35 in each mRNA-1273 dose group.
- At Day 29, the seroconversion rates based on the MN endpoint titers and MN₅₀ titers were 78.0% and 65.5%, respectively, in the mRNA-1273 50 µg group and 88.9% and 76.7%, respectively, in the mRNA-1273 100 µg group.
- At Day 43 and Day 57, 100% of participants met seroconversion criteria based on MN endpoint titers and MN₅₀ titers in both mRNA-1273 dose groups.
- Generally, no apparent difference in MN endpoint titers and MN₅₀ titers was observed between Cohort 1 and Cohort 2.

Conclusions: This study was designed to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1273 vaccine, administered in 2 doses (50 µg or 100 µg) 28 days apart.

- mRNA-1273 demonstrated an acceptable safety profile in the participant population enrolled in this study at both dose levels in two age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).
- Vaccination with mRNA-1273 resulted in significant immune responses to SARS-CoV-2 in participants 18 years and older at both dose levels, confirming the selection of the 100- μ g dose that was brought forward in the pivotal Phase 3 (COVE) study.

This report is based on the primary analysis through Day 57. The full study analyses will be presented in the end-of-study CSR. The 13-month end-of-study assessment of this study and the ongoing Phase 3 (COVE) study may provide additional longer-term data on the safety and effectiveness of mRNA-1273 vaccine.

Date of This Report: 23 February 2021

List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	adverse event
ANCOVA	analysis of covariance
AR	adverse reaction
bAb	binding antibody
BMI	body mass index
CDC	Centers for Disease Control and Prevention (US)
CFR	Code of Federal Regulations (US)
CI	confidence interval
CoV	coronavirus
COVID-19	coronavirus disease 2019
CSR	clinical study report
CT	cycle threshold
DMID	Division of Microbiology and Infectious Diseases
DP	Drug Product
DSPC	1,2-distearoyl-sn-glycero-3-phosphocholine
eCRF	electronic case report form
eDiary	electronic diary
ELISA	enzyme-linked immunosorbent assay
EOS	end of study
FAS	Full Analysis Set
FDA	Food and Drug Administration (US)
FSH	follicle-stimulating hormone
GCP	Good Clinical Practice
GM	geometric mean
GMFR	geometric mean fold-rise
GMT	geometric mean titer
HCP	healthcare practitioner
HIV	human immunodeficiency virus
ICF	informed consent form
IgG	immunoglobulin G
ICH	International Council for Harmonisation
IM	intramuscular
IP	investigational product

Abbreviation	Definition
IRB	institutional review board
IRT	interactive response technology
LLOQ	lower limit of quantification
LNP	lipid nanoparticle
MAAE	medically attended adverse event
MedDRA	Medical Dictionary for Regulatory Activities
MERS	Middle East Respiratory Syndrome
MN	microneutralization
mRNA	messenger RNA
nAb	neutralizing antibody
NP	nucleocapsid
OD	optical density
PCR	polymerase chain reaction
PEG2000-DMG	1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000
PP	Per-Protocol
PT	preferred term
RT-PCR	reverse transcription polymerase chain reaction
SAE	serious adverse event
SAP	Statistical Analysis Plan
SARS-CoV-2	severe acute respiratory syndrome coronavirus that causes COVID-19
SD	standard deviation
SMC	Safety Monitoring Committee
SMQ	Standardized MedDRA Query
SOC	system organ class
SOP	standard operating procedure
TEAE	treatment-emergent adverse event
TMB	3,3',5,5'-tetramethylbenzidine
ULOQ	upper limit of quantification
USP	United States Pharmacopeia

1 Introduction

1.1 Background

Coronaviruses (CoVs) are a large family of viruses that cause illness ranging from the common cold to more severe diseases, such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome. Coronaviruses are zoonotic, meaning that they can be transmitted from animals to people.

An outbreak of the CoV disease (coronavirus disease 2019 [COVID-19]) caused by the 2019 novel CoV (severe acute respiratory syndrome coronavirus that causes COVID-19 [SARS-CoV-2]) began in Wuhan, Hubei Province, China in December 2019 and has spread throughout China and to over 200 other countries and territories, including the United States ([WHO 2020a](#)). A CoV ribonucleic acid was quickly identified in some of these patients.

On 11 Mar 2020, the World Health Organization declared COVID-19 a pandemic. As of 01 Nov 2020, more than 46 million cases and over 1.2 million deaths worldwide have been attributed to the COVID-19 pandemic ([WHO 2020b](#)), and in the United States, the US Centers for Disease Control and Prevention (CDC) reported 9,921,022 confirmed and probable cases of COVID-19 across all 50 states and 5 jurisdictions, with 230,383 total deaths ([CDC 2020a](#)). The CDC have reported that the highest risk of disease burden is in older adults (≥ 65 years old) and people of any age who have certain underlying medical conditions such as cancer, chronic kidney disease, chronic obstructive pulmonary disease, serious heart conditions, immunocompromised state, obesity, sickle cell disease, smoking, and diabetes ([CDC 2020b](#)).

Global efforts to evaluate novel antivirals and therapeutic strategies to treat severe SARS-CoV-2 infections have intensified, and there is an urgent public health need for rapid development of novel interventions to prevent the spread of this disease.

ModernaTX, Inc. has developed a rapid-response, proprietary vaccine platform based on a messenger RNA (mRNA) delivery system. The platform is based on the principle and observations that cells in vivo take up mRNA, translate it, and then express protein viral antigen(s) on the cell surface. The delivered mRNA does not enter the cellular nucleus or interact with the genome, is nonreplicating, and is expressed transiently. mRNA vaccines have been used to induce immune responses against infectious pathogens such as cytomegalovirus (NCT03382405), human metapneumovirus and parainfluenza virus type 3 (NCT03392389), and influenza virus (NCT03076385 and NCT03345043).

The Sponsor has used its mRNA-based platform to develop a novel lipid nanoparticle (LNP)-encapsulated mRNA-based vaccine against SARS-CoV-2 (mRNA-1273). mRNA-1273 encodes for the full-length spike protein of SARS-CoV-2, modified to introduce 2 proline residues to stabilize the S-2P spike protein into a prefusion conformation. The CoV spike protein mediates attachment and entry of the virus into host cells (by fusion), making it a primary target for neutralizing antibodies (nAbs) that prevent infection ([Johnson et al 2016](#); [Wang et al 2015](#); [Wang et al 2018](#); [Chen et al 2017](#); [Corti et al 2015](#); [Yu et al 2015](#); [Kim et al 2019](#); [Widjaja et al 2019](#)).

The development of the mRNA-1273 vaccine is being expedited given the current global public health emergency, although it is important to stress that Phase 1, Phase 2, and Phase 3 development are ongoing, and no steps in the development and approval process have been eliminated. Should mRNA-1273 be demonstrated to be safe and efficacious, it may be used to address the current COVID-19 outbreak as a result of the uniquely rapid and scalable manufacturing process for mRNA-1273.

1.2 Nonclinical Studies

Animal studies were performed in young and aged wild type mice and rhesus macaques (nonhuman primates). These studies were designed to evaluate the binding and nAbs induced at varying dose levels of mRNA-1273, and to assess the potential protection of the animals when challenged with SARS-CoV-2 virus. Additional studies captured immunogenicity endpoints that would be predictive of enhanced respiratory disease and also to evaluate if, at protective or subprotective dose levels of mRNA-1273, evidence of disease enhancement would be observed after challenge of the animals with SARS-CoV-2. These nonclinical studies demonstrated that mRNA-1273 is safe and well tolerated in different animal species, is immunogenic; drives a robust SARS-CoV-2 specific antibody, neutralization, and Th1-directed CD4 T-cell response; fully protects animals from challenge at dose levels as low as 1 µg/dose in mice and 30 µg/dose in nonhuman primates; and does not lead to evidence of enhanced respiratory disease at protective or subprotective dose levels ([Corbett et al 2020a](#); [Corbett et al 2020b](#)).

1.3 Clinical Studies

No clinical studies have been completed with mRNA-1273. Four clinical studies of mRNA-1273 are ongoing.

Phase 3 Study mRNA-1273-P301 (NCT04470427) is a pivotal randomized, observer-blind, placebo-controlled, stratified, efficacy, immunogenicity, and safety study being conducted in 99 sites across the United States. The study includes participants 18 years of age and older who

are at increased risk of COVID-19. In addition, prespecified cohorts of participants who are either ≥ 65 years of age or 18 to < 65 years of age with comorbid medical conditions placing them at increased risk for severe COVID-19 disease are included. The study participants were randomly assigned to receive two injections separated by one month of either 100 μg of mRNA-1273 vaccine or a placebo control in a 1:1 randomization ratio. Assignment was stratified by age and health risk. Participants are being monitored for 24 months after their second dose to enable assessment of long-term safety and durability of vaccine efficacy.

At the time of the 25 Nov 2020 data snapshot a total of 30,351 participants were followed for a median of 63 days following the second injection for the development of COVID-19. Solicited adverse reactions (ARs) were reported more frequently among vaccine participants than placebo participants. The most frequently reported ARs after any dose in the vaccine group were pain at the injection site, fatigue, headache, myalgia, and chills. Solicited local and systemic ARs had median durations of 3 days (range: 1 to 3 days) and 2 days (range: 1 to 2 days), respectively. Grade 3 solicited local ARs were more frequently reported after Dose 2 than after Dose 1. In the participants who received the vaccine, solicited systemic ARs were reported numerically more frequently by vaccine participants after Dose 2 than after Dose 1.

Unsolicited adverse events (AEs) that occurred within 28 days following each vaccination were reported by 23.9% of participants who received mRNA-1273 and 21.6% of participants who received placebo. As of 25 Nov 2020, serious AEs (SAEs) were reported by 1.0% (n=147) of participants who received mRNA-1273 and 1.0% (n=153) of participants who received placebo. In these analyses, 87.9% of study participants had at least 28 days of follow-up after Dose 2, and the median follow-up time for all participants was 9 weeks after Dose 2.

Phase 2/3 Study mRNA-1273-P203 (NCT04649151) is a Phase 2/3, randomized, observer-blind, placebo-controlled study being conducted to assess the safety and infer the effectiveness of mRNA-1273 in an adolescent population aged 12 to < 18 years. The study includes 2 arms: 100 μg of mRNA-1273 and placebo. Approximately, 3,000 participants between 12 to < 18 years of age will be randomly assigned in a 2:1 ratio to receive mRNA-1273 (n=2,000) or placebo (n=1,000). All participants are being monitored for 12 months following the second dose of vaccine or placebo to enable assessment of safety and immunogenicity.

Phase 1 DMID Study-20-0003 (NCT04283461) is a dose-escalation, open-label study to assess the safety and immunogenicity of mRNA-1273 in healthy adults aged 18 years and older. Study 101 was sponsored by the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID). Participants were planned to be enrolled into 1 of up to 13 cohorts based on age. A total of 10 cohorts enrolled participants.

Participants received 2 injections of 25 µg, 50 µg, 100 µg, or 250 µg of mRNA-1273. As a control, a panel of convalescent sera was obtained from 41 patients recovering from COVID-19 and were used as a benchmark immunogenicity comparator for antibodies induced by natural infection. Blood sample collection time points are baseline, Days 8, 15, 29 (prior to injection 2), 36, 43, and 57, as well as 3, 6, and 12 months after the second vaccination (Days 119, 209, and 394, respectively). Interim results from 45 participants within 18 to 55 years of age group who have received 2 doses of 25, 100, and 250 µg have been published ([Jackson et al 2020](#)). Data on 40 older adults > 55 years of age who received 2 doses of either 25 or 100 µg in the same Phase 1 DMID study were also published ([Anderson et al 2020](#)). Interim results from 120 participants (age cohorts 18 to 55 years, 56 to 70 years, and ≥ 71 years) showed that the most solicited local and systemic ARs were mild or moderate in severity. Severe solicited ARs predominantly occurred at the highest dose (250 µg). Most solicited ARs had onsets within 4 to 6 days after vaccination, with median durations of 1 to 2 days. All severe solicited ARs resolved within 1 to 2 days. The incidence of solicited local ARs was generally comparable after the first and second injection. The incidence of solicited systemic ARs regardless of severity was higher after the second injection (86% participants) than after the first injection (53% participants). The incidence of unsolicited AEs was generally comparable among vaccination groups across all age groups (ranging from 73% to 77%). Most of unsolicited AEs were mild or moderate in severity. There have been no SAEs or triggering of study pause rules.

Phase 2a Study mRNA-1273-P201 (NCT04405076) is the current blinded, randomized, placebo-controlled dose-confirmation study in adults 18 years and older. This clinical study report (CSR) is for the primary analysis of safety and immunogenicity data through Day 57 (data cutoff date 05 Nov 2020). The analysis was performed after all participants completed Day 57 study procedures and all data relevant to the primary study analysis through Day 57 were cleaned (as much as possible) and locked. The analyses of all endpoints will be performed after all participants complete the Month 13 study procedures (ie, at end of study [EOS]) and will be presented in the EOS CSR.

2 Study Objectives and Endpoints

The study objectives and endpoints are presented in [Table 1](#). For this primary analysis CSR, primary safety and immunogenicity endpoint results are presented and described through the Day 57 time point. A final analysis of all endpoints will be performed after the EOS.

Table 1: Objectives and Endpoints

Objectives	Endpoints
Primary safety	
To evaluate the safety and reactogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart	- Solicited local and systemic ARs through 7 days after each injection - Unsolicited AEs through 28 days after each injection - MAAEs through the entire study period - SAEs throughout the entire study period - Safety laboratory abnormalities at Day 29 and Day 57 (Cohort 2 only) - Vital sign measurements and physical examination findings
Primary immunogenicity	
To evaluate the immunogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, as assessed by the level of specific bAb	Level of SARS-CoV-2-specific bAb measured by ELISA on Day 1, Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13)
Secondary	
To evaluate the immunogenicity of 2 dose levels of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, as assessed by the titer of nAb	- Titer of SARS-CoV-2-specific nAb on Day 1, Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13) - Seroconversion on Day 29 (M1), Day 43, Day 57 (M2), Day 209 (M7), and Day 394 (M13) as measured by an increase of SARS-CoV-2-specific nAb titer either from below the LLOQ to equal to or above LLOQ, or a 4-times higher titer in participants with pre-existing nAb titers
Exploratory	
- To profile S protein-specific serum Ig class and subclass and nAb in serum - To describe the ratio or profile of specific bAb relative to nAb in serum - To describe initial immunogenicity responses following the first dose (Day 1) and prior to the second dose (Day 29) - To characterize the clinical profile and immune response of participants infected by SARS-CoV-2 - To evaluate the effect of the mRNA-1273 vaccine on the incidence of SARS-CoV-2 infection	- Serum titers of S protein-specific binding Ig assessed by class and subclass and nAb in serum - Relative amounts or profiles of S protein-specific bAb and specific nAb levels/titers in serum - Clinical severity and immune response of participants infected by SARS-CoV-2 - Number of cases and incidence of confirmed SARS-CoV-2 infection using an assay designed to detect nonvaccine antigens of SARS-CoV-2

Abbreviations: AE=adverse event; AR=adverse reaction; bAb=binding antibody; ELISA=enzyme-linked immunoabsorbent assay; Ig=immunoglobulin; LLOQ=lower limit of quantification; M=month; MAAE=medically attended adverse event; nAb=neutralizing antibody; S=spike; SAE=serious adverse event; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

3 Investigational Plan

3.1 Overall Study Design and Plan

The mRNA-1273-P201 was a randomized, observer-blind, and placebo-controlled study, with adult participants at least 18 years of age.

This primary analysis CSR provides the primary analysis of safety and immunogenicity data through Day 57 (data cutoff 05 Nov 2020). The EOS CSR will include final analysis of all endpoints and will be completed after all participants have completed the Month 13 study procedures and the database is cleaned and locked.

Two dose levels, 50 µg and 100 µg, were evaluated in this study, based in part on initial safety data from the Phase 1 DMID study of mRNA-1273 ([Section 3.1.1](#)). The study included 2 age cohorts: Cohort 1 ≥ 18 to < 55 years old (300 participants planned) and Cohort 2 ≥ 55 years old (300 participants planned). Eligible participants (approximately 600 planned) received either mRNA-1273 or saline placebo control according to a 1:1:1 randomization ratio; ie, within each age cohort, 100 participants received mRNA-1273 50 µg, 100 participants received mRNA-1273 100 µg, and 100 participants received saline placebo. The study schematic is presented in [Figure 1](#).

The study was initiated with a parallel enrollment of all 300 participants in Cohort 1 (≥ 18 to < 55 years old) and a sentinel group of 50 participants in Cohort 2 (≥ 55 years old) receiving study treatment ([Figure 2](#)). Before initiating study treatment of the remaining participants in Cohort 2, safety data through Day 7 from the sentinel group of Cohort 2 and all available data from Cohort 1 were reviewed by the Safety Monitoring Committee (SMC). No safety concerns were found, and Cohort 2 enrollment continued.

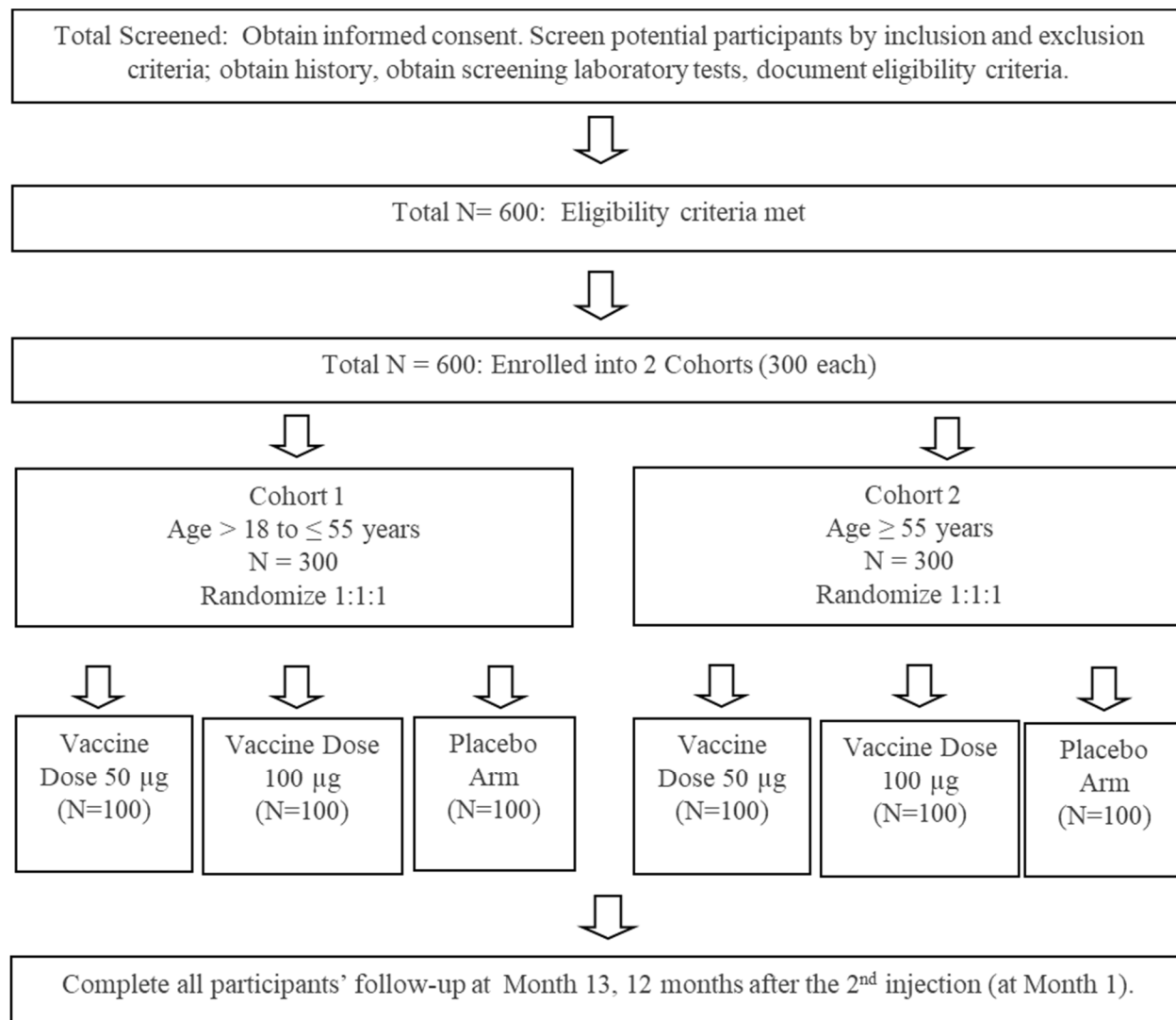
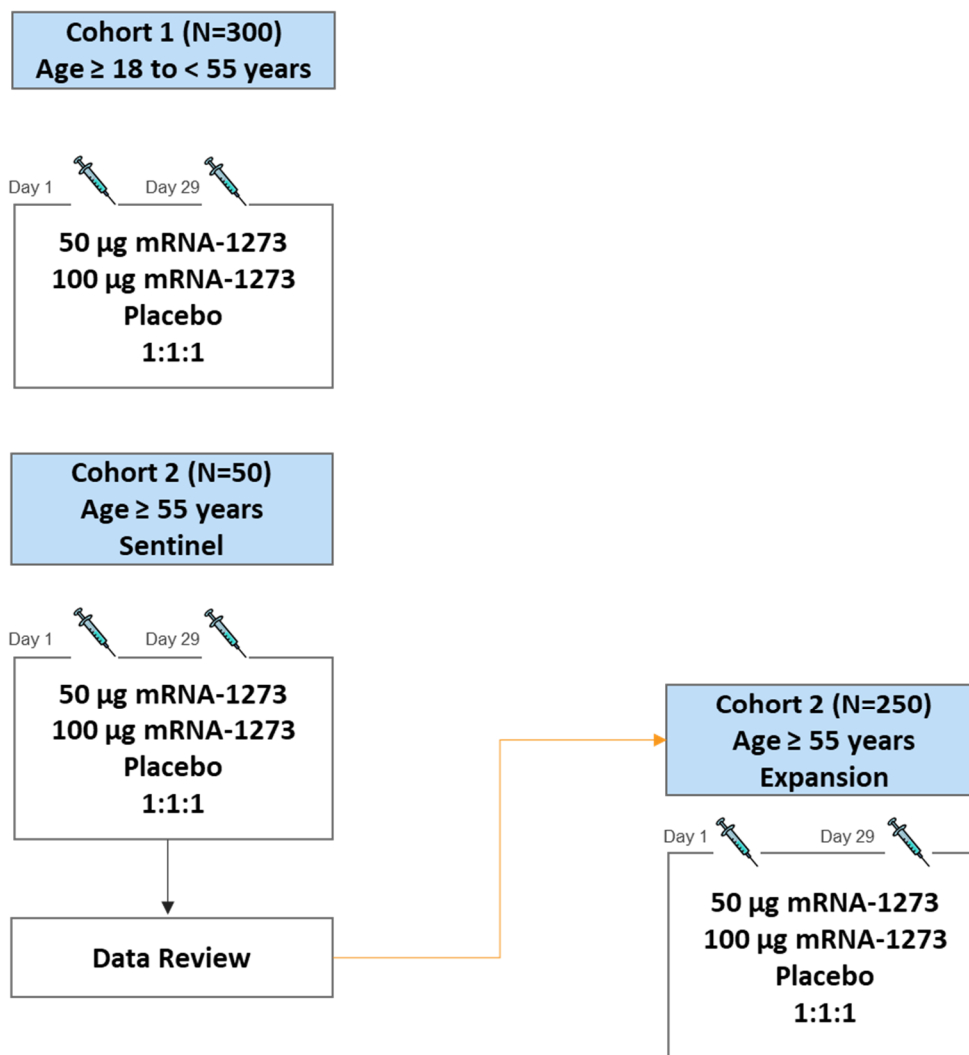
Figure 1: Study Flow Schema

Figure 2: Sentinel and Expansion Cohort Schema

Note: The remaining participants in Cohort 2 (N=250) did not initiate study treatment until after safety data through Day 7 from the sentinel group of Cohort 2 and all available data from Cohort 1 were reviewed by the Safety Monitoring Committee.

The full study comprised 10 scheduled study site visits: Screening, Day 1, Day 8, Day 15, Day 29 (Month 1), Day 36, Day 43, Day 57 (Month 2), Day 209 (Month 7), and Day 394 (Month 13). Scheduled participant contact continued approximately every 2 weeks after Day 57 to collect medically attended adverse events (MAAEs), AEs leading to withdrawal, SAEs, concomitant medications associated with these events, receipt of nonstudy vaccinations, exposure to someone with known COVID-19 or SARS-CoV-2 infection, and participant experience of COVID-19 symptoms as indicated in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol Table 7; Appendix 16.1.1](#)). Every 4 weeks from Day 71 through Day 183

and from Day 223 through Day 363, each participant completed a questionnaire in an electronic diary (eDiary) that was reviewed by study site personnel ([Section 3.7.1.1](#)). Safety telephone calls occurred every 4 weeks from Day 85 through Day 197 and from Day 237 through Day 377 ([Section 3.7.1.2](#)). At study completion, the study duration for each participant will be approximately 14 months: a screening period of up to 1 month and a study period of 13 months, which includes the first dose of investigational product (IP) on Day 1 and the second dose on Day 29. A participant's final visit will be Day 394 (Month 13), 12 months after the second dose of the IP on Day 29 (Month 1).

To test for the presence of SARS-CoV-2, nasopharyngeal swab samples were collected at Day 1, Day 29, and Day 57. During the course of the study, participants meeting prespecified disease criteria that suggested possible SARS-CoV-2 infection were asked to contact the study site to arrange for a prompt, thorough, and careful assessment ([Section 3.7.2.3](#)).

Each participant received 2 injections of mRNA-1273 or placebo by 0.5 mL intramuscular (IM) injection on Day 1 and Day 29. Investigational product accountability, dose preparation, and administration were performed by unblinded pharmacy personnel who did not participate in any other aspects of the study. The remainder of the study staff, all participants, and Sponsor personnel (or its designees) remained blinded to dosing assignment ([Section 3.6.4](#)).

All participants were followed for safety and reactogenicity and provided pre- and postinjection blood specimens for immunogenicity through 12 months after the last dose of IP. An SMC met on a regular basis to assess safety throughout the study conduct and could have convened on an ad hoc basis if study pause rules were met ([Section 3.8.5](#)).

The EOS was defined as the release of the last testing result of samples collected at Visit 9 or the completion of the last participant's last visit, whichever occurred later. Participants will be considered to have completed the study if they completed the final visit on Day 394 (Month 13), 12 months after the second injection on Day 29 (Month 1).

At each dosing visit, participants were instructed (Day 1) or reminded (Day 29) how to document and report solicited ARs within an eDiary application and/or device provided to them. Solicited ARs were assessed for 7 days (the day of injection and the following 6 days) after each injection and unsolicited AEs were assessed for 28 days after each injection; SAEs and MAAEs were assessed throughout the study.

Participants provided blood samples for the assessment of safety and immunogenicity at scheduled study visits. Blood samples were drawn from participants in case of any medical

concerns according to the investigator's judgment. In addition, participants provided blood samples at unscheduled visits for acute respiratory symptoms.

The content of this CSR is based on [mRNA-1273-P201 Clinical Study Protocol Amendment 3](#), dated 02 Sep 2020, and the final [mRNA-1273-P201 Statistical Analysis Plan \(SAP\)](#), dated 27 Oct 2020. The Schedule of Events is provided in the [mRNA-1273-P201 Clinical Study Protocol \(Table 7, Appendix 16.1.1\)](#).

3.1.1 Discussion of Study Design

The randomized, placebo-controlled, dose-confirmation design of this Phase 2a was appropriate to evaluate the safety, reactogenicity, and immunogenicity of a new vaccine, mRNA-1273. The doses selected (50 µg and 100 µg) were based on the assessment of available safety and immunogenicity data from the Phase 1 DMID study and Phase 1 studies of mRNA-1647 and mRNA-1443 and supported the selection of the appropriate dose for the planned Phase 3 study. At the time of the data lock, there were no licensed SARS-CoV-2 vaccines available, and thus 0.9% sodium chloride was used as a placebo control for the safety and immunogenicity assessments. Consequently, the mRNA-1273 and placebo injections were different in appearance, and administration was blinded ([Section 3.6.2](#)).

Healthy adults were recruited for enrollment, including healthy older adults (≥ 55 years old), who are at greater risk for COVID-19. The 2 age cohorts, ≥ 18 to < 55 years old and ≥ 55 years old, were established to better understand the relationships among dose, tolerability, and immunogenicity in different age groups, one being healthy older adults. The older cohort corresponds to the 2 older age cohorts in the Phase 1 DMID study.

The study design included a sample size of 600 participants and a placebo to improve the ability of this study to better understand safety data, including AEs, compared with that of the Phase 1 DMID study, which is small (105 participants at 4 dose levels) and does not incorporate a placebo.

With SARS-CoV-2 expected to be circulating in the general population during the study, all participants provided pre-injection blood samples and postinjection blood samples for antibody analysis through 12 months after the last dose of IP. In addition, participants had nasopharyngeal swab samples collected at Day 1 and Day 29, before the injections, and at Day 57. Furthermore, participants were monitored both actively (safety telephone calls weekly from Day 85 through Day 165) and passively from signs and symptoms of SARS-CoV-2 infection as defined by CDC ([CDC 2020c](#)), exposure to an individual confirmed to be infected with SARS-CoV-2, and any

MAAEs suggestive of SARS-CoV-2 infection ([Section 3.7.2.3](#)). With any signs or symptoms or MAAE suggesting SARS-CoV-2 infection in a participant, an additional nasopharyngeal swab sample and a blood sample were taken to confirm the diagnosis of SARS-CoV-2 via serology and reverse transcription polymerase chain reaction (RT-PCR). Additionally, clinical information was carefully collected to evaluate the severity of the clinical case.

As it is possible that participants are naturally exposed to SARS-CoV-2 through community exposure, the nasopharyngeal swab samples collected before study injection may help discriminate between natural infection and vaccine-induced antibody responses, should such discrimination be needed.

3.2 Protocol Amendments and Other Changes in the Conduct of the Study

3.2.1 Changes in the Conduct of the Study

At the time of the data cutoff for this primary analysis report, the original [mRNA-1273-P201 Clinical Study Protocol](#), dated 22 Apr 2020, had been amended 3 times. [Table 2](#) provides a summary of the major changes implemented with each amendment. The original protocol and each amendment, including a summary of changes, are provided in [Appendix 16.1.1](#).

Table 2: Summary of Major Changes Implemented With Each Amendment

Protocol Amendment	Summary of Major Changes
Protocol (22 Apr 2020)	Original
Amendment 1 (18 May 2020)	- Updated protocol title - Added an exploratory objective and endpoint to evaluate the effect of the mRNA-1273 vaccine on the incidence of SARS-CoV-2 infection - Decreased the highest dose of mRNA-1273 from 250 µg to 100 µg - Updated the Month 7 and Month 13 visits to Day 209 and Day 394, respectively, to allow for 6-month and 12-month intervals, respectively, after the second injection on Day 29 (Month 1) - Updated the scheduled EOS assessments at Day 394 (Month 13) to allow for a 12-month interval after the second vaccination on Day 29 (Month 1) - Updated the biweekly safety phone calls from Day 211 through Day 351 to Day 223 through Day 377 - Updated enrollment and preliminary safety data from the ongoing Phase 1 DMID study - Updated inclusion criterion #7 to exclude sperm donations through 3 months after the last injection - Updated the method to maintain the blind of the dosing assignment from an opaque sleeve to a blinding label - Added more intense monitoring of participants confirmed to have SARS-CoV-2 infection

Protocol Amendment	Summary of Major Changes
	Added a convalescent visit with blood collection for participants confirmed to have SARS-CoV-2 infection
Amendment 2 (01 Jul 2020)	- Added eDiary questionnaires to the procedure for safety follow-up after the Day 57 visit, with completion of eDiary questionnaires alternating with safety telephone calls approximately every 2 weeks after the Day 57 visit - Added to the list of events queried during scheduled safety telephone calls any exposure to someone with known COVID-19 or SARS-CoV-2 infection and participant experience of COVID-19 symptoms - Added descriptions of the primary study analysis and EOS analysis and respective CSRs, replacing descriptions of interim analyses and reports. Specifically, the primary analysis of safety and immunogenicity data would be performed after all participants completed Day 57 study procedures. All data relevant to the primary study analysis through Day 57 would be cleaned (ie, data that are as clean as possible) and locked. A limited number of Sponsor and clinical research organization personnel would be unblinded to perform the primary study analysis and prepare a final CSR, including individual listings. The study site staff, investigators, study monitors, and participants will remain blinded until the conclusion of the study (this was changed to participant level unblinding once EUA was granted by the FDA and participants who were EUA-eligible were offered the mRNA-1273 vaccine). The EOS analysis of all endpoints will be performed after all participants have completed Month 13 study procedures and after the database is cleaned and locked. Results of this analysis will be presented in an EOS CSR, including individual listings. - Added that all analyses would be performed by treatment group overall (for the 2 cohorts combined) and for the 2 cohorts separately, unless specified otherwise - Revised geometric mean titer to geometric mean for the primary immunogenicity endpoint - Added instructions for asymptomatic participants who had a confirmed SARS-CoV-2 infection - Decoupled life threatening and grade 4 in the severity assessment - Added clarification on when an adverse event would be defined as serious
Amendment 3 (02 Sep 2020)	- Added information about potential participant populations to be included in the primary analysis of safety and immunogenicity after completion of Day 57 procedures, clarifying that data can be analyzed in multiple batches based on availability of participants who have reached the Day 57 visit - Clarified that separate summaries of grade 3 or higher solicited adverse reactions are not planned - Clarified that window around the Day 29 visit is + 7 days

Abbreviations: COVID-19=coronavirus disease 2019; CSR=Clinical Study Report; DMID=Division of Microbiology and Infectious Diseases; eDiary=electronic diary; EOS=end of study; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

3.3 Investigators and Study Administrative Structure

ModernaTX, Inc. was the Sponsor of this clinical study. A total of 8 study sites in the United States enrolled at least one participant in the study. The first participant's first visit for this study was 22 May 2020. This study is ongoing; this primary analysis CSR includes data through Day 57 (data cutoff, 05 Nov 2020).

The contract research organization, PPD (Wilmington, North Carolina, USA), was responsible for the following: biostatistics and programming (including randomization), clinical site management (including clinical site monitoring as outlined in the study monitoring plan), data management, data analytics, electronic data capture, interactive response technology (IRT), project management, safety monitoring and pharmacovigilance, and medical writing and publishing. Additionally, PPD clinical supplies provided the placebo (0.9% sodium chloride), assisted with management for delivery of IP, and provided other study supplies to sites (eg, oral thermometers, rulers, participant cards).

PPD Central Laboratory (Highland Heights, Kentucky, USA) provided central laboratory services for hematology, serum chemistry, and coagulation testing as well as screening serology and follicle-stimulating hormone (FSH) testing, if required.

ModernaTX, Inc. (Norwood, Massachusetts, USA) manufactured and supplied mRNA-1273.

Medidata (Pittston, Pennsylvania, USA) supplied eDiaries either as an application downloaded on participants' smartphone or on a separate device, which participant used for data entry of solicited ARs.

IQVIA (Durham, North Carolina, USA) was responsible for SAE reconciliation, including individual case safety report collection, evaluation, safety database entry, regulatory reporting, development safety update reports, medical review, and literature surveillance.

For immunogenicity samples, Battelle (West Jefferson, Ohio, USA) performed live virus neutralization assays for nAb titers, Viracor-Eurofins (Lee's Summit, Missouri, USA) performed COVID-19 RT-PCR testing and Biofire® respiratory panel screening, and the PPD Vaccine Laboratory (Richmond, Virginia, USA) performed enzyme-linked immunosorbent assay (ELISA) for binding antibody (bAb) levels.

An SMC, composed of external independent consultants with relevant expertise, provided safety oversight. Members of the SMC were independent from the study conduct and free of conflict of interest. The SMC met on a regular basis to assess safety throughout the study conduct and could

have convened on an ad hoc basis if study pause rules were met. Details regarding the SMC are provided in [Section 3.8.5](#).

A list of all investigators and clinical sites and other administrative structure/information is provided in [Appendix 16.1.4](#).

3.4 Ethical Considerations

3.4.1 Institutional Review Board

Before study onset, the institutional review board (IRB) at each study site approved the protocol, protocol amendments, informed consent, advertisements used for the recruitment of study participants, and any other written information regarding this study provided to the participant. Documentation of all IRB approvals and of the IRB compliance with the International Council for Harmonisation (ICH) E6(R2) guidelines was maintained by the site and was available for review by the Sponsor or its designee.

All IRB approvals were signed by the IRB chairman or designee and identified the IRB name and address, the clinical protocol by title or protocol number or both, and the date approval or a favorable opinion was granted.

A list of all IRBs is provided in [Appendix 16.1.3](#).

3.4.2 Ethical Conduct of the Study

The investigator agreed to conduct the study according to the principles of ICH E6(R2). The investigator conducted all aspects of this study in accordance with all national, state, and local laws or regulations. The study was conducted in compliance with the protocol, current Good Clinical Practice (GCP) guidelines – adopting the principles of the Declaration of Helsinki – and all applicable regulatory requirements.

3.4.3 Participant Information and Consent

Written informed consent in compliance with US Code of Federal Regulations (CFR) Title 21 Part 50 was obtained from each participant before he or she entered the study or before any unusual or nonroutine procedure that involved risk to the participant was performed. If any institution-specific modifications to study-related procedures were proposed or made by the site, the consent was reviewed by the Sponsor or its designee or both before IRB submission. Once reviewed, the investigator submitted the informed consent form (ICF) to the IRB for review and

approval before the start of the study. If the ICF was revised during the course of the study, all active participating participants signed the revised form.

Before recruitment and enrollment, each prospective participant was given a full explanation of the study, was allowed to read the approved ICF, and was given answers to any questions. Once the investigator was assured that the participant understood the implications of participating in the study, the participant was asked to give his or her consent to participate in the study by signing the ICF. Separate counseling and consent was provided for human immunodeficiency virus (HIV) testing as applicable per local laws or regulations.

The ICF also explained that excess serum from immunogenicity testing may be used for future research, which may be performed at the discretion of the Sponsor to further characterize the immune response to SARS-CoV-2, additional assay development, and the immune response across CoV.

The investigator or designee provided a copy of the ICF to the participant. The original form was maintained in the participant's medical records at the site.

A sample ICF is provided in [Appendix 16.1.3](#).

3.5 Selection of Study Population

Healthy male or female participants were enrolled at study sites in the United States.

3.5.1 Inclusion Criteria

Each participant must have met all of the following criteria during the screening period and at Day 1, unless noted otherwise, to be enrolled in this study:

1. Male or female, 18 years of age or older at the time of consent (Screening Visit, Day 0).
2. Understood and agreed to comply with the study procedures and provided written informed consent.
3. According to the assessment of the investigator, was in good general health and could comply with study procedures.
4. Body mass index (BMI) of 18 kg/m² to 30 kg/m² (inclusive) at the Screening Visit (Day 0).
5. Female participants of nonchildbearing potential were enrolled in the study. Nonchildbearing potentials was defined as surgically sterile (history of bilateral tubal

ligation, bilateral oophorectomy, hysterectomy) or postmenopausal (defined as amenorrhea for ≥ 12 consecutive months prior to Screening (Day 0) without an alternative medical cause). An FSH level may have been measured at the discretion of the investigator to confirm postmenopausal status.

6. Female participants of childbearing potential were enrolled in the study if the participant fulfilled all the following criteria:

- Had a negative pregnancy test at Screening (Day 0) and on the day of the first injection (Day 1).
- Practiced adequate contraception or abstained from all activities that could have resulted in pregnancy for at least 28 days prior to the first injection (Day 1).
- Agreed to continue adequate contraception through 3 months following the second injection (Day 29).
- Was not currently breastfeeding.

Adequate female contraception was defined as consistent and correct use of a Food and Drug Administration (FDA)-approved contraceptive method in accordance with the product label. For example:

- Barrier method (such as condoms, diaphragm, or cervical cap) used in conjunction with spermicide
- Intrauterine device
- Prescription hormonal contraceptive taken or administered via oral (pill), transdermal (patch), subdermal, or IM route
- Sterilization of a female participant's monogamous male partner prior to entry into the study

Note: periodic abstinence (eg, calendar, ovulation, symptothermal, postovulation methods) and withdrawal were not acceptable methods of contraception.

7. Male participants engaging in activity that could have resulted in pregnancy of sexual partners must have agreed to practice adequate contraception and refrain from sperm donation from the time of the first injection and through 3 months after the last injection.

Adequate contraception for male participants was defined as:

- Monogamous relationship with a female partner using an intrauterine device or hormonal contraception (described above)
- Use of barrier methods and spermicide
- History of surgical sterilization

Male participants with partners who became pregnant prior to Screening were eligible to participate in the study.

3.5.2 Exclusion Criteria

Participants meeting any of the following criteria at the Screening Visit (Day 0) or at Day 1, unless noted otherwise, were excluded from the study:

1. Known history of SARS-CoV-2 infection or known exposure to someone with SARS-CoV-2 infection or COVID-19.
2. Travel outside of the United States in the 28 days prior to the Screening Visit (Day 0).
3. Pregnant or breastfeeding.
4. Was acutely ill or febrile 24 hours prior to or at the Screening Visit (Day 0). Fever was defined as a body temperature $\geq 38.0^{\circ}\text{C}/100.4^{\circ}\text{F}$. Participants meeting this criterion may have been rescheduled within the relevant window periods. Afebrile participants with minor illnesses could have been enrolled at the discretion of the investigator.
5. Prior administration of an investigational CoV (eg, SARS-CoV-2, SARS-CoV, MERS-CoV) vaccine.
6. Current treatment with investigational agents for prophylaxis against COVID-19.
7. Had a medical, psychiatric, or occupational condition that may have posed additional risk as a result of participation, or that could have interfered with safety assessments or interpretation of results according to the investigator's judgment.
8. Was a healthcare worker or a member of an emergency response team.
9. Current use of any inhaled substance (eg, tobacco or cannabis smoke, nicotine vapors).
10. History of chronic smoking (≥ 1 cigarette a day) within 1 year of the Screening Visit (Day 0).

11. History of illegal substance use or alcohol abuse within the past 2 years. This exclusion did not apply to historical cannabis use that was formerly illegal in the participant's state but was legal at the time of Screening.
12. Known history of hypertension, or systolic blood pressure > 150 mm Hg in participants in Cohort 1 (≥ 18 to < 55 years old) or systolic blood pressure > 160 mm Hg in participants in Cohort 2 (≥ 55 years old) at the Screening Visit (Day 0).
13. Known history of hypotension or systolic blood pressure < 85 mm Hg at the Screening Visit (Day 0).
14. Diabetes mellitus.
15. Diagnosis of chronic pulmonary disease (eg, chronic obstructive pulmonary disease, asthma).
16. Chronic cardiovascular disease.
17. Resided in a nursing home.
18. Grade 1 or higher toxicity on clinical safety laboratory testing at the Screening Visit (Day 0).
19. Current or previous diagnosis of immunocompromising condition, immune-mediated disease, or other immunosuppressive condition.
20. Received systemic immunosuppressants or immune-modifying drugs for > 14 days in total within 6 months prior to the Screening Visit (Day 0) (for corticosteroids ≥ 20 mg/day of prednisone equivalent). Topical tacrolimus was allowed if not used within 14 days prior to the Screening Visit (Day 0).
21. Anticipated the need for immunosuppressive treatment at any time during participation in the study.
22. Positive serology for hepatitis B virus surface antigen, hepatitis C virus antibody, or HIV type 1 or 2 antibodies identified at the Screening Visit (Day 0).
23. History of anaphylaxis, urticaria, or other significant AR requiring medical intervention after receipt of a vaccine.

24. Bleeding disorder considered a contraindication to IM injection or phlebotomy.
25. Diagnosis of malignancy within previous 10 years (excluding nonmelanoma skin cancer).
26. Received or planned to receive a licensed vaccine $\leq$ 28 days prior to the first injection (Day 1) or planned to receive a licensed vaccine within 28 days before or after any study injection. Licensed influenza vaccines could have been received more than 14 days before or after any study injection.
27. Received systemic immunoglobulins or blood products within 3 months prior to the Screening Visit (Day 0) or receipt planned during the study.
28. Donated $\geq$ 450 mL of blood products within 28 days prior to the Screening Visit (Day 0) or planned to donate blood products during the study.
29. Participated in an interventional clinical study within 28 days prior to the Screening Visit (Day 0) or planned to do so while participating in this study.
30. Was an immediate family member or household member of study personnel.

3.5.3 Withdrawal of Participants From the Study or Study Treatment

3.5.3.1 Participant Withdrawal From the Study

Participants could have withdrawn consent and discontinued from the study at any time, for any reason, without prejudice to further treatment the participant may have needed.

If a participant desired to withdraw from the study because of an AE, the investigator tried to obtain agreement to follow-up with the participant until the event was considered resolved or stable and then completed the EOS electronic case report form (eCRF).

The reasons for withdrawing a participant from the study included the following:

- AE (COVID-19 infection)
- AE (other, specified)
- Death
- Lost to follow-up
- Physician decision
- Pregnancy
- Protocol deviation (specified)

- Study terminated by Sponsor
- Consent withdrawal (other, specified)
- Consent withdrawal (COVID-19 noninfection related)
- Other (specified)

When a participant withdrew or was withdrawn from the study, the reason(s) for withdrawal was recorded by the investigator on the relevant page of the eCRF. These participants were requested to complete the EOS assessments scheduled for Day 394 (Month 13).

A participant was considered lost to follow-up if he or she repeatedly failed to return for scheduled visits without stating an intention to withdraw consent and was unable to be contacted by the study site. The sites pursued multiple follow-up actions if a participant failed to return to the study site for a required study visit, as detailed in [mRNA-1273-P201 Clinical Study Protocol Section 3.3.3 \(Appendix 16.1.1\)](#).

3.5.3.2 Replacements

At the Sponsor's discretion, participant replacement was allowed in this study in the event that a participant was withdrawn, was significantly outside the allowed injection window, or was lost to follow-up from the study.

3.5.3.3 Participant Withdrawal From Study Treatment

Every reasonable attempt was made to follow-up with participants for safety throughout the entire study period, even if further injection was withheld or the participant missed one or more visits. Unless consent was withdrawn, a participant who withdrew or was withheld from receiving the second dose of the IP remained in the study and completed all scheduled visits and assessments. Events that constituted contraindications to administration of the IP at certain time points are summarized in [Section 3.6.1.2](#).

The possible reasons for withdrawal from further injection were identical to those listed in [Section 3.5.3.1](#) for withdrawal from the study.

3.6 Study Treatment

3.6.1 Investigational Products Administered

There were 2 age cohorts in this study: participants ≥ 18 to < 55 years old in Cohort 1 and participants ≥ 55 years old in Cohort 2. Within each age cohort, participants were randomly assigned to 1 of 3 treatments in a 1:1:1 ratio, as follows:

- mRNA-1273 50 μg
- mRNA-1273 100 μg
- placebo

Investigational product was administered as an 0.5 mL IM injection into the deltoid muscle (preferably the nondominant arm) on a 2-dose injection schedule on Day 1 and Day 29, with a 28-day interval between doses. The second dose of IP should have been administered in the same arm as the first dose.

At each visit when IP was administered, participants were monitored for a minimum of 60 minutes after administration. Assessments performed included vital sign measurements and monitoring for local or systemic reactions, as specified in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol Table 7; Appendix 16.1.1](#)). The study site was appropriately staffed and prepared in the event of any severe reactions (eg, anaphylaxis or urticaria) that required immediate intervention, including having staff trained on emergency resuscitation and rescue medications in stock (such as epinephrine, steroids, antihistamines, and intravenous fluids).

The study followed rules for pausing dosing and the study, as detailed in [Section 3.6.1.1](#).

Eligibility for subsequent IP injection was determined per the criteria outlined in [Section 3.6.1.2](#).

3.6.1.1 Pause Rules

The investigators, study medical monitor, and Sponsor monitored for predefined events that would have triggered a study pause ([Table 3](#)).

Table 3: Pause Rule Criterion, Events, and Thresholds

Pause Rule Criterion	Event	Participant Threshold for Triggering Study Pause
1	Any death due to SARS-CoV-2 infection	≥ 1
2	Any SAE or grade 4 AE that cannot be reasonably attributed to a cause other than injection	≥ 3
3	ICU admissions in Cohort 1 due to SARS-CoV-2 infection	≥ 3
4	ICU admissions in Cohort 2 due to SARS-CoV-2 infection	≥ 6

Abbreviations: AE=adverse event; ICU=intensive care unit; SAE=serious adverse event; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

If any of the thresholds for a study pause were met, the Sponsor immediately suspended further enrollment and/or study dosing by notifying all investigators. Such a suspension remained in force until the threshold event was adjudicated by the SMC ([Section 3.8.5](#)).

At the time of the data cutoff for this report, no pause criterion was met. Investigator and Sponsor responsibilities in the event of a pause criterion being met, including notification to the SMC, are outlined in [mRNA-1273-P201 Clinical Study Protocol Section 3.4.2.1 \(Appendix 16.1.1\)](#).

3.6.1.2 Contraindications to Subsequent Injection

Prior to receiving a second injection, participants were reassessed to ensure that they continued to meet eligibility requirements as outlined below.

The following events in a participant constituted absolute contraindications to any further administration of IP to that participant. If any of these events occurred during the study, the participant should not have received additional doses of the IP but was encouraged to continue study participation for safety through 12 months following last injection ([Section 3.5.3.1](#)).

- Diagnosed COVID-19. If COVID-19 was suspected, further administration of IP was withheld until COVID-19 test results were available.
- Anaphylaxis or systemic hypersensitivity reaction following the administration of the IP.
- Any SAE judged by investigator or Sponsor to be related to the IP.
- Pregnancy.
- Any clinically significant medical condition that, in the opinion of the investigator, posed an additional risk to the participant if he/she continued to participate in the study.

The following events constituted contraindications to administration of the IP at certain points in time, and if any of these events occurred at the time scheduled for injection, the participant may have been injected at a later date, within the time window specified in the Schedule of Events (mRNA-1273-P201 Clinical Study Protocol Table 7; Appendix 16.1.1), or the participant may be withdrawn from dosing at the discretion of the investigator (Section 3.5.3.1):

- Acute moderate or severe infection with or without fever at the time of injection
- Fever, defined as body temperature $\geq 38.0^{\circ}\text{C}$ (100.4°F) at the time of injection

Participants with a minor illness without fever, as assessed by the investigator, could have been administered IP. Participants with a fever of 38.0°C (100.4°F) or higher were contacted within the time window acceptable for participation and reevaluated for eligibility.

3.6.2 Identity of Investigational Products

The investigation products in this study were mRNA-1273 and placebo (0.9% sodium chloride; Table 4). The Sponsor supplied mRNA-1273 and PPD supplied placebo to the sites.

Table 4: Investigational Products

Investigational Product	Dose Strength	Dosage Form	Packaging	Lot Numbers
mRNA-1273	50 μg and 100 μg	Sterile liquid for injection	Study-labeled carton, containing 1 labeled 2R USP Type I borosilicate glass vials with PLASCAP vial seal containing a 13 mm FluroTec-coated plug stopper (with 0.6 mL fill volume)	8520100102 8520100103
Placebo	NA	0.9% sodium chloride (normal saline) solution for injection, USP	Single-use 10 mL vial	NA

Abbreviations: NA=not applicable; USP=United States Pharmacopeia.

The mRNA-1273 drug product (DP) is an LNP dispersion of an mRNA encoding the prefusion stabilized spike protein of SARS-CoV-2 formulated in LNPs composed of 4 lipids (1 proprietary and 3 commercially available): the proprietary ionizable lipid SM-102; cholesterol; DSPC; and PEG2000-DMG. mRNA-1273 DP was provided as a sterile liquid for injection, white to

off-white dispersion in appearance, at a concentration of 0.5 mg/mL in 20 mM Tris buffer containing 87 g/L sucrose and 10.7 mM sodium acetate at pH 7.5.

The placebo was supplied as 0.9% sodium chloride (normal saline) injection, USP (United States Pharmacopeia).

Unblinded pharmacy personnel, who did not participate in any other aspect of the study, performed IP accountability, dose preparation, and IP administration ([Section 3.6.4](#)). Unblinded clinical team personnel used a centralized IRT to manage, track, order, and resupply mRNA-1273 and placebo for the study.

mRNA-1273 DP was packaged and labeled by the Sponsor in accordance with the standard operating procedures (SOPs) of the Sponsor or of its designee, CFR Title 21, Good Manufacturing Practice guidelines, ICH GCP guidelines, guidelines for Quality System Regulations, and applicable regulations.

The 0.9% sodium chloride injection, which was used as both a placebo and a diluent to mRNA-1273, had a commercial label and did not contain study-specific identification.

mRNA-1273 DP was stored at -60°C to -90°C (-76°F to -130°F) in a secure area with limited access (unblinded pharmacy staff only) and protected from moisture and light until it is prepared for administration. Details for mRNA-1273 DP storage and handling requirements are detailed in [mRNA-1273-P201 Clinical Study Protocol Section 3.4.4 \(Appendix 16.1.1\)](#). The 0.9% sodium chloride injection (USP) was stored at 20°C to 25°C (68°F to 77°F) in a restricted access area.

Further description of the IP and instructions for the receipt, storage, preparation, administration, accountability, and destruction of the IP were described in the mRNA-1273-P201 Pharmacy Manual.

3.6.3 Method of Assigning Participants to Study Treatment groups

On Day 1, after eligibility was confirmed, participants were randomly assigned to treatment groups in a 1:1:1 ratio in a blinded manner using a centralized IRT, in accordance with a pregenerated randomization schedule. The randomization schedule was provided after the database was locked for the primary analysis ([Appendix 16.1.7](#)). Only the unblinded pharmacy personnel ([Section 3.6.4](#)) had controlled access to which arm the participant was randomly assigned. Access to the randomization code was strictly controlled at the pharmacy.

Dose group assignment in each cohort within each cohort is summarized in [Table 5](#).

Table 5: Dose Group Assignment

Cohort	Treatment Group	Investigational Product	No. of Participants Planned
Cohort 1 ≥ 18 to < 55 years old	mRNA-1273 Arm	mRNA-1273 50 µg	100
	mRNA-1273 Arm	mRNA-1273 100 µg	100
	Placebo Arm	Placebo	100
Cohort 2 ≥ 55 years old	mRNA-1273 Arm	mRNA-1273 50 µg	100
	mRNA-1273 Arm	mRNA-1273 100 µg	100
	Placebo Arm	Placebo	100

3.6.4 Blinding and Unblinding

This was an observer-blind study. The investigator, study staff, study participants, site monitors, and Sponsor personnel (or its designees) were blinded to the IP administered until study end, with the following exceptions:

- Unblinded pharmacy personnel (of limited number) were assigned to IP accountability procedures and prepared and administered mRNA-1273 (or placebo) to all participants. These pharmacy personnel had no study functions other than IP management, documentation, accountability, preparation, and administration. They were not involved in participant evaluations and did not reveal the identity of IP to either the participant or the blinded study site personnel involved in the conduct of the study unless this information was necessary in the case of an emergency.
- Unblinded site monitors, not involved in other aspects of monitoring, were assigned as the IP accountability monitors. They were responsible for ensuring that sites followed all proper IP accountability, preparation, and administration procedures.
- Designated statistician(s) and programmer(s) from the PPD unblinded team, who were not involved in the study design, had access to the unblinded treatment group information during the study. The unblinded PPD personnel secured access to unblinded information per PPD SOPs throughout the study. The roles and responsibilities of the Sponsor and PPD study teams in receiving access to unblinded data during the clinical study are described in the Data Blinding Plan. A separate Blinding Plan for Immunogenicity Data further detailed the transfer of immunogenicity data from vendors to the designated unblinded PPD team, including specifications for data handling and processes for maintaining the blind for blinded Sponsor and PPD teams.
- A primary analysis of safety and immunogenicity data was performed after all participants completed Day 57 study procedures. All data relevant for primary study analysis through Day 57 and included in this CSR were cleaned (ie, data that were as

clean as possible) and locked. A limited number of Sponsor and PPD personnel were unblinded to perform and review the primary study analysis and prepare this CSR, including individual listings. The study site staff, investigators, study monitors, and participants remained blinded until the conclusion of the study. The Data Blinding Plan details the responsibilities of the Sponsor and the PPD study teams for receiving access to unblinded data during the clinical study.

- The SMC reviewed unblinded study data at specific time points, as detailed in the SMC charter, and ad hoc ([Section 3.8.5](#)).
- At each analysis, pre-identified Sponsor personnel were unblinded to review treatment-level results as defined in the study Data Blinding Plan. Unblinded data were provided by the designated PPD statisticians and programmers, who were not involved in study design. A strict firewall between the PPD blinded and unblinded teams was maintained during study conduct. Sponsor personnel who had access to review unblinded results was documented. The results of the primary analysis were not shared with the investigators before completion of the study.

The dosing assignment was concealed by having the unblinded pharmacy personnel prepare the IP in a secure location that was not accessible or visible to other study staff. A blinding label over the syringe used for injection maintained the blind at the time of injection, as the doses containing mRNA-1273 were different in appearance from the placebo. Only delegated unblinded site staff conducted the injection procedure. Once the injection was completed, only the blinded study staff performed further assessments and interacted with the participants. The investigator designated an unblinded clinical team member to provide oversight to the administration of IP so that it proceeded according to the procedures stipulated in the study protocol and the mRNA-1273-P201 Pharmacy Manual. Study-specific training was provided.

A participant or participants could have been unblinded in the event of an SAE or other severe event, or if there is a medical emergency requiring the identity of the product to be known to properly treat a participant. If a participant became seriously ill or pregnant during the study, the blind could have been broken if knowledge of the administered IP affected that participant's dosing options. In the event of a medical emergency requiring identification of the IP administered to an individual participant, the investigator was to make every attempt to contact the Sponsor medical lead to explain the need for opening the code within 24 hours of opening the code. The investigator was responsible for documenting the time, date, reason for the code break, and the names of the personnel involved.

3.6.5 Dosing Compliance

All doses of IP were administered at the study site, ideally under direct observation of unblinded pharmacy personnel as specified in the protocol. Administration of IP was appropriately recorded (date and time) in the eCRF. Unblinded pharmacy personnel confirmed that the participant received the entire dose of the IP. If a participant did not receive the IP or did not receive all of the planned doses, the reason for the missed dose was recorded. Dosing errors that occurred during the study, as summarized in [Section 5.3](#), were included in a data listing ([Listing 16.2.5.2](#)). Corrective and preventative actions were implemented at both sites where dosing errors occurred and guidelines were developed in a blinded manner for dosing error collection and handling in statistical analysis. Documentation related to the dosing errors is included in the electronic trail master file.

The required process followed if a participant missed the second injection due to noncompliance with the visit schedule (not due to a safety pause) and for ensuring participants complied with the allowed study windows are described in [mRNA-1273-P201 Clinical Study Protocol Section 3.4.7 \(Appendix 16.1.1\)](#).

3.6.6 Prior and Concomitant Medications and Therapies

3.6.6.1 Prior Medications and Therapies

A prior medication was defined as a medication received before first injection. Information about prior medications (including any prescription or over-the-counter medications, vaccines, or blood products) taken by the participant within the 28 days before providing informed consent (or as designated in the inclusion/exclusion requirements) were recorded in the participant's eCRF.

3.6.6.2 Concomitant Medications and Therapies

A concomitant medication was defined as a medication that continued or was newly received at or after the first injection through 28 days after the last injection. A post medication was defined as a medication received more than 28 days after the last injection. At each study visit, study site staff questioned the participant regarding any medications taken and vaccinations the participant received and recorded the information in the eCRF. The information recorded for concomitant medications, nonstudy vaccination, and treatment medication is described in [mRNA-1273-P201 Clinical Study Protocol Section 3.4.8 \(Appendix 16.1.1\)](#).

Concomitant medications and/or vaccines that did not require withdrawal of the participant from the study but may have determined a participant's eligibility to receive a second dose or evaluability in the per-protocol (PP) analysis are listed in [mRNA-1273-P201 Clinical Study Protocol Section 3.4.8 \(Appendix 16.1.1\)](#). Contraindications for administration of the second dose are provided in [Section 3.6.1.2](#).

If a participant took a prohibited drug therapy, the investigator and the PPD's medical monitor made a joint decision about continuing or withholding further injection of the participant based on the time the medication was administered, the drug's pharmacology and pharmacokinetics, and whether use of the medication compromised the participant's safety or interpretation of the data. It was the investigator's responsibility to ensure that details regarding the concomitant medications were adequately recorded in the eCRF.

3.7 Safety and Immunogenicity Measurements Assessed and Schedule of Assessments

For this primary analysis CSR, endpoint results are presented and described up to and including the Day 57 time point.

3.7.1 Study Assessments and Schedule of Events

The Schedule of Events for all participants is presented in [mRNA-1273-P201 Clinical Study Protocol Table 7 \(Appendix 16.1.1\)](#).

A participant also could have had an unscheduled visit at any time during the study. An unscheduled visit could have been prompted by reactogenicity issues or new or ongoing AEs. The site also had the discretion to make reminder telephone calls or send text messages to inform the participant about visits, review eDiary requirements, or follow-up on ongoing or outstanding issues.

In accordance with "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency" ([DHHS 2020](#)), investigators could have converted study site visits to telemedicine visits with the approval of the Sponsor. Such action was taken to protect the safety and well-being of study participants and study site staff or to comply with state or municipal mandates.

3.7.1.1 Use of Electronic Diary

Before enrollment on Day 1, the participant was instructed to download the eDiary application or was provided an eDiary device to record solicited ARs ([Section 3.7.1.1](#)) beginning within 60 minutes after injection on Day 1.

At each injection visit, participants were instructed (Day 1) or reminded (Day 29) on thermometer usage to measure body temperature, ruler usage to measure injection site erythema and swelling/induration (hardness), and self-assessment for localized axillary swelling or tenderness on the same side as the injection arm.

Participants recorded data into the eDiary at each injection visit, starting approximately 1 hour after injection under supervision of the study site staff to ensure successful entry of assessments. The site staff performed retraining as necessary. Study participants continued to record data in the eDiary after they left the study site, preferably in the evening and at the same time each day, on the day of injection and for 6 days following injection.

Participants recorded the following data in the eDiary:

- Solicited local and systemic reactogenicity ARs, as defined in [Section 3.7.2.1](#), that occurred on the day of each IP administration and during the 7 days after IP administration (ie, the day of injection and 6 subsequent days). Any solicited AR that was ongoing beyond Day 7 was reported in the eDiary until resolution. Adverse reactions recorded in diaries beyond Day 7 were reviewed by study site staff either during the next scheduled telephone call or at the next study site visit.
- Daily oral body temperature measurement should have been performed at approximately the same time each day using the thermometer provided by the study site. If body temperature was taken more than once in a given day, only the highest temperature reading should have been recorded.
- Measurement, as applicable, for solicited local ARs (injection site erythema and swelling/induration); the size measurements were performed using the ruler provided by the study site.
- Participants were queried by the eDiary about any medications that were taken to treat or prevent pain or fever on a day of injection or for the 6 subsequent days.

The eDiary was the only source document allowed for solicited systemic or local ARs (including body temperature measurements). Participants were instructed to complete eDiary entries daily. The participant had a limited window on the following day to complete assessments for the

previous day; quantitative temperature recordings and measurement of any injection site erythema or swelling/induration reported on the following day may have been excluded from the analyses of solicited ARs.

Any new safety information reported during safety telephone calls or at site visits (including a solicited reaction) that was not already captured in the eDiary was described in the source documents as a verbally reported event. Any AR reported in this manner was described as an unsolicited event and therefore entered on the AE eCRF.

The eDiary also was used after the Day 57 visit to capture the occurrence of AEs, MAAEs, SAEs, or AEs leading to study withdrawal and is detailed in the [mRNA-1273-P201 Clinical Study Protocol Section 3.5.2 \(Appendix 16.1.1\)](#); the EOS CSR will include eDiary data captured after Day 57.

If an eDiary record resulted in identification of relevant safety events according to the study period or of symptoms of COVID-19, the site followed up with the participant via telephone and assessed the need for an unscheduled visit.

Completion of eDiary questionnaires alternated with safety telephone calls ([Section 3.7.1.2](#)) as the procedure for safety follow-up approximately every 2 weeks after the Day 57 visit.

3.7.1.2 Safety Telephone Calls

A safety telephone call was a telephone call made to the participant by trained site personnel. This call followed a script, which facilitated the collection of relevant safety information. Safety telephone calls were scheduled for every 4 weeks from Day 85 through Day 197 and from Day 237 through Day 377. The participant was interviewed according to the script about occurrence of AEs, MAAEs, SAEs, AEs leading to study withdrawal, concomitant medications associated with those events, and any nonstudy vaccinations ([Section 3.7.2.1](#)). In addition, study personnel collect information on known participant exposure to someone with known COVID-19 or SARS-CoV-2 infection and on participant experience of COVID-19 symptoms. All safety information collected from the telephone contact was documented in source documents as described by the participant and not documented on the script used for the safety telephone contact.

3.7.2 Safety Assessments

The safety endpoints are provided in [Section 2](#). Safety assessments included monitoring and recording of the following for each participant:

- Solicited local and systemic ARs ([Section 3.7.2.1](#)) that occurred during the 7 days following each injection (ie, the day of injection and 6 subsequent days). Solicited ARs were recorded daily using eDiaries ([Section 3.7.1.1](#)).
- Unsolicited AEs observed or reported during the 28 days following each injection (ie, the day of injection and 27 subsequent days). Unsolicited AEs were AEs that were not included in the protocol-defined solicited ARs ([Section 3.7.2.1](#)).
- AEs leading to discontinuation from dosing and/or study participation from Day 1 through Day 394 or withdrawal from the study.
- MAAEs from Day 1 through Day 394 or withdrawal from the study.
- SAEs from Day 1 through Day 394 or withdrawal from the study.
- Results of safety laboratory tests.
- Vital sign measurements.
- Physical examination findings.
- Assessments for SARS-CoV-2 infection from Day 1 through study completion ([Section 3.7.2.3](#)).

3.7.2.1 Solicited Adverse Reactions

The term “reactogenicity” refers to the occurrence and intensity of selected signs and symptoms (ARs) occurring after IP administration. The eDiary ([Section 3.7.1.1](#)) solicited participant reporting of ARs using a structured checklist. Participants recorded such occurrences in an eDiary on the day of each IP administration and for the 6 days after a day of injection. Additionally, any AR reported during safety telephone calls or at site visits that was not already captured in the eDiary must have been described as an unsolicited event and, therefore, entered on the AE eCRF (and marked as “Yes” for the AE eCRF question “Was this a solicited adverse reaction?”). Such ARs were included in the evaluation of solicited ARs in addition to the eDiary data, as detailed in [Section 4.2.2.1](#).

The following local ARs were solicited by the eDiary: pain at injection site, erythema (redness) at injection site, swelling/induration (hardness) at injection site, and localized axillary swelling or tenderness ipsilateral to the injection arm.

The following systemic ARs were solicited by the eDiary: headache, fatigue, myalgia (muscle aches all over the body), arthralgia (aching in several joints), nausea/vomiting, rash, body temperature (potentially fever), and chills.

The study site staff contacted the participant within 24 hours of becoming aware of the event if any of the following occurred within 7 days after study injection:

- Severe (grade 3) local or systemic ARs ([mRNA-1273-P201 Clinical Study Protocol Table 4; Appendix 16.1.1](#)),
- Presence of any rash, or
- Presence of any underarm swelling or tenderness on the same side as the injection arm.

The purpose of the contact was to assess the nature of AR, including assessment of potential pause rules. If a rash or underarm swelling or tenderness on the same side as the injection arm was reported, the participant was asked to return to the study site for assessment by the investigator.

The investigator reviewed, confirmed, and graded reactogenicity according to grading scales (grade 0 through grade 4) modified from the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials ([DHHS 2007](#); see [mRNA-1273-P201 Clinical Study Protocol Table 4; Appendix 16.1.1](#)).

If a solicited local or systemic AR continued beyond 7 days after injection, the participant was prompted to capture solicited local or systemic ARs in the eDiary until resolution. Adverse reactions recorded in eDiaries beyond Day 7 should have been reviewed either via telephone call or at the following study visit. All solicited ARs (local and systemic) were considered causally related to injection.

In case of any rash episode observed within 7 days after study injection, the participant was instructed to contact the study site within 24 hours. During participant evaluation, the investigator categorized the rash as one of the following:

- Rash no longer present and history not consistent with urticaria.
- Rash no longer present but history is consistent with urticaria.
- Rash present but clinical findings are not consistent with urticaria. Alternative diagnosis should be specified as an AE.
- Rash present and clinical findings consistent with urticaria.

Rash was graded as follows:

- Grade 0 = no rash
- Grade 1 = localized without associated symptoms
- Grade 2 = maculopapular rash covering < 50% body surface area
- Grade 3 = urticarial rash covering > 50% body surface area
- Grade 4 = generalized exfoliative, ulcerative or bullous dermatitis

Any solicited AR that met any of the following criteria were entered into the participant's source document and recorded as an AE in the participant's AE eCRF:

- Solicited local or systemic AR that resulted in a visit to an healthcare practitioner (HCP) (MAAE)
- Solicited local or systemic AR that lead to the participant withdrawing from the study or the participant being withdrawn from the study by the investigator (AE leading to withdrawal)
- Solicited local or systemic AR that lasted beyond 7 days post injection
- Solicited local or systemic AR that led to participant withdrawal from IP administration
- Solicited local or systemic AR that otherwise met the definition of an SAE
- Solicited AR with a toxicity score of grade 3 or greater

3.7.2.2 Unsolicited Adverse Events, Serious Adverse Events, and Medically Attended Adverse Events

The investigator was responsible for reporting all AEs that were observed or reported during the study, regardless of their relationship to the IP or their clinical significance. If there was any doubt as to whether a clinical observation was an AE, the event was reported.

The AE and SAE definitions are provided in the [mRNA-1273-P201 Clinical Study Protocol Section 3.5.8.1](#) and [Section 3.5.8.3 \(Appendix 16.1.1\)](#). A treatment-emergent AE (TEAE) was defined as any event not present before exposure to the IP or any event already present that worsened in intensity or frequency after exposure.

An unsolicited AE is any AE reported by the participant that is not specified as a solicited AR in the protocol or was specified as a solicited AR in the protocol but started outside the protocol-defined postinjection period for reporting solicited ARs (ie, for the 7 days after each injection).

An MAAE was an AE that leads to an unscheduled visit to an HCP. This included visits to a study site for unscheduled assessments (eg, rash assessment, abnormal laboratory follow-up, SARS-CoV-2 infection [[Section 3.7.2.3](#)]) and visits to HCPs external to the study site (eg, urgent care, primary care physician). Investigators reviewed unsolicited AEs for the occurrence of any MAAEs. All MAAEs were fully reported on the MAAE page of the eCRF.

An AR was any AE for which there was a reasonable possibility that the IP caused the AE ([Section 3.7.2.1](#)). For the purposes of investigational new drug safety reporting, “reasonable possibility” means that there was evidence to suggest a causal relationship between the IP and the AE.

The following information on AEs was obtained:

- Type: MAAE, Solicited AR
- Seriousness
- Duration (start and stop dates)
- Severity: mild/grade 1, moderate/grade 2, severe/grade 3, or grade 4
- Relationship to IP: Not related, related, not applicable (if event occurred before first dose)
- Relationship to study procedure: Not related, related, not applicable (if event occurred before first dose)
- Actions taken
- Outcome

Additional information on reporting and documenting AEs and SAEs as well as assessment of causality and severity are provided in the [mRNA-1273-P201 Clinical Study Protocol Section 3.5.8 \(Appendix 16.1.1\)](#).

Unsolicited AEs were captured from Day 1 through 28 days after each dose up to Day 57 (-3/+7 days). Both MAAEs and SAEs were captured from Day 1 throughout entire study duration (Day 394 for all participants), as specified in the [mRNA-1273-P201 Clinical Study Protocol Section 3.5.8.6 \(Appendix 16.1.1\)](#). Any AEs that occurred before receipt of the IP were analyzed separately from TEAEs.

At every study site visit or telephone contact, participants were asked a standard question to elicit any medically related changes in their well-being according to the scripts provided ([Section 3.7.1.2](#)). Participants were also asked if they had been hospitalized, had any accidents,

used any new medications, changed concomitant medication regimens (both prescription and over-the-counter medications), or had any nonstudy vaccinations.

In addition to participant observations, data from clinical laboratory test results, physical examination findings, or other documents relevant to participant safety classified as an AE were documented on the AE page of the eCRF.

All AEs, SAEs, and MAAEs were reported in detail on the appropriate page of the eCRF and followed until the event was resolved or stable or judged by the investigator to be not clinically significant.

3.7.2.3 Assessment of SARS-CoV-2 Infection

The number of cases and incidence of confirmed SARS-CoV-2 infection was an exploratory endpoint ([Section 2](#)).

Study participants had nasopharyngeal swab samples collected for SARS-CoV-2 testing at time points specified in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol, Table 7; Appendix 16.1.1](#)).

A study illness visit or a consultation was arranged within 24 hours or as soon as possible to collect a nasopharyngeal swab sample to ascertain the presence of SARS-CoV-2 via RT-PCR if a participant experienced any of the following:

- Signs or symptoms of SARS-CoV-2 infection as defined by the CDC ([CDC 2020c](#))
- Exposure to an individual confirmed to be infected with SARS-CoV-2
- MAAE suggesting a SARS-CoV-2 infection

Additionally, clinical information was carefully collected to evaluate the severity of the clinical case. All findings were recorded in the eCRF.

If scheduled, a study site illness visit may have included assessments such as medical history, physical examination, blood sampling for clinical laboratory testing, and nasopharyngeal swab sampling for viral polymerase chain reaction (PCR) (including multiplex PCR for respiratory viruses including SARS-CoV-2) to evaluate the severity of the clinical case. Radiologic imaging studies also may have been conducted. Blood samples were collected at all illness visits for potential future immunologic assessment of SARS-CoV-2 infection.

The process followed for participants confirmed to have SARS-CoV-2 infection, including participants who were asymptomatic, is detailed in [mRNA-1273-P201 Clinical Study Protocol Section 3.5.1 \(Appendix 16.1.1\)](#).

Any confirmed SARS-CoV-2 infection occurring in participants, except asymptomatic infection diagnosed at Day 1, was captured as an MAAE (defined in [Section 3.7.2.2](#)) along with relevant concomitant medications and details about severity, seriousness, and outcome.

3.7.2.4 Pregnancy

Any pregnancy that occurred in participants after enrollment was reported to Sponsor or designee within 72 hours of the site learning of its occurrence. If the participant agreed to submit this information, the pregnancy was followed to determine the outcome. Details regarding pregnancy follow-up and reporting are provided in [mRNA-1273-P201 Clinical Study Protocol, Section 3.5.8.7 \(Appendix 16.1.1\)](#).

3.7.2.5 Safety Laboratory Assessments

Laboratory tests were performed by the central laboratory ([Section 3.3](#)) unless otherwise specified.

The following laboratory testing was performed at Screening for all participants and at Visit 4 (Day 29) and Visit 7 (Day 57) for Cohort 2 (≥ 55 years of age):

Hematology: complete blood count with differential

Chemistry: alanine alkaline phosphatase, aminotransferase, aspartate aminotransferase, total and direct bilirubin, blood urea nitrogen, creatinine, and blood urea nitrogen/creatinine ratio

Coagulation: prothrombin time, international normalized ratio, activated partial thromboplastin time

Additional tests included the following:

Urine pregnancy test: A point-of-care urine pregnancy test was performed at the Screening Visit (Day 0) and before each IP administration (Day 1 and Day 29). At any time, a blood or point-of-care urine pregnancy test could have been performed, at the discretion of the investigator.

FSH: If not documented in a female participant's medical records, an FSH test was performed at the Screening Visit (Day 0), as necessary, and at the discretion of the investigator, to confirm postmenopausal status.

Serology (at Screening only for all participants): Hepatitis B surface antigen, hepatitis C virus antibody, and HIV virus (types 1 and 2) antibody

3.7.2.6 Vital Sign Measurements

Vital sign measurements included systolic and diastolic blood pressure, heart rate, respiratory rate, and body temperature (preferred route was oral). Vital signs were measured at the time points indicated in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol, Table 7](#)) and as described in [mRNA-1273-P201 Clinical Study Protocol Section 3.5.9 \(Appendix 16.1.1\)](#). Any participant with fever detected at Day 1 and Day 29 visits were managed as detailed in [Section 3.6.1.2](#).

If any of the vital sign measurements met the toxicity grading criteria for clinical abnormalities of grade 3 or greater, as provided in the [mRNA-1273-P201 Clinical Study Protocol \(Table 8; Appendix 16.1.1\)](#), the abnormal value and grade were documented on the AE page of the eCRF (unless there was another known cause of the abnormality that resulted in an AE classification). The investigator continued to monitor the participant with additional assessments until the vital sign value reached the reference range, returned to the vital sign value at baseline, was considered stable, or until the investigator determined that follow-up was no longer medically necessary.

3.7.2.7 Physical Examinations

A full physical examination, including height and weight, was performed at scheduled time points as indicated in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol, Table 7; Appendix 16.1.1](#)). The full examination included assessment of skin, head, ears, eyes, nose, throat, neck, thyroid, lungs, heart, cardiovascular, abdomen, lymph nodes, and musculoskeletal system/extremities. Any clinically significant finding identified during a study visit was reported as a MAAE.

Symptom-directed physical examinations may have been performed at other time points at the discretion of the investigator. On each injection day before injection and again 7 days after injection, the arm receiving the injection was examined and the associated lymph nodes evaluated.

Body mass index was calculated at the Screening Visit (Day 0) only.

3.7.3 Immunogenicity Assessments

The primary, secondary, and exploratory immunogenicity endpoints are provided in [Section 2](#). Blood samples for immunogenicity assessments were collected at the time points indicated in the Schedule of Events ([mRNA-1273-P201 Clinical Study Protocol Table 7; Appendix 16.1.1](#)). On Day 1 and Day 29, blood samples for immunogenicity assessment were collected before IP administration. The following were the immunogenicity assessment performed:

- Serum bAb level against SARS-CoV-2 as measured by ELISA specific to the SARS-CoV-2 spike protein
- Serum nAb titer against SARS-CoV-2 as measured by pseudovirus and/or live virus neutralization assays
- Serum bAb level against SARS-CoV-2 as measured by ELISA specific to the SARS-CoV-2 nucleocapsid (NP) protein (as a measure of asymptomatic infection)

The analysis for exploratory endpoints are not included in this CSR but will be included in the EOS CSR.

Sample collection, including backup samples, is described in [mRNA-1273-P201 Clinical Study Protocol Section 3.5.5 \(Appendix 16.1.1\)](#). Handling and preparation of the samples for analysis, as well as shipping and storage requirements, were provided in a separate study manual.

The ELISAs and measurement of nAb titers were performed in Sponsor-designated laboratories ([Section 3.3](#)).

For participants who provided consent, serum from immunogenicity testing may be used for future research ([Section 3.4.3](#)).

3.7.3.1 Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum

The detection and measurement of human immunoglobulin G (IgG) specific to SARS-CoV-2 spike protein was done through a quantitative ELISA developed in collaboration with PPD. Briefly, microtiter plates were coated overnight with commercially available SARS-CoV-2 S-2P spike protein (GenScript, Catalog #U578BFC290). After blocking, serum samples were added in duplicate and incubated for 2 hours. Bound antigen-antibody complex was detected using purified goat anti-human IgG horseradish peroxidase conjugate. Color was developed with the

addition of TMB [3,3',5,5'-tetramethylbenzidine] substrate and color intensity was measured spectrophotometrically (optical density [OD] 450 nm). The color intensity was directly proportional to the IgG antibody concentration present in the serum sample. Four quality controls and a negative control (blank) were analyzed in duplicate on each assay plate. Data were processed using the PPD Preclarus[®] LIMS processor, in accordance with PPD SOPs. For the qualified assay, the standard curve was generated using the anti-SARS-CoV spike monoclonal antibody [clone CR3022] (Rockland, Inc, Limerick, Pennsylvania, USA). Quantitation of the human IgG antibody to SARS-CoV-2 spike, or antibody concentration ($\mu\text{g/mL}$), was determined by interpolation from an 11-point dilution of CR3022 analyzed on each assay plate. Human sera from SARS-CoV-2 convalescent symptomatic patients (N=119), collected at least 15 days after infection confirmed by RT-PCR, served as reference control titers on each assay plate (BioIVT, Westbury, New York, USA; and Aalto Bio Reagents Ltd, Dublin, Ireland).

3.7.3.2 SARS-CoV-2 Microneutralization Assay

In addition to pure binding activity, it is desirable to have a way to measure if vaccine elicited antibodies are able to mediate a functional activity. Typically, in the case of viral pathogens this is done through the quantification of the ability of antibodies to neutralize the virus and render it non- or less infectious. Thus, the SARS-CoV-2 microneutralization (MN) assay was designed to quantify serum nAbs against SARS-CoV-2 using an in situ ELISA readout. Sera samples with both baseline and postbaseline nAb data were included in this analysis (Cohort 1: 92 participants in the placebo group and 90 and 95 participants in the 50 μg and 100 μg mRNA-1273 groups; Cohort 2: 89 participants in the placebo group and 89 and 91 participants in the 50 μg and 100 μg mRNA-1273 groups). The SARS-CoV-2 MN assay was qualified for the evaluation of human serum and conducted in accordance with the provider laboratory SOPs (Battelle) and with the use of qualified critical reagents. Briefly, dilutions of heat-inactivated serum samples and controls were incubated with an infective SARS-CoV-2 viral stock (isolate USA-WA1/2020) prior to inoculation onto a cell culture plate containing a confluent VERO E6 cell monolayer. Following a 40- to 46-hour incubation, the inoculum was removed and an in situ ELISA performed to detect SARS-CoV-2 antigen. The OD value of each sample well was measured using a microplate reader using a wavelength of 405 nm and a 490 nm reference. Finally, the OD values were analyzed using BioAssay in accordance with Battelle's SOPs. The final reportable value for each sample is the MN_{50} and an endpoint titer.

3.7.3.3 Detection of IgG Specific to SARS-CoV-2 Nucleocapsid Protein in Human Serum

The detection and measurement of human IgG specific to SARS-CoV-2 NP protein was done through a quantitative ELISA. Briefly, microtiter plates are coated overnight with commercially available SARS-CoV-2 NP (full length) recombinant protein (MyBiosource, Catalog #MBS596190). After blocking, serum samples were added in duplicate and incubated for 2 hours. Bound antigen-antibody complex was detected using purified goat anti-human IgG horseradish peroxidase conjugate. Color was developed with the addition of TMB substrate and color intensity was measured spectrophotometrically (OD 450 nm). The color intensity was directly proportional to the IgG antibody concentration present in the serum sample. Quantitation of the human IgG antibody to SARS-CoV-2 NP, or antibody concentration (arbitrary units per mL or AU/mL), was determined by interpolation from an 11-point standard curve derived from a panel of human sera from SARS-CoV-2 convalescent patients analyzed on each assay plate. In addition, 4 quality controls and a negative control (blank) were analyzed in duplicate on each assay plate.

3.7.3.4 Assessment of SARS-CoV-2 Infection by Detection of SARS-CoV-2 Genomic RNA by RT-PCR in Nasopharyngeal Samples

A real-time RT-PCR test was used for the detection of SARS-CoV-2 genomic RNA in patient samples. This qualitative diagnostic assay was granted Emergency Use Authorization ([Viracor 2020](#)) to the performing laboratory, Viracor-Eurofins Clinical Diagnostics. Briefly, nucleic acid extractions were performed using a bioMerieux NucliSENS easyMAG or eMAG instrument with bioMerieux NucliSENS nucleic acid extraction reagents. RNA was reverse transcribed using oligonucleotide primers specific nucleotide sequences of the SARS-CoV-2 N gene, then amplified in the presence of thermostable DNA polymerase (*Thermus aquaticus*) enzyme and deoxyribonucleotide triphosphates. A dual-labeled oligonucleotide probe to an internal sequence of the amplification product was also present in the RT-PCR reaction mixture with dye label FAM at the 5' end, and a fluorescence-quenching molecule (eg, Black Hole Quencher 1) at the 3' end of the probe. Additionally, oligonucleotide primers and a TaqMan probe for PCR detection of an internal extraction and amplification control were also present in the SARS-CoV-2 RT-PCR reaction mix. This allowed for the simultaneous detection of internal extraction/amplification control DNA in a multiplex reaction for each sample. Fluorescence intensity for both SARS-CoV-2 amplification and internal control amplification was measured in individual wells during each of the 40 amplification cycles. A sample was considered positive when the signal intensity exceeded a predetermined baseline threshold value based on cycle

number, referred to as the cycle threshold (CT). Detection of SARS-CoV-2 RNA in a sample was determined by a CT value of 38.

3.7.4 Appropriateness of Measurements

The safety measures included in this study were appropriate for a preventative vaccine for an infectious disease, including assessment of solicited ARs and unsolicited AEs. The immunogenicity measures and methodology (ELISA and RT-PCR) used in this study were standard and appropriate.

Categorization of local and systemic solicited ARs, clinical laboratory test results, and vital sign measurements observed during this study followed the guidance outlined in the Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials ([DHHS 2007](#)).

Due to circulation of SARS-CoV-2 in the general population, assessments included pre-injection blood samples and postinjection blood samples for antibody analysis through 12 months after the last dose of IP. Nasopharyngeal swab sample and blood samples were taken to confirm the diagnosis of SARS-CoV-2 and enhanced monitoring of participants was followed for participants with confirmed SARS-CoV-2 infection.

Nasopharyngeal swab samples were collected before study injection to help discriminate between natural infection and vaccine-induced antibody responses, as required.

3.8 Data Quality Assurance

All aspects of the study were monitored for compliance with applicable government regulations with respect to current ICH harmonised tripartite guideline E6(R2): GCP and current SOPs.

Due to safety review requirements, study sites followed the data entry and availability instructions provided by the Sponsor in the study readiness trainings. As a quality measure, timeliness of data entry and data query resolution were followed closely. Other issues of data quality that may have hindered safety review or posed a concern with participant safety were brought to the attention of the Sponsor or PPD, with appropriate awareness to the SMC if needed.

3.8.1 Data Collection and Management

As part of the responsibilities assumed by participating in the study, the investigator agreed to maintain adequate case histories for participants treated as part of the research under the

protocol. The investigator agreed to maintain accurate eCRFs and source documentation as part of the case histories. These source documents included laboratory reports, as provided from the central laboratory ([Section 3.3](#)), and similar sources.

Electronic case report forms were used in this study and accessed through iMedidata® via the internet. This electronic data capture system was validated and compliant with US Title 21 of CFR Part 11. Each person involved with the study had an individual identification code and password that allowed for record traceability. Thus, the system, and subsequently any investigative reviews, identified coordinators, investigators, and individuals who entered or modified records, as well as the time and date of any modifications.

Each eCRF was presented as an electronic copy, allowing data entry by site personnel, who could add and edit data, add new participants, identify and resolve discrepancies, and view records. This system provided immediate direct data transfer to the database, as well as immediate detection of discrepancies, enabling site coordinators to resolve and manage discrepancies in a timely manner. Data entered via eCRFs and into the iMedidata were combined with data provided from other sources (eg, data for clinical laboratory tests, immunogenicity tests, nasopharyngeal swab, and IRT).

Clinical data management was performed in accordance with applicable PPD SOPs. PPD Clinical Data Management supported centralized monitoring by edit checks and listing review, as outlined in the Data Validation Manual, and by reviewing query responses, tracking, and reporting tools. Solicited ARs, unsolicited AEs, and medical history were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 23.0. Prior and concomitant medications and nonstudy vaccination were coded using World Health Organization Drug Dictionary (WHODrug)-Global-B3, March 2020.

3.8.2 Study Monitoring

Ongoing safety monitoring was performed in a blinded manner by PPD's medical monitor, the Sponsor's medical monitor, and the individual investigators throughout the study.

The study monitor, as a representative of the Sponsor, was obligated to follow the study closely. In doing so, the monitor visited the investigator and study facility at periodic intervals, in addition to maintaining necessary telephone and letter contact. The monitor maintained current personal knowledge of the study through observation, review of study records and source documentation, and discussion of the conduct of the study with the investigator and staff. The

monitor was blinded to dose assignments. A separate unblinded study monitor was responsible for IP accountability.

All aspects of the study were carefully monitored by the Sponsor or its designee for compliance with applicable government regulation with respect to current ICH E6(R2) guidelines and SOPs.

3.8.3 Audits

Each investigator and institution permitted audits. In the event of an audit, the investigator was to promptly notify the Sponsor and forward copies of any received audit reports to the Sponsor, as detailed in [mRNA-1273-P201 Clinical Study Protocol Section 6.1.3 \(Appendix 16.1.1\)](#).

At the time of the data cutoff for this primary analysis CSR, the Sponsor completed 3 site audits. Audit certificates are provided in [Appendix 16.1.8](#).

3.8.4 COVID-19

In response to the COVID-19 pandemic, the FDA released guidance for documenting missed visits/assessments. The data collection requirements for COVID-19 were collected on the COVID-19 Impact eCRF. In addition, missed visits/assessments related to COVID-19 were collected as protocol deviations and were reconciled with Medidata.

Per the FDA guidance, investigators could have converted study site visits to telemedicine visits with the approval of the Sponsor ([Section 3.7.1](#)).

3.8.5 Safety Monitoring Committee

Safety oversight was under the direction of an SMC composed of external independent consultants with relevant expertise. Members of the SMC were independent from the study conduct and free of conflict of interest. The SMC met on a regular basis to assess safety throughout the study conduct. The SMC operated under the rules of an approved charter that was written and reviewed at the organizational meeting of the SMC. Details regarding the SMC composition, responsibilities, procedures, and frequency of data review are defined in its charter.

The SMC could have convened on an ad hoc basis if any of the pause rules were met ([Section 3.6.1.1](#)). For any ad hoc meeting convened, the SMC reviewed all available unblinded study data to adjudicate any potential study pauses and made recommendations on further study conduct, including requesting additional information, recommending stopping the study, recommending changes to study conduct and/or the protocol, or recommending additional operational considerations due to safety issues that arose during the study.

3.8.6 Risk Management

This study was conducted according to ICH E6(R2) risk and quality processes. Throughout the project lifecycle, risks and mitigation plans were regularly reviewed and communicated. Critical data and processes were determined during an initial risk assessment and were monitored as part of ongoing risk management, as defined in the Sponsor's SOP on risk management. A centralized monitoring strategy with key risk indicators was utilized, and centralized statistical monitoring and data trending analyses were performed. Further, a risk register was established with preplanned and ad hoc review meetings and discussions. Finally, centralized risk-based monitoring was implemented using an adaptive and intelligent monitoring strategy

Given the short duration of the mRNA-1273-P201 study, the Sponsor decided not to implement monitoring of quality tolerance limits for this study. A small sample size and/or short study duration amplifies the challenges in identifying systematic errors early enough to allow sufficient time for improvement based on root cause analysis and subsequent implementation of mitigation steps.

4 Statistical Analysis Methods Planned in the Protocol and Determination of Sample Size

4.1 Statistical Methods

All analyses were conducted using SAS software (SAS Institute, Inc, Cary, North Carolina) Version 9.4 or higher. The final [mRNA-1273-P201 SAP](#), version 3.0, dated 27 Oct 2020, is provided in [Appendix 16.1.9](#).

4.1.1 General Considerations

- Continuous variables were summarized using the mean, standard deviation (SD), median, minimum value, and maximum value. Categorical variables were summarized using frequency counts and percentages.
- Solicited ARs, unsolicited AEs, and medical history were coded by system organ class (SOC) and preferred term (PT) according to the MedDRA version 23.0.
- Prior, concomitant, post medications, and nonstudy vaccination were coded using the WHODrug-Global-B3, March 2020.
- Local and systemic solicited ARs, clinical laboratory test results, and vital sign measurements were categorized based on Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials ([DHHS 2007](#)). For any laboratory abnormalities, grading only occurred if the values were outside of the normal values established by the central laboratory. Study-specific laboratory normal ranges and associated toxicity grades were detailed in the Central Laboratory Manual.
- Baseline value, unless specified otherwise, was defined as the most recent nonmissing measurement (scheduled or unscheduled) collected before the first dose of study injection. For immunogenicity and nasal swab tests, baseline was defined as the most recent nonmissing measurement (scheduled or unscheduled) collected before or on the date of first dose of study injection (Day 1).
- For calculation regarding antibody levels/titers, antibody values reported as below the lower limit of quantification (LLOQ) was replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the upper limit of quantification (ULOQ) was converted to the ULOQ. Missing results were not imputed.

- Study day was calculated relative to first injection as follows:
 1. Before first injection: date of assessment/event – date of the first injection
 2. On or after the date of the first injection: date of assessment/event – date of the first injection + 1
- Study day was calculated relative to the most recent injection as follows:
 1. Study day prior to the first injection: date of assessment/event – date of the first injection
 2. Study day on or after the date of the first injection but before the second injection (if applicable): date of assessment/event – date of the first injection + 1
 3. Study day on or after the date of the second injection: date of assessment/event – date of the second injection + 1. If study day was on the same day as the second injection, date and time were compared with the second injection date and time. If date was prior to the second injection, study day was calculated per #2. If date was after the second injection or the time was missing or not available, study day was calculated as: date of assessment/event – date of the second injection + 1.
- The analysis visit windows for protocol-defined visits are provided in [mRNA-1273-P201 SAP Appendix B \(Appendix 16.1.9\)](#).
- The following treatment groups were used for summary purposes: placebo, mRNA-1273 50 µg, mRNA-1273 100 µg, and mRNA-1273 total. If a participant received any injection that was at a nonprotocol dose, the participant was assigned to a protocol dose (placebo, mRNA-1273 50 µg, or mRNA-1273 100 µg) for that injection according to the following rule:
 - mRNA-1273 50 µg if the received dose > 0 µg and ≤ 75 µg, or
 - mRNA-1273 100 µg if the received dose > 75 µg
- All analyses and data summaries/displays were provided by overall treatment group (the 2 age cohorts combined) and for each age cohort (≥ 18 to < 55 years old, ≥ 55 years old), unless otherwise specified.
- This study was divided into the following stages: vaccination, follow-up, overall, and 28 days after any injection. Detailed definitions of each stage are provided in [mRNA-1273-P201 SAP Section 6.1 \(Appendix 16.1.9\)](#).

4.1.2 Determination of Sample Size

There was no hypothesis testing in this study. The number of proposed participants was considered sufficient to provide a descriptive summary of the safety and immunogenicity of different dose levels of mRNA-1273.

Approximately 600 participants were randomly assigned in a 1:1:1 ratio to mRNA-1273 50 µg, mRNA-1273 100 µg, or placebo. A total of 400 participants were planned to receive mRNA-1273, 200 participants in each dose level, or 100 participants in each age cohort and dose level. Table 6 presents the 95% confidence interval (CI) for 1 participant with an AE and the lowest AE rate detectable with at least 95% probability for each selected sample size. The 2-sided 95% CI was calculated using the Clopper-Pearson method for one proportion in SAS 9.4 software. The 2-sided 95% CI was estimated (0.01%, 1.38%) at a sample size of 400 with 1 participant reporting an AE. Furthermore, a sample size of 400 had at least a 95% probability to observe at least 1 participant with an AE at a true 0.75% AE rate.

Table 6: 95% CI for One Participant With AE and the Lowest Detectable Incidence Rate at 95% Probability in Selected Sample Size

Sample Size Receiving mRNA-1273	Rate and 95% CI (%) at One Participant With AE			Lowest Detectable Rate (%) With 95% Probability
	AE Rate	Lower CI	Upper CI	
100	1.00	0.03	5.45	2.95
200	0.50	0.01	2.75	1.49
400	0.25	0.01	1.38	0.75

Abbreviations: AE=adverse event; CI=confidence interval.

4.1.3 Analysis Sets

The following were the analysis sets defined for this study:

- **Randomized Set:** All participants who were randomized in the study, regardless of the participant's treatment status in the study. Participants were included in the treatment group to which they were randomized.
- **Solicited Safety Set:** All participants who were randomized and received any study injection, and contributed any solicited AR data, ie, had at least one postbaseline solicited safety assessment. The Solicited Safety Set was used for the analyses of solicited ARs, and participants were included in the treatment group corresponding to the study injection they actually received. In addition, the following Solicited Safety Set was defined for each injection separately.

- **First (Second) Injection Solicited Safety Set:** All participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data from the time of first (second) study injection through the following 6 days.

Participants were analyzed according to the treatment group a participant received, rather than the treatment group to which the participant was randomized. Participants who received a second injection that was different from the first injection were summarized under the higher dose of treatment group (eg, placebo < mRNA-1273 50 µg < mRNA-1273 100 µg).

- **Safety Set:** All randomized participants who received any study injection. The Safety Set was used for analysis of safety, except for the solicited ARs. Participants were included in the treatment group corresponding to the vaccination they actually received. Participants who received a second injection that was different from the first injection were summarized under the higher dose of treatment group (eg, placebo < mRNA-1273 50 µg < mRNA-1273 100 µg).
- **Full Analysis Set (FAS)** was defined as follows:
 - **FAS for SARS-CoV-2-specific bAb:** All randomized participants who received any study vaccination, had baseline (Day 1) SARS-CoV-2-specific bAb data available, and had at least one postinjection SARS-CoV-2-specific bAb assessment for the analysis endpoint. Participants were included in the treatment group to which they were randomized.
 - **FAS for SARS-CoV-2-specific nAb:** All randomized participants who received any study vaccination, had baseline (Day 1) SARS-CoV-2-specific nAb data available, and had at least one postinjection SARS-CoV-2-specific nAb assessment for the analysis endpoint. Participants were included in the treatment group to which they were randomized.

- **Per-Protocol (PP) Set** was defined as follows:

- **PP Set for SARS-CoV-2-specific bAb:** All FAS for SARS-CoV-2-specific bAb participants who meet all of the following criteria:

- Complied with the injection schedule
- Complied with the timings of immunogenicity blood sampling to have postinjection results available for at least one assay component corresponding to the immunogenicity analysis objective for SARS-CoV-2-specific bAb
- Did not have SARS-CoV-2 infection at baseline
- Had had no major protocol deviations that impacted immune response during the period corresponding to the immunogenicity analysis objective

The PP Set for SARS-CoV-2-specific bAb served as the primary population for the analysis of SARS-CoV-2-specific bAb immunogenicity data in this study. Participants were included in the treatment group to which they were randomized.

- **PP Set for SARS-CoV-2-specific nAb** consisted of all FAS for SARS-CoV-2-specific nAb participants who meet all of the following criteria:

- Complied with the injection schedule
- Complied with the timings of immunogenicity blood sampling to have postinjection results available for at least one assay component corresponding to the immunogenicity analysis objective for SARS-CoV-2-specific nAb
- Did not have SARS-CoV-2 infection at baseline
- Had no major protocol deviations that impacted immune response during the period corresponding to the immunogenicity analysis objective

The PP Set for SARS-CoV-2-specific nAb served as the primary population for the analysis of SARS-CoV-2-specific nAb data in this study. Participants were included in the treatment group to which they were randomized.

4.1.4 Handling of Missing Data

Imputation rules for missing or partial dates for prior and concomitant medications, nonstudy vaccinations, and procedures are provided in [mRNA-1273-P201 SAP Appendix C](#), and imputation rules for missing AE dates are provided in [mRNA-1273-P201 SAP Appendix D \(Appendix 16.1.9\)](#).

For laboratory assessments, if the majority of results were indefinite, imputation of these values was considered. If the laboratory results were reported as below the LLOQ (eg, < 0.1), the numeric values were imputed by $0.5 \times \text{LLOQ}$ in the summary. If the laboratory results were reported as greater than the ULOQ (eg, > 3000), the numeric values were imputed by ULOQ in the summary.

Other incomplete/missing data were not imputed, unless specified otherwise.

4.1.5 Primary Analyses

A primary analysis of safety and immunogenicity data was performed after all participants completed Day 57 study procedures. All data relevant to the primary study analysis through Day 57 were cleaned (as clean as possible) and locked. A limited number of Sponsor and PPD personnel were unblinded to perform the primary study analysis and prepare this final CSR ([Section 3.6.4](#)).

4.1.6 End of Study Analysis

The EOS analysis of all endpoints will be performed after all participants have completed Month 13 study procedures and after the database is cleaned and locked. Results of this analysis will be presented in an EOS CSR, including individual listings.

4.1.7 Multiplicity Adjustments

No adjustments were made to control for multiple comparisons or multiplicity.

4.1.8 Multicenter Studies

No analyses were performed based on grouping or excluding any of the study sites.

4.1.9 Adjustment for Covariates

Immunogenicity analyses included adjustments for covariates, as detailed in [Section 4.2.3.1](#).

4.1.10 Examination of Subgroups

There are 2 age cohorts in this study: participants ≥ 18 to < 55 years old in Cohort 1 and participants ≥ 55 years old in Cohort 2.

4.1.11 Active-Control Studies Intended to Show Equivalence

No active comparator groups were used in this study.

4.2 Population, Safety, and Immunogenicity Statistical Analyses

4.2.1 Study Population

4.2.1.1 Disposition

The number and percentage of participants in the following categories were summarized by overall treatment group (age cohorts combined) and by age cohort based on the Randomized Set: Randomized Set, Solicited Safety Set, Safety Set, FAS, and PP Set. The percentage was based on participants in an age cohort and treatment group within the Randomized Set.

The number of participants in the following categories were summarized based on participants screened: number of participants screened; and number and percentage of screen failure participants and the reason for screen failure.

The number and percentage of participants in each of the following disposition categories were summarized by overall treatment group and by age cohort based on the Randomized Set: randomized by site, received each study injection, prematurely discontinued study injection and the reason for discontinuation, completed study, and prematurely discontinued the study and the reason for discontinuation. The denominator for all percentages was the number of participants in the age cohort and treatment group within the Randomized Set.

Participant disposition was provided in a listing. A separate listing was provided for screen failure participants with reasons for screen failure.

For the EOS CSR, a participant who completed 12 months of follow-up after the last injection received was considered to have completed the study.

4.2.1.2 Major Protocol Deviations

Major protocol deviations were a subset of protocol deviations that significantly impacted the completeness, accuracy, or reliability of the study data or that significantly affected a participant's rights, safety, or well-being. Major protocol deviations rules were developed and finalized before database lock.

The number and percentage of the participants with each major protocol deviation type were summarized by overall treatment groups and by age cohort based on the Randomized Set.

Major protocol deviations were presented in a listing.

4.2.1.3 Demographics and Baseline Characteristics

Descriptive statistics were calculated for the following continuous demographic and baseline characteristics: age (years), weight (kg), height (cm), and BMI (kg/m²). Number and percentage of participants were provided for categorical variables, such as gender, race, ethnicity. The summaries were presented by overall treatment group and by age cohort based on the Safety Set, PP Set, and FAS.

For screened failure participants, age (years), gender, race, and ethnicity were presented in a listing.

Participants with any inclusion and exclusion criteria violation also were presented in a listing.

4.2.1.4 Medical History

The number and percentage of participants with any medical history was summarized by SOC and PT based on the Safety Set. A participant was counted only once for multiple events within each SOC and PT. The SOC was displayed in internationally agreed order, and PTs were displayed in descending order of frequency of total mRNA-1273 and then alphabetically within SOC.

Medical history data were presented in a listing.

4.2.1.5 Prior, Concomitant, and Post Medications

Prior, concomitant, and post medications are defined in [Section 3.6.6](#).

The summary of concomitant medications was based on the Safety Set. The number and percentage of participants using concomitant medications and nonstudy vaccination during the 7-day follow-up period (ie, on the day of injection and the 6 subsequent days) and during the 28-day follow-up period after each injection (ie, on the day of injection and the 27 subsequent days) were summarized by overall treatment group and by age cohort as follows:

- Any concomitant medications and nonstudy vaccination within 7 days after injection
- Any concomitant medications and nonstudy vaccination within 28 days after injection
- Prophylactic antipyretics or analgesics medication within 28 days after injection
- Antipyretic or analgesic medication within 28 days after injection

Concomitant medications and nonstudy vaccinations that continued or were newly received at or after the first injection through 28 days after the last injection were summarized by PT in descending frequency in the mRNA-1273 group with both dose levels combined.

Prior, concomitant, and post medications and nonstudy vaccinations were presented in a listing. Concomitant procedures were presented in a listing.

4.2.1.6 eDiary Compliance, Exposure, and COVID-19 Impact

Solicited ARs were recorded in an eDiary as summarized in [Section 3.7.1.1](#). The completion status of the eDiaries among the 7-day period and on each individual day was summarized.

Investigational product administration and COVID-19 impact were separately presented in listings. These data were not summarized for this primary analysis CSR.

4.2.2 Safety Analyses

All safety analyses were conducted on the Safety Set, except summaries of solicited ARs, which were based on the Solicited Safety Set.

4.2.2.1 Solicited Adverse Reactions

Solicited ARs, including local and systemic ARs collected in the eDiary, are described in [Section 3.7.2.1](#). Any new safety information reported during safety telephone calls or at site visits (including a solicited AR) that was not already captured in the eDiary was described in the source documents as a verbally reported event. Any AR reported in this manner must have been described as an unsolicited event and, therefore, entered on the AE eCRF (and marked as “Yes” for the AE eCRF question “Was this a solicited adverse reaction?”), and was included in the evaluation of solicited ARs in addition to the eDiary data.

All solicited ARs (local and systemic) were considered causally related to injection.

All solicited ARs analyses were summarized by overall treatment group and by age cohort for the first injection, second injection, and any injection, unless otherwise specified. The following summary tables were provided:

- The number and percentage of participants who reported each individual solicited local AR (severity $\geq$ grade 1) and solicited systemic AR (severity $\geq$ grade 1) during the 7-day follow-up period after each injection were summarized by severity grade.

- The number and percentage of participants who reported each individual solicited AR were summarized by severity grade and day of reporting, within this summary the number and percentage of participants experiencing fever ($\geq 38.0^{\circ}\text{C}/100.4^{\circ}\text{F}$; oral, axillary, or tympanic route) were summarized by severity grade.
- The number and percentage of participants with onset of individual solicited AR were summarized by study day relative to the corresponding injection (Day 1 through Day 7), where onset of individual solicited AR was defined as the time point after each injection at which the respective solicited AR first occurred.
- The number of days reporting each solicited AR was summarized descriptively and summarized by the following time windows: 1 to 2 days, 3 to 4 days, 5 to 6 days, and ≥ 7 days. Calculation of the day of the solicited AE relative to injection is provided in [mRNA-1273-P201 SAP Section 6.3.2.1 \(Appendix 16.1.9\)](#).
- The number and percentage of participants who reported solicited rash and lymphadenopathy, as assessed by HCP, were summarized by severity grade.

In the summary by severity grade and summary by severity grade and day of reporting, a 2-sided 95% exact CI using the Clopper-Pearson method was provided for the percentage of participants who reported any solicited local AR, solicited systemic AR, or any solicited AR. Within each summary of systemic ARs, the number and percentage of participants experiencing fever ($\geq 38.0^{\circ}\text{C}/100.4^{\circ}\text{F}$; oral, axillary, or tympanic route) were summarized by severity grade.

Separate listings of individual participant solicited AR data, as collected in the eDiary and the AE eCRF and with the maximum grade from the eDiary and AE eCRF, were provided for the following: solicited local ARs, solicited systemic ARs, solicited ARs (including rash) that continued beyond 7 days post injection, solicited rash, and solicited lymphadenopathy.

4.2.2.2 Unsolicited Adverse Events

Definitions and details regarding AEs are provided in [Section 3.7.2.1](#).

All summary tables for unsolicited TEAEs (except for the overall summary of TEAEs) were presented by SOC and PT for TEAEs with counts of participants included. All safety analyses were summarized by overall treatment group and by age cohort, unless otherwise specified.

The following considerations applied:

- Unsolicited TEAEs were summarized separately by stage (28 days after any vaccination stage and overall stage [Day 1 to Day 57 for this primary analysis; the EOS CSR will provide overall stage Day 1 to Day 394]).
- All summary tables (except for the overall summary of TEAEs) for unsolicited TEAEs were presented by SOC and PT for TEAEs with participant counts included.
- Preferred terms were displayed in descending order of frequency of total mRNA-1273 and then alphabetically within SOC.
- Participants with multiple occurrences of the same AE or a continuing AE were counted once in summaries within each SOC and PT.
- Participants who reported multiple events under the same SOC and/or PT were presented in summaries according to the highest severity (the strongest relationship).
- Percentages were based upon the number of participants in the Safety Set within each treatment group.

The overall summaries of unsolicited TEAEs (number and percentage) for each stage included the following: any unsolicited TEAEs, any serious TEAEs, any unsolicited TEAEs that are MAAEs, any unsolicited TEAEs leading to discontinuation from IP, any unsolicited TEAEs leading to discontinuation from participation in the study, any unsolicited severe TEAEs, and any unsolicited fatal TEAEs. The overviews also included a summary of participants with treatment-related TEAEs in each category.

The following summary tables of TEAEs were be provided by SOC and PT using frequency counts and percentages (ie, number and percentage of participants with an event):

- All unsolicited TEAEs
- All treatment-related unsolicited TEAEs
- All serious TEAEs
- All treatment-related serious TEAEs
- All unsolicited TEAEs leading to discontinuation from participation in the study
- All severe unsolicited TEAEs
- All severe unsolicited treatment-related TEAEs
- All unsolicited TEAEs that were MAAEs

A summary of TEAEs by SOC, PT, and severity (mild, moderate, and severe) using frequency counts and percentages was provided for all unsolicited TEAEs and all treatment-related unsolicited TEAEs.

All unsolicited TEAEs were summarized, with PTs presented in descending order according to the total column for mRNA-1273.

Separate listings of individual participant AE data were provided for the following: unsolicited AEs, unsolicited TEAEs leading to discontinuation from IP, unsolicited TEAEs leading to discontinuation from participation in the study, SAEs, and unsolicited MAAEs.

4.2.2.3 Safety Laboratory Evaluations

Laboratory test results for hematology, serum chemistry, coagulation, and pregnancy testing were presented in the data listings. Results that were outside the reference ranges were flagged. The abnormalities meeting the toxicity grading criteria in any safety laboratory (hematology, serum chemistry, and coagulation) were listed separately. If a participant had an abnormal laboratory test at any postinjection visit, all results for that participant and laboratory tests were presented in the listing.

For continuous hematology, serum chemistry, and coagulation measurements, the observed values and changes from baseline were summarized at each visit by treatment group for Cohort 2. The number and percentage who had any abnormal result based on toxicity grades in hematology, serum chemistry, or coagulation measurements also were summarized by visit and treatment group for Cohort 2. Shift from baseline in the toxicity grades to the worst postbaseline result in the vaccination stage was summarized by treatment group for Cohort 2.

4.2.2.4 Vital Sign Measurements

All vital sign measurement data were presented in a data listing. Values meeting the toxicity grading criteria were flagged. The abnormalities meeting the toxicity grading criteria (grade 2 or higher) in any vital sign measurement were listed separately. If a participant has a vital sign result of grade 2 or higher at any postinjection visit, all results of vital sign measurement for that participant were presented in the listing.

Observed values and changes from baseline for all vital sign measurements were summarized at each visit by overall treatment group and by age cohort. Shift from baseline in the toxicity grades at each visit and shift from baseline in the toxicity grades to the worst postbaseline result also were summarized by overall treatment group and by age cohort.

4.2.3 Immunogenicity Analysis

The primary and secondary immunogenicity endpoints are provided in [Section 2](#). The immunogenicity assessments performed for serum bAb level against SARS-CoV-2 serum nAb titer against SARS-CoV-2 are summarized in [Section 3.7.3](#).

The analyses of immunogenicity were based on the PP Set and were performed by treatment group for each age cohort separately. If the number of participants in the FAS and PP Sets differed (defined as the difference divided by the total number of participants in the PP Set) by more than 10% (for each age cohort), supportive analyses of immunogenicity would have been conducted using the FAS. The supportive analysis was required if the condition was met.

The formula used to calculate geometric mean (GM) titer (GMT) and GM level is provided in [mRNA-1273-P201 SAP Section 6.4 \(Appendix 16.1.9\)](#).

4.2.3.1 Analysis of Antibody-Mediated Immunogenicity Endpoints

For each group, the following evaluations were performed at each time point at which blood samples were collected for immunogenicity (unless otherwise specified):

- The GM level of SARS-CoV-2-specific bAb levels with corresponding 95% CI were provided at each time point. The 95% CIs were calculated based on the t-distribution of the log-transformed values then back transformed to the original scale for presentation. The GM level and corresponding 95% CI were plotted at each time point. The following descriptive statistics were also provided at each time point: the number of participants, median, minimum, and maximum.
- The GM fold-rise (GMFR) of SARS-CoV-2-specific bAb levels with corresponding 95% CI were provided at each postbaseline time point over pre-injection baseline at Day 1. The 95% CIs were calculated based on the t-distribution of the log-transformed values then back transformed to the original scale for presentation. The GMFR and corresponding 95% CI were plotted at each time point. The following descriptive statistics were also provided at each time point: the number of participants, median, minimum, and maximum.
- The GMT of SARS-CoV-2-specific nAb titers with corresponding 95% CI were provided at each time point using the same method mentioned above.
- The GMFR of SARS-CoV-2-specific nAb titers with corresponding 95% CI were provided at each postbaseline time point over pre-injection baseline at Day 1 using the same method mentioned above. The proportion of participants with fold-rise ≥ 2 , fold-rise ≥ 3 , and fold-rise ≥ 4 of serum SARS-CoV-2-specific nAb titers from Day 1

(baseline) at each postinjection time points were tabulated with 2-sided 95% Clopper-Pearson CIs.

- The proportion of participants with seroconversion were tabulated with 2-sided 95% Clopper-Pearson CIs at each postbaseline time point. Seroconversion at a participant level was defined as a change of nAb titer from below the LLOQ to equal to or above LLOQ (respectively) or a 4-times higher titer ratio in participants with pre-existing nAb titers.
- The GM level, GMT, and GMFR with corresponding 95% CI were also evaluated using an analysis of covariance (ANCOVA) model with baseline level/titer as a covariate and age cohort as a factor in the analysis in the overall group. The model was conducted based on the log-transformed values then back transformed to the original scale for presentation.
- Per the study protocol, if the visit for the second dose (Day 29) was disrupted and could not be completed at Day 29 (+7 days) as a result of the COVID-19 pandemic (self-quarantine or disruption of clinical site activities following business continuity plans and/or local government mandates for “stay at home” or “shelter in place”), the window was allowed to be extended to Day 29 + 21 days. Additional sensitivity analysis of immunogenicity data was conducted for the above endpoints using the “adjusted” PP Set based on the more rigid visit window, -3/+7 for the Day 29 visit, as appropriate.

4.2.4 Exploratory Endpoint Analyses

4.2.4.1 Exploratory Immunogenicity Analyses

Analysis of the exploratory endpoints is not included in this primary analysis CSR. These results will be included in the EOS CSR ([Section 4.1.6](#)). Details of the planned exploratory analyses of immunogenicity, which will be included in the EOS CSR, are provided in the [mRNA-1273-P201 SAP Section 6.5.1 \(Appendix 16.1.9\)](#).

4.2.4.2 Nasopharyngeal Swab Samples

Nasopharyngeal swab samples were collected for SARS-CoV-2 testing. The number and percentage of participants with detected and not detected SARS-CoV-2 were summarized at each visit by age cohort and treatment group.

4.2.4.3 SARS-CoV-2 Exposure and Symptoms

The number and percentage of participants who had close contact with a person with SARS-CoV-2 infection or COVID-19, reasons for exposure, participants with any symptoms of

potential COVID-19, and participants with each symptoms were presented by visit, age cohort, and treatment group. Descriptive statistics were provided for length of exposure in days and time from exposure to first symptom by age cohort and treatment group.

In addition, the following listings were provided for participants infected by SARS-CoV-2:

- Serum bAb level against SARS-CoV-2
- Serum nAb titer against SARS-CoV-2
- Solicited ARs
- Unsolicited AEs

4.3 Changes to the Planned Analyses

4.3.1 Changes from Planned Analyses in Protocol

The final [mRNA-1273-P201 SAP](#) included the following changes to the planned analysis provided in the protocol:

- Antibody values reported as below LLOQ were replaced by $0.5 \times \text{LLOQ}$, rather than by $0.5 \times \text{limit of detection}$ or $0.5 \times \text{LLOQ}$.
- Seroconversion at the participant level was defined as a change of nAb titer from below the LLOQ to equal to or above LLOQ, rather than from below the limit of detection or LLOQ to equal to or above limit of detection or LLOQ (respectively), or a 4-times or higher titer ratio in participants with pre-existing nAb titers.
- PP Set for SARS-CoV-2-specific nAb was redefined because 2 different virus lots were used for the neutralization assays; only results from the first lot were included the primary analysis ([Section 5.2](#)), and the data from both the first lot and the second lot were presented in the sensitivity analysis

4.3.2 Ad Hoc Analyses

The following summary tables not described in the protocol or final SAP were produced after the study was unblinded to supplement the safety analyses:

- To further investigate reactogenicity, ad hoc summaries were produced for participant use of medications to prevent or treat solicited ARs of pain or fever based on participant-recorded eDiary entries and reported analgesic/antipyretic use recorded on the concomitant page of the eCRF.

- To thoroughly characterize all potential treatment-emergent immune-mediated disorders of interest, ad hoc summaries of AEs of special interest were produced by searching the database using individual Standardized MedDRA Queries (SMQs).

5 Study Populations

5.1 Disposition of Participants

Of the 1090 participants screened for entry into the study, 490 were screen failures, primarily because of inclusion or exclusion criteria (418/1090 [85.3%]; [Table 14.1.1.3](#) and [Figure 3](#)).

A total of 600 participants were randomly assigned to study treatment: 200 participants each in the placebo, mRNA-1273 50 µg, and mRNA-1273 100 µg groups ([Table 7](#) and [Figure 3](#)). Within each treatment group, 100 participants each were included in Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) ([Table 14.1.1.1](#)). Participant randomization was balanced across study sites (range: 72/600 [12.0%] to 97/600 [16.2%]), with the exception of one site that randomized 33 of 600 participants (5.5%; [Table 14.1.1.2](#)).

In each treatment group, all participants received the first injection of IP and the majority of participants in both age cohorts ($\geq 97\%$) received the second injection ([Table 7](#) and [Figure 3](#)). Two participants, one randomly assigned to the placebo group and one to the mRNA-1273 100 µg group, received the incorrect IP at the first injection because the unblinded staff switched their prepared treatments, with each participant receiving the other's assigned treatment ([Listing 16.2.5.2](#)). At the second injection, each participant received the same treatment as for the first injection, under the coordination of the unblinded study personnel. In safety and reactogenicity analyses, each participant was included in the treatment group corresponding to the treatment received, while for analyses conducted on the Randomized Set, they were included according to the planned treatment group. The dose switches were considered major deviations and are discussed further in [Section 5.3.1](#).

Seven of 400 (1.8%) participants who received mRNA-1273 (5/200 [2.5%] and 2/200 [1.0%] in the mRNA-1273 50 and 100 µg groups, respectively) and 6 of 200 (3.0%) participants who received placebo discontinued the IP ([Table 7](#) and [Figure 3](#)). A comparable percentage of participants in Cohort 1 (4/200 [2.0%]) and Cohort 2 (3/200 [1.5%]) discontinued mRNA-1273 ([Table 14.1.1.1](#)). All 6 participants who discontinued placebo were in Cohort 1.

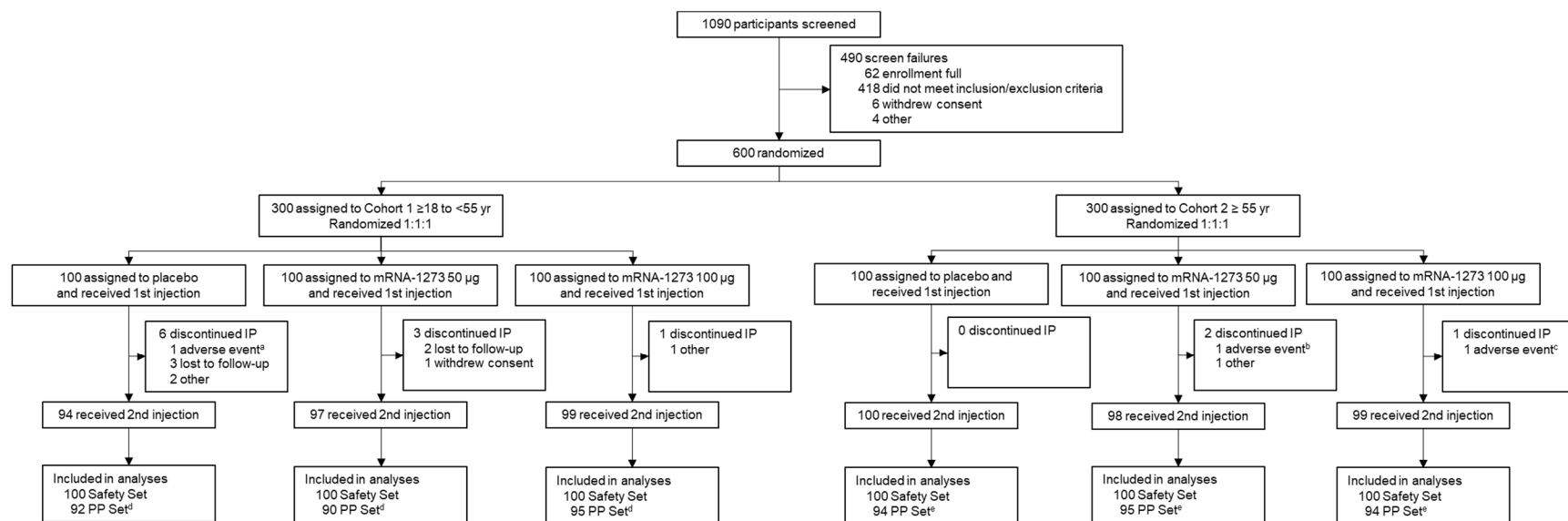
The reasons for mRNA-1273 discontinuation were AEs (other), lost follow-up, and "other" reasons (each 2/400 [0.5%]); and withdrawal of consent (1/400 [0.3%]; [Table 7](#)). Of the 2 participants who discontinued IP due to AEs, the participant in the mRNA-1273 100 µg group specifically discontinued due to solicited ARs. These ARs were reported on the AE eCRF following the instructions specified in the mRNA-1273-P201 Clinical Study Protocol ([Section 3.7.2.1](#); Appendix 16.1.1). This participant reported three grade 3 solicited ARs (fatigue, myalgia, and arthralgia) that were initially captured on the AE eCRF. However, per feedback the

Sponsor received from the FDA before the primary analysis, these ARs should not have been reported as unsolicited TEAEs because none lasted > 7 days post injection or met the criteria for an SAE. Therefore, this participant is tabulated in disposition summaries as having had an AE that led to IP discontinuation but is not included in any summaries of TEAEs that led to IP discontinuation ([Section 7.3.3.1](#)). For participants with the reason indicated as “other,” one participant (mRNA-1273 50 µg) had a positive COVID-19 test result ([Section 7.3.3.1](#)), and one participant (mRNA-1273 100 µg) had a false-positive COVID-19 test result that was identified as false after the allowed window for the second injection had passed. Additional details for participants with COVID-19 infections are provided in [Section 7.3.3.6](#) and [Section 8.3.1](#).

The reasons for discontinuation of placebo were AE (COVID-19 infection; 1/200 [0.5%]), lost to follow-up (3/200 [1.5%]), and “other” reasons (2/200 [1.0%]; related to false-positive COVID-19 results).

Few participants who received mRNA-1273 or placebo discontinued from the study ([Table 7](#)). The primary reasons for discontinuation were lost to follow-up (5/400 [1.3%] in mRNA-1273 overall group and 4/200 [2.0%] in placebo group) and withdrawal of consent (COVID-19 noninfection related; 1/200 [0.5%] in the mRNA-1273 50 µg group).

An overview of participant disposition in this study is shown in [Figure 3](#).

Figure 3 Participant Disposition

Abbreviations: bAb=binding antibody; COVID-19= coronavirus disease 2019; IP=investigational product; nAb=neutralizing antibody; PP=per protocol; SARS-CoV-2= severe acute respiratory syndrome coronavirus that causes COVID-19.

Note: The “other” reasons for IP discontinuation included 3 participants with false-positive COVID-19 infection results and 1 participant (mRNA-1273 50 µg) with a positive COVID-19 infection result.

^a COVID-19 infection.

^b Serious treatment-emergent adverse event of pneumonia that occurred > 28 days after IP administration and led to IP discontinuation.

^c Participant in the mRNA-1273 100 µg group is indicated as having discontinued IP due to adverse event (other) in disposition summaries but participant had 3 solicited adverse reactions that led to IP discontinuation.

^d Participant totals: 92, 90, and 95 in the PP Set for SARS-CoV-2-specific bAb and PP Set for SARS-CoV-2-specific nAb (first lot) for placebo, mRNA-1273 50 µg, and mRNA-1273 100 µg groups, respectively.

^e Participant totals: 92, 90, and 95 in the PP Set for SARS-CoV-2-specific bAb and 89, 89, and 91 in the PP Set for SARS-CoV-2-specific nAb (first lot) for placebo, mRNA-1273 50 µg, and mRNA-1273 100 µg groups, respectively.

Source: [Table 14.1.1.1](#), [Table 14.1.2](#), and [Table 14.1.1.3](#) and [Listing 16.2.1.1](#).

Table 7: Participant Disposition (Randomized Set)

	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)	Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Number of subjects					
Received first injection	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
Received second injection	194 (97.0)	195 (97.5)	198 (99.0)	393 (98.3)	587 (97.8)
Discontinued study vaccine	6 (3.0)	5 (2.5)	2 (1.0)	7 (1.8)	13 (2.2)
Reason for discontinuation of study vaccine					
Adverse event (COVID-19 infection)	1 (0.5)	0	0	0	1 (0.2)
Adverse event (other)	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Death	0	0	0	0	0
Lost to follow-up	3 (1.5)	2 (1.0)	0	2 (0.5)	5 (0.8)
Physician decision	0	0	0	0	0
Pregnancy	0	0	0	0	0
Protocol deviation	0	0	0	0	0
Study terminated by Sponsor	0	0	0	0	0
Withdrawal of consent (COVID-19 non-infection related)	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Withdrawal of consent (other)	0	0	0	0	0
Other	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)	4 (0.7)
Completed study ^a	0	0	0	0	0
Discontinued from study	4 (2.0)	5 (2.5)	1 (0.5)	6 (1.5)	10 (1.7)
Reason for discontinuation of study					
Adverse event (COVID-19 infection)	0	0	0	0	0
Adverse event (other)	0	0	0	0	0
Death	0	0	0	0	0
Lost to follow-up	4 (2.0)	4 (2.0)	1 (0.5)	5 (1.3)	9 (1.5)
Physician decision	0	0	0	0	0
Pregnancy	0	0	0	0	0
Protocol deviation	0	0	0	0	0
Study terminated by sponsor	0	0	0	0	0
Withdrawal of consent (COVID-19 non-infection related)	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Withdrawal of consent (other)	0	0	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)	Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Other	0	0	0	0	0

Percentages are based on the number of randomized subjects.

^a Study completion is defined as a subject who completed 12 months of follow-up after the last injection received.

Source: [Table 14.1.1.1.](#)

5.2 Study Analysis Sets

All 600 participants in the Randomized Set received IP and were included in the Safety Set and the Solicited Safety Set (Table 8). All participants who received mRNA-1273 (50 or 100 µg) were included in the First Injection Solicited Safety Set; one participant in the placebo group who received the first injection was not included in the First Injection Solicited Safety Set because the participant did not contribute any solicited AR data after the first injection (Listing 16.2.3.1). Inclusion in the Second Injection Solicited Safety Set was $\geq 97\%$ in each treatment group.

The primary analysis sets were the PP Sets for SARS-CoV-2-specific bAb and nAb (defined in Section 4.1.3). However, the primary analysis set for SARS-CoV-2-specific nAb was redefined because 2 different virus lots were used for the neutralization assays, with the majority of the assays performed from a single lot. The primary analysis set for nAb is the PP Set for SARS-CoV-2-specific nAb from the First Lot (546/600 [91.0%]; (Table 8) and included participants with results from the first virus lot used in the assays. A second PP Set for nAb was defined that included data from all the viral lots used (ie, 14 additional participants), the PP Set for SARS-CoV-2-specific nAb from All Lots (560/600 [93.3%]); results based on this analysis set were used to identify any meaningful differences with the nAb primary analysis.

Participants were not included in the primary analysis PP Sets if they met any of the criteria listed in Section 4.1.3. The majority ($> 90\%$) of participants who received mRNA-1273 or placebo were included in the PP Set for SARS-CoV-2-specific bAb (374/400 [93.5%] and 186/200 [93.0%], respectively), with no notable differences observed for the Day 29 and Day 57 analyses (Table 8). Similarly, the majority ($> 90\%$) of participants who received mRNA-1273 or placebo were included in the PP Set for SARS-CoV-2-specific nAb from the First Lot (365/400 [91.3%] and 181/200 [90.5%], respectively), with no notable differences observed for the Day 29 and Day 57 analyses.

The disposition profile of each FAS was comparable to the corresponding PP Set, and the number of participants in the FAS and PP Sets did not differ by $> 10\%$ (as defined in Section 4.2.3); thus, supportive analyses of immunogenicity based on the FAS were not required.

Age Cohorts

The percentage of participants included in the Safety Set, Solicited Safety Sets, and PP Sets were comparable between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) (Table 14.1.2).

Table 8: Number of Participants in Each Analysis Set (Randomized Set)

	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)	Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Safety set	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
Solicited safety set	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
First injection solicited safety set	199 (99.5)	200 (100)	200 (100)	400 (100)	599 (99.8)
Second injection solicited safety set	194 (97.0)	195 (97.5)	198 (99.0)	393 (98.3)	587 (97.8)
Full analysis set ^a					
Full analysis set for SARS-CoV-2-specific bAb	196 (98.0)	198 (99.0)	197 (98.5)	395 (98.8)	591 (98.5)
Day 29	194 (97.0)	196 (98.0)	195 (97.5)	391 (97.8)	585 (97.5)
Day 57	196 (98.0)	194 (97.0)	197 (98.5)	391 (97.8)	587 (97.8)
Full analysis set for SARS-CoV-2-specific nAb from the first lot	191 (95.5)	192 (96.0)	195 (97.5)	387 (96.8)	578 (96.3)
Day 29	188 (94.0)	180 (90.0)	187 (93.5)	367 (91.8)	555 (92.5)
Day 57	191 (95.5)	167 (83.5)	170 (85.0)	337 (84.3)	528 (88.0)
Full analysis set for SARS-CoV-2-specific nAb from all lots	196 (98.0)	198 (99.0)	198 (99.0)	396 (99.0)	592 (98.7)
Day 29	194 (97.0)	191 (95.5)	192 (96.0)	383 (95.8)	577 (96.2)
Day 57	196 (98.0)	186 (93.0)	192 (96.0)	378 (94.5)	574 (95.7)
Per-protocol (PP) set ^b					
PP set for SARS-CoV-2-specific bAb	186 (93.0)	185 (92.5)	189 (94.5)	374 (93.5)	560 (93.3)
Day 29	184 (92.0)	184 (92.0)	189 (94.5)	373 (93.3)	557 (92.8)
Day 57	175 (87.5)	176 (88.0)	177 (88.5)	353 (88.3)	528 (88.0)

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	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)	Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
PP set for SARS-CoV-2-specific nAb from the first lot	181 (90.5)	179 (89.5)	186 (93.0)	365 (91.3)	546 (91.0)
Day 29	178 (89.0)	168 (84.0)	180 (90.0)	348 (87.0)	526 (87.7)
Day 57	171 (85.5)	150 (75.0)	152 (76.0)	302 (75.5)	473 (78.8)
PP set for SARS-CoV-2-specific nAb from all lots	186 (93.0)	185 (92.5)	189 (94.5)	374 (93.5)	560 (93.3)
Day 29	184 (92.0)	179 (89.5)	185 (92.5)	364 (91.0)	548 (91.3)
Day 57	175 (87.5)	168 (84.0)	171 (85.5)	339 (84.8)	514 (85.7)

Abbreviations: bAb=binding antibody; nAb=neutralizing antibody-19.

Percentages are based on the number of randomized subjects.

For the summaries using Safety Set and Solicited Safety Set, if a subject received any study vaccination injection that is at a nonprotocol dose, the subject is assigned to a protocol dose (placebo if received placebo, mRNA-1273 vaccine 50 µg if the received dose > 0 µg and ≤ 75 µg, or mRNA-1273 vaccine 100 µg if the received dose > 75 µg) for that injection. Subjects who received a second injection that is different from the first injection are assigned to the higher dose of vaccination group (eg, Placebo < mRNA-1273 50 µg < mRNA-1273 100 µg).

- ^a Full Analysis Set for each visit includes all subjects who received any study vaccination, and had immunogenicity data available at both baseline and the corresponding postinjection visit.
- ^b The PP Set for each visit includes all subjects in the Full Analysis Set who did not have SARS-CoV-2 infection at baseline, did not have a major protocol deviation that impact immune response, complied with the injection schedule and the timing of immunogenicity blood sampling to have postinjection results available for at least one assay component at the corresponding visit.

Source: [Table 14.1.2](#).

5.3 Protocol Deviations

The most common ($\geq 2\%$ of participants) major protocol deviations in the Randomization Set were visit scheduling (70/600 [11.7%]), missing endpoint assessments (31/600 [5.2%]), and study procedure/assessments (16/600 [2.7%]; [Table 9](#)). The incidence of each common major deviation was comparable for participants who received mRNA-1273 (50 or 100 μg) and placebo, with no apparent differences observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) ([Table 14.1.1.4](#)).

Visit scheduling and study procedure/assessment deviations included participants with COVID-19–related missed visits or assessments, which are described further in [Section 5.6](#). The missing endpoint assessment deviations primarily involved participants who missed completing entries in the eDiary for solicited ARs ([Listing 16.2.2.2](#)).

Additional subject-level major deviations of interest include dosing errors (summarized in [Section 5.3.1](#)), entry criteria deviations, and concomitant medication deviations. Ten of 600 participants (1.7%) in the Randomization Set met exclusion criteria and were randomly assigned to treatment ([Table 9](#)): 4 participants had exclusion criteria deviations identified on the Inclusion/Exclusion Criteria eCRF ([Listing 16.2.2.1](#)) and 6 additional participants were identified per clinical monitoring ([Listing 16.2.2.2](#)). Seven participants (5 in the mRNA-1273 100 μg group and 1 each in mRNA-1273 50 μg and placebo group) met Exclusion Criterion 18 (clinical safety laboratory test result $\geq$ grade 1); and 3 participants (1 in mRNA-1273 50 μg group and 2 in placebo group) were found to be related to study site staff, in violation of Exclusion Criterion 30 (additional details provided in [Section 5.3.2](#)). One participant (1/200 [0.5%]) randomized to placebo had a screening BMI which was greater than the allowed upper limit per defined in Inclusion Criterion 4 (30 kg/m^2); the deviation was captured on the Inclusion/Exclusion Criteria eCRF ([Listing 16.2.2.1](#)) and the site reported that the participant's height may have been incorrectly measured ([Listing 16.2.2.2](#)). One participant each in the mRNA-1273 50 and 100 μg group received a prohibited concomitant medication; both received a shingles vaccine < 28 days after an IP injection ([Listing 16.2.4.4](#)).

5.3.1 Deviations Related to Dosing Errors

Three dosing errors occurred during the study ([Listing 16.2.5.2](#)). One participant received a volume of IP > 0.5 mL, and 2 participants received the incorrect IP at the first injection.

The first IP injection for one participant in the mRNA-1273 100 μg group had a dose volume > 0.5 mL (> 100 to 125 μg ; [Listing 16.2.5.1](#)). This was reported as major deviation of study treatment administration/dispensing ([Listing 16.2.2.2](#)). The dosing error occurred when an

unblinded staff personnel withdrew more IP than was stated in the Pharmacy Manual and dose preparation instructions. The participant received the correct dose of IP at the second injection. The site completed a corrective and preventative action report and unblinded study site staff were retrained on proper dosing preparation procedures.

Two participants who were at the clinical site at the same time received the incorrect IP for the first injection after an unblinded study site personnel inadvertently switched the prepared treatment doses, with the participant assigned to placebo receiving mRNA-1273 100 µg and the participant assigned to mRNA-1273 100 µg receiving placebo. These were reported as a major protocol deviations. At the second injection, each participant received the same treatment as for the first injection.

For the purpose of the safety analysis all 3 participants were included in the treatment group they actually received, as summarized in [Section 5.1](#).

5.3.2 Site GCP and Protocol Noncompliance

Site US207, which randomized 72 participants ([Table 14.1.1.2](#)), was found to be noncompliant with GCP.

In August 2020, the site's parent company notified the Sponsor that the site director, who was also the study coordinator, had removed participant study records from the site. Upon notification, the Sponsor immediately initiated an investigation that included conducting blinded and unblinded monitoring visits by clinical research associates, carrying out 100% source document verification, and conducting a GCP for-cause audit. The site fully cooperated with these activities.

The GCP for-cause audit and site monitoring visits confirmed that at no point was the participants' safety compromised. Furthermore, they revealed that the former site director had removed records from the clinical site in deviation from the site's SOPs, and also had directed the unblinded study pharmacy staff to complete and sign dosing worksheets for 3 participants, indicating that pharmacy staff had administered IP to the participants, when in fact it could not be confirmed that IP had been administered. Additionally, 3 participants who were related to study site staff were enrolled into the study, in violation of Exclusion Criterion 30 ([Section 3.5.2](#)). In immediate response, the site terminated the employment of the site director and 3 other staff. Participants' study records initially reported as missing from the study site were returned. Records for all participants were confirmed as being on site. For any data that were not

supported by the available source documentation, the data were removed from the electronic data capture system and were documented as protocol deviations.

As of October 2020, 100% source document verification was completed for all 72 participants through Day 57. An acceptable corrective and preventative actions plan was provided by the site to address the observations from the for-cause audit. Actions included retraining of current staff, hiring of additional experienced staff, implementation of enhanced quality control procedures, and the addition of regular quality oversight meetings.

The unblinded clinical research associate completed the IP accountability, and the IP has been removed from the site to a qualified clinical depot for reconciliation and destruction.

Based on all evidence reviewed, the root cause for the noncompliance was isolated and specific to Site US207. The noncompliance was determined to be the result of the misconduct of a single staff member, the site director, who also served as the site's blinded study coordinator. Furthermore, insufficient oversight of the site director by the investigator permitted the occurrence of the noncompliance.

The Sponsor notified the FDA and the central IRB of the noncompliance, and the corrective and preventative actions put in place. At the time the noncompliance was identified, all dosing had been completed.

Table 9: Major Protocol Deviations (Randomized Set)

Deviation Type	Placebo (N=200) n (%)	mRNA-1273			Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
Concomitant medication	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Exclusion criteria	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)	10 (1.7)
ICF process/timing	2 (1.0)	3 (1.5)	6 (3.0)	9 (2.3)	11 (1.8)
Inclusion criteria	1 (0.5)	0	0	0	1 (0.2)
Informed consent	3 (1.5)	1 (0.5)	0	1 (0.3)	4 (0.7)
Inv record keeping source docs	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
Missing endpoint assessments	10 (5.0)	12 (6.0)	9 (4.5)	21 (5.3)	31 (5.2)
Study procedures/assessments	6 (3.0)	1 (0.5)	9 (4.5)	10 (2.5)	16 (2.7)
Study treatment admin/dispense	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)	8 (1.3)
Study treatment compliance	1 (0.5)	0	0	0	1 (0.2)
Visit scheduling	17 (8.5)	28 (14.0)	25 (12.5)	53 (13.3)	70 (11.7)

Source: [Table 14.1.1.4.](#)

5.4 Demographics and Other Baseline Characteristics

The participants in the Safety Set were approximately two-thirds female (390/600 [65.0%] overall) and mostly White (569/600 [94.8%] overall) and not of Hispanic or Latino descent (552/600 [92.0%]), with a mean (SD) age of 50.8 (15.85) years and an age range of 18 to 87 years ([Table 10](#)). No apparent differences were observed in baseline demographics across treatment groups.

Participant demographics for the Randomized Set and the primary analysis PP Sets for SARS-CoV-2–specific bAb and nAb were comparable to those observed for the Safety Set ([Table 14.1.3.2](#), [Table 14.1.3.3](#), and [Table 14.1.3.4](#)).

Age Cohorts

With the exception of age and gender, baseline demographics in Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were comparable between age cohorts and generally consistent with the overall Safety Set. The overall mean age was 37.4 years (range: 18 to 54 years) for Cohort 1, and 64.3 years (range: 55 to 87 years) for Cohort 2. Cohort 1 comprised 177/300 (59.0%) females, and Cohort 2 comprised 213/300 (71.0%) females ([Table 14.1.3.1](#)). Within each cohort, baseline demographics were generally balanced across treatment groups.

Table 10: Baseline Demographics (Safety Set)

	mRNA-1273				
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
Age (years)					
n	200	200	200	400	600
Mean (SD)	50.8 (15.77)	50.6 (16.30)	51.1 (15.55)	50.8 (15.91)	50.8 (15.85)
Median	54.0	54.5	54.5	54.5	54.5
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	71 (35.5)	63 (31.5)	76 (38.0)	139 (34.8)	210 (35.0)
Female	129 (64.5)	137 (68.5)	124 (62.0)	261 (65.3)	390 (65.0)
Race, n (%)					
White	193 (96.5)	188 (94.0)	188 (94.0)	376 (94.0)	569 (94.8)
Black or African American	3 (1.5)	5 (2.5)	8 (4.0)	13 (3.3)	16 (2.7)
Asian	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
American Indian or Alaska Native	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.5)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.3)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Not reported	0	0	0	0	0
Unknown	0	0	0	0	0
Ethnicity, n (%)					
Hispanic or Latino	16 (8.0)	15 (7.5)	16 (8.0)	31 (7.8)	47 (7.8)
Not Hispanic or Latino	184 (92.0)	184 (92.0)	184 (92.0)	368 (92.0)	552 (92.0)
Not reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0
Weight (kg)					
n	200	200	200	400	600
Mean (SD)	73.57 (12.727)	74.21 (11.563)	73.61 (13.548)	73.91 (12.583)	73.80 (12.621)
Median	73.05	73.90	73.00	73.60	73.40
Min, Max	42.8, 103.7	47.9, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					

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	mRNA-1273				
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
n	200	200	200	400	600
Mean (SD)	169.93 (10.087)	170.03 (8.776)	171.01 (10.435)	170.52 (9.642)	170.32 (9.788)
Median	168.00	168.90	170.05	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body mass index (kg/m ²)					
n	200	200	200	400	600
Mean (SD)	25.35 (2.855)	25.60 (2.920)	25.02 (2.944)	25.31 (2.943)	25.32 (2.912)
Median	25.73	26.11	25.24	25.64	25.67
Min, Max	18.0, 30.4	17.9, 30.7	18.2, 30.1	17.9, 30.7	17.9, 30.7

Abbreviations: Max=maximum; Min=minimum; SD=standard deviation.

Percentages are based on the number of safety subjects.

Source: [Table 14.1.3.1.](#)

5.5 Medical History

The incidence of participants reporting at least one medical history condition was comparable for those who received mRNA-1273 (overall; 350/400 [87.5%]) and placebo (179/200 [89.5%]; [Table 11](#)). The 2 most commonly reported medical history conditions in each treatment group were postmenopause and seasonal allergy, each reported by approximately $\geq 24\%$ of participants. Among the other most common medical history conditions ($\geq 10\%$ in any 1 treatment group) were drug hypersensitivity, anxiety, depression, hysterectomy, and female sterilization.

Age Cohorts

Certain medical history conditions that are often more prevalent in older populations were more common in Cohort 2 (≥ 55 years) than Cohort 1 (≥ 18 to < 55 years) across all treatment groups, including hypercholesterolemia and osteoarthritis ([Table 14.1.5.1](#)). As expected, given the higher number of females in Cohort 2, postmenopause, menopause, and hysterectomy were more frequently reported in Cohort 2 than Cohort 1 in each treatment group. Other medical conditions were either comparable between age cohorts or the small number of participants with each condition precluded a meaningful comparison.

Table 11: Summary of Most Common Medical History (Reported in 5% or More Participants in Any Treatment Group) by System Organ Class and Preferred Term (Safety Set)

System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects with at least one medical history	179 (89.5)	181 (90.5)	169 (84.5)	350 (87.5)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (10.5)	17 (8.5)	20 (10.0)	37 (9.3)
Uterine leiomyoma	8 (4.0)	5 (2.5)	10 (5.0)	15 (3.8)
Immune system disorders	74 (37.0)	92 (46.0)	76 (38.0)	168 (42.0)
Seasonal allergy	54 (27.0)	64 (32.0)	49 (24.5)	113 (28.3)
Drug hypersensitivity	24 (12.0)	32 (16.0)	37 (18.5)	69 (17.3)
Metabolism and nutrition disorders	32 (16.0)	35 (17.5)	27 (13.5)	62 (15.5)
Hypercholesterolaemia	11 (5.5)	19 (9.5)	13 (6.5)	32 (8.0)
Hyperlipidaemia	10 (5.0)	3 (1.5)	3 (1.5)	6 (1.5)
Psychiatric disorders	61 (30.5)	59 (29.5)	47 (23.5)	106 (26.5)
Anxiety	28 (14.0)	27 (13.5)	22 (11.0)	49 (12.3)
Depression	20 (10.0)	23 (11.5)	19 (9.5)	42 (10.5)
Insomnia	19 (9.5)	16 (8.0)	18 (9.0)	34 (8.5)
Attention deficit hyperactivity disorder	7 (3.5)	11 (5.5)	10 (5.0)	21 (5.3)
Nervous system disorders	31 (15.5)	40 (20.0)	24 (12.0)	64 (16.0)
Migraine	15 (7.5)	18 (9.0)	10 (5.0)	28 (7.0)
Headache	7 (3.5)	13 (6.5)	7 (3.5)	20 (5.0)
Eye disorders	13 (6.5)	40 (20.0)	27 (13.5)	67 (16.8)
Myopia	5 (2.5)	19 (9.5)	9 (4.5)	28 (7.0)

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System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders	29 (14.5)	35 (17.5)	30 (15.0)	65 (16.3)
Gastroesophageal reflux disease	13 (6.5)	17 (8.5)	13 (6.5)	30 (7.5)
Musculoskeletal and connective tissue disorders	41 (20.5)	51 (25.5)	43 (21.5)	94 (23.5)
Osteoarthritis	11 (5.5)	15 (7.5)	14 (7.0)	29 (7.3)
Back pain	6 (3.0)	12 (6.0)	4 (2.0)	16 (4.0)
Surgical and medical procedures	104 (52.0)	96 (48.0)	91 (45.5)	187 (46.8)
Hysterectomy	26 (13.0)	20 (10.0)	26 (13.0)	46 (11.5)
Female sterilisation	20 (10.0)	13 (6.5)	13 (6.5)	26 (6.5)
Vasectomy	16 (8.0)	12 (6.0)	10 (5.0)	22 (5.5)
Cholecystectomy	12 (6.0)	12 (6.0)	7 (3.5)	19 (4.8)
Appendicectomy	10 (5.0)	9 (4.5)	8 (4.0)	17 (4.3)
Tonsillectomy	3 (1.5)	3 (1.5)	11 (5.5)	14 (3.5)
Social circumstances	64 (32.0)	63 (31.5)	62 (31.0)	125 (31.3)
Postmenopause	52 (26.0)	58 (29.0)	47 (23.5)	105 (26.3)
Menopause	12 (6.0)	4 (2.0)	15 (7.5)	19 (4.8)

Percentages are based on the number of safety subjects.

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Source: [Table 14.1.5.1](#).

5.6 COVID-19 Impact

COVID-19 impacted protocol-specified procedures for 10 participants: 2 in the mRNA-1273 50 µg group, 1 in the mRNA-1273 100 µg group, and 7 in the placebo group ([Listing 16.2.2.3](#)). Of the 19 impacts for these 10 participants, the most common COVID-19 impact category was “missed assessment,” and the most common relationships of the impact to COVID-19 were “exposure to COVID-19.”

5.7 Prior and Concomitant Medications

Participant use of prior medications is provided in [Listing 16.2.4.4](#).

The majority of participants received at least 1 concomitant medication during the study (336/400 [84.0%] in mRNA-1273 overall group and 148/200 [74.0%] in the placebo group; [Table 14.1.4.2](#)). Use of concomitant medications was comparable in the mRNA-1273 50 µg and 100 µg groups (165/200 [82.5%] and 171/200 [85.5%], respectively). The most commonly ($\geq 10\%$ of participants) reported concomitant medications in participants who received mRNA-1273 were ibuprofen (116/400 [29.0%]), paracetamol (90/400 [22.5%]), and vitamins not otherwise specified (47/400 [11.8%]).

In the mRNA-1273 overall group, the use of any concomitant medications or nonstudy vaccination within 7 days post injection was more than double that of the placebo group ([Table 12](#)), and remained higher in the mRNA-1273 groups (50 µg, 100 µg, and overall) within 28 days post injection. Use of antipyretic or analgesic medications within 28 days post injection in the mRNA-1273 overall group was almost doubled compared with that in the placebo group. Use of any concomitant medications or nonstudy vaccines within 7 or 28 days post injection or antipyretic or analgesic medication within 28 days post injection was higher in the mRNA-1273 100 µg group compared with that in the 50 µg group. No participants in any treatment group used prophylactic antipyretic or analgesic medication within 28 days post injection.

Nonstudy vaccination use was limited to 2 participants who received a nonstudy vaccine > 7 days but < 28 days after the second injection: 1 participant in the mRNA-1273 50 µg group received the influenza and shingles vaccine on Day 54; and 1 participant in the mRNA-1273 100 µg group received the shingles vaccine on Day 41 ([Listing 16.2.4.4](#)). Note that each receipt of the shingles vaccine was a major protocol deviation ([Section 5.3](#)), while the influenza vaccine was allowed as it was received > 14 days after the second injection ([Section 3.5.2](#)).

Age Cohorts

In the mRNA-1273 groups, the percentages of participants reporting any concomitant medications or nonstudy vaccination within 7 or 28 days post injection and any antipyretic or analgesic medication within 28 days post injection were numerically higher in Cohort 1 (≥ 18 to < 55 years) than in Cohort 2 (≥ 55 years) ([Table 12](#)).

Table 12: Summary of Concomitant Medication (Safety Set)

	Placebo (N=200) n (%)	mRNA-1273						
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)				
Any concomitant medications or non-study vaccination within 7 days post injection	34 (17.0)	82 (41.0)	112 (56.0)	194 (48.5)				
Any concomitant medications or non-study vaccination within 28 days post injection	56 (28.0)	94 (47.0)	122 (61.0)	216 (54.0)				
Prophylactic antipyretics or analgesics medication within 28 days post injection	0	0	0	0				
Antipyretic or analgesic medication within 28 days post injection	31 (15.5)	80 (40.0)	102 (51.0)	182 (45.5)				
	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Any concomitant medications or non-study vaccination within 7 days post injection	13 (13.0)	46 (46.0)	61 (61.0)	107 (53.5)	21 (21.0)	36 (36.0)	51 (51.0)	87 (43.5)
Any concomitant medications or non-study vaccination within 28 days post injection	23 (23.0)	50 (50.0)	62 (62.0)	112 (56.0)	33 (33.0)	44 (44.0)	60 (60.0)	104 (52.0)
Prophylactic antipyretics or analgesics medication within 28 days post injection	0	0	0	0	0	0	0	0
Antipyretic or analgesic medication within 28 days post injection	14 (14.0)	46 (46.0)	59 (59.0)	105 (52.5)	17 (17.0)	34 (34.0)	43 (43.0)	77 (38.5)

Percentages are based on the number of safety subjects.

Source: [Table 14.1.4.1.](#)

5.8 Exposure and Compliance

A total of 600 participants (100%) received the first injection and 587 participants (97.8%) received the second injection ([Table 7](#)). Three dosing errors occurred during the study ([Listing 16.2.5.2](#)); these are described in detail in [Section 5.3](#).

6 Efficacy Results

Not applicable.

7 Safety Results

7.1 Solicited Adverse Reactions

Summaries of solicited ARs were based on participant-recorded events in the eDiary on the day of each injection administration and during the 7 days after each IP administration and from any verbally reported ARs during safety telephone calls or at site visits not already captured in the eDiary, as detailed in [Section 4.2.2.1](#).

Participant eDiary compliance over the 7 days after the first and second injection was $\geq 99.5\%$ and 100%, respectively, across treatment groups ([Table 14.3.1.19](#)). Daily compliance was high on each day from the first hour on Day 1 through Day 7 after the first (range: 94.5% to 99%) and second (range: 92.3% to 100%) injection.

The solicited ARs for participants with SARS-CoV-2 infection are summarized in [Section 7.3.3.6](#).

7.1.1 Summary of Solicited Adverse Reactions

7.1.1.1 After Any Injection

More participants reported solicited ARs within 7 days of any injection in the mRNA-1273 overall group (374/400 [93.5%]) than in the placebo group (103/200 [51.5%]; [Table 13](#)). The incidence of solicited local and systemic ARs within 7 days of any injection were both higher for participants who received mRNA-1273 (overall) than placebo, with a higher magnitude of difference for solicited local ARs (356/400 [89.0%] and 38/200 [19.0%], respectively) than for solicited systemic ARs (315/400 [78.8%] and 91/200 [45.5%], respectively; [Table 13](#)).

For the mRNA-1273 groups, the percentage of participants who reported any solicited ARs, solicited local ARs, and solicited systemic ARs after any injection were numerically higher for the 100 μg mRNA-1273 group than the 50 μg mRNA-1273 group; however, the 95% CIs overlapped for these 3 categories.

The most common ($> 20\%$ of participants) solicited ARs after any injection included the following ([Table 14.3.1.1.3](#)):

- Pain: 183/200 (91.5%) for 100 μg mRNA-1273, 171/200 (85.5%) for 50 μg mRNA-1273, and 32/200 (16.0%) for placebo
- Fatigue: 138/200 (69.0%) for 100 μg mRNA-1273, 113/200 (56.5%) for 50 μg mRNA-1273, and 61/200 (30.5%) for placebo

- Headache: 115/200 (57.5%) for 100 µg mRNA-1273, 111/200 (55.5%) for 50 µg mRNA-1273, and 59/200 (29.5%) for placebo
- Myalgia: 111/200 (55.5%) for 100 µg mRNA-1273, 87/200 (43.5%) for 50 µg mRNA-1273, and 26/200 (13.0%) for placebo
- Arthralgia: 79/200 (39.5%) for 100 µg mRNA-1273, 74/200 (37.0%) for 50 µg mRNA-1273, and 21/200 (10.5%) for placebo
- Chills: 83/200 (41.5%) for 100 µg mRNA-1273, 52/200 (26.0%) for 50 µg mRNA-1273, and 11/200 (5.5%) for placebo
- Nausea: 43/200 (21.5%) for 100 µg mRNA-1273, 31/200 (15.5%) for 50 µg mRNA-1273, and 11/200 (5.5%) for placebo

Across all treatment groups, the majority of solicited ARs were grade 1 or grade 2; no grade 4 solicited ARs were reported. More grade 3 solicited ARs were reported by participants who received mRNA-1273 (overall) (57/400 [14.3%]) than those who received placebo (6/200 [3.0%]; [Table 13](#)). After any injection, grade 3 solicited local ARs were reported by 8/200 (4.0%) participants who received 100 µg mRNA-1273 and 3/200 (1.5%) participants who received 50 µg mRNA-1273; no participants who received placebo reported grade 3 solicited local ARs. Grade 3 solicited systemic ARs were reported by 26/200 (13.0%) participants who received 100 µg mRNA-1273, 23/200 (11.5%) participants who received 50 µg mRNA-1273, and 6/200 (3.0%) participants who received placebo. In the mRNA-1273 overall group, the most common (> 5% of participants) grade 3 solicited ARs after any injection were fatigue (31/400 [7.8%]), myalgia (26/400 [6.5%]), and headache (20/400 [5.0%]; [Table 14.3.1.1.3](#)).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for the incidences of any solicited ARs, local ARs, and systemic ARs after any injection ([Table 14.3.1.1.3](#)). In the mRNA-1273 groups, Grade 3 solicited ARs were reported by 30/200 (15.0%) participants in Cohort 1 and 27/200 (13.5%) participants in Cohort 2 after any injection.

7.1.1.2 After the First Injection

Consistent with results for solicited ARs within 7 days after any injection, more participants reported solicited ARs, local ARs, and systemic ARs in the mRNA-1273 groups than in the placebo group within 7 days after the first injection ([Table 14](#)).

After the first injection there were dose-related increases in the incidence of solicited local ARs. In participants who received 50 and 100 µg doses of mRNA-1273, the incidence of solicited local ARs was 131/200 (65.5%) and 168/200 (84.0%), respectively. This contributed to the greater incidence of any solicited AR observed in the 100 µg mRNA-1273 group (176/200 [88.0%]) compared with the 50 µg mRNA-1273 group (142/200 [71.0%]). The incidence of solicited systemic ARs after the first injection was comparable between the 50 and 100 µg mRNA-1273 groups (83/200 [41.5%] and 89/199 [44.7%], respectively).

The most common (> 20% of participants) solicited ARs after the first injection included the following (Table 14):

- Pain: 166/199 (83.4%) for 100 µg mRNA-1273, 131/200 (65.5%) for 50 µg mRNA-1273, and 21/199 (10.6%) for placebo
- Headache: 43/199 (21.6%) for 100 µg mRNA-1273, 58/200 (29.0%) for 50 µg mRNA-1273, and 36/199 (18.1%) for placebo
- Fatigue: 50/199 (25.1%) for 100 µg mRNA-1273, 48/200 (24.0%) for 50 µg mRNA-1273, and 35/199 (17.6%) for placebo

Grade 3 solicited ARs were reported infrequently after the first injection in the 50 µg (5/200 [2.5%]) and 100 µg (2/200 [1.0%]) mRNA-1273 groups, with no apparent difference observed compared with the placebo (4/199 [2.0%]) group.

Age Cohorts

The percentage of participants who reported any solicited ARs, solicited local ARs, and solicited systemic ARs after the first injection were generally numerically higher for Cohort 1 (≥ 18 to < 55 years) than Cohort 2 (≥ 55 years); however, the 95% CIs overlapped for these 3 categories of ARs (Table 14.3.1.1.1). In the mRNA-1273 groups, grade 3 solicited ARs were reported by 2/200 (1.0%) participants in Cohort 1 and 5/200 (2.5%) participants in Cohort 2 after the first injection.

Solicited local reactions were reported by 73/100 (73.0%), 87/100 (87.0%), and 17/100 (17.0%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 1, and by 58/100 (58.0%), 81/100 (81.0%), and 10/99 (10.1%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 2. The most commonly reported solicited local AR after the first injection was pain in the 50 µg (73.0%) and 100 µg (86.0%) mRNA-1273 and placebo (14.0%) groups in Cohort 1, and 50 µg (58.0%) and 100 µg (80.8%) mRNA-1273 and placebo (7.1%) groups in Cohort 2.

Solicited systemic reactions were reported by 46/100 (46.0%), 52/100 (52.0%), and 30/100 (30.0%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 1, and by 37/100 (37.0%), 37/99 (37.4%), and 34/99 (34.3%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 2. The most commonly reported solicited local AR after the first injection was headache in the 50 µg (29.0%) and 100 µg (25.0%) mRNA-1273 and placebo (18.0%) groups in Cohort 1, and 50 µg (29.0%) and 100 µg (18.2%) mRNA-1273 and placebo (18.2%) groups in Cohort 2. Fatigue was also commonly reported in the 50 µg (24.0%) and 100 µg (30.0%) mRNA-1273 and placebo (17.0%) groups in Cohort 1, and 50 µg (24.0%) and 100 µg (20.2%) mRNA-1273 and placebo (18.2%) groups in Cohort 2.

7.1.1.3 After the Second Injection

Consistent with results for solicited ARs within 7 days after any injection, more participants reported solicited ARs, local ARs, and systemic ARs in the mRNA-1273 groups than in the placebo group within 7 days after the second injection ([Table 15](#)).

For the mRNA-1273 groups, the incidence of any ARs after the second injection was numerically higher than of those after the first injection (349/393 [88.8%] and 318/400 [79.5%]), respectively), suggesting increased reactogenicity after the second injection ([Table 14](#) and [Table 15](#)).

The incidence of solicited local ARs within 7 days after injection was comparable after the first and second injections for the mRNA-1273 overall group (299/400 [74.8%] versus 326/393 [83.0%] versus; [Table 14](#) and [Table 15](#)). The incidence of solicited local ARs was numerically higher after the second injection than after the first injection for the 50 µg mRNA-1273 group (156/195 [80.0%] versus 131/200 [65.5%]); however, the incidence of solicited local ARs were comparable after the first and second injections for the 100 µg mRNA-1273 group (168/200 [84.0%] versus 170/198 [85.9%]). As a result, the dose-related increase in the incidence of solicited local ARs observed after the first injection ([Section 7.1.1.2](#)) was not apparent after the second injection.

In the mRNA-1273 overall group, the incidence of solicited systemic ARs was numerically higher after the second injection than after the first injection (288/393 [73.3%] and 172/399 [43.1%], respectively; [Table 15](#) and [Table 14](#)). In the 50 and 100 µg mRNA-1273 groups, the incidence of solicited systemic ARs was numerically higher after the second injection (135/195 [69.2%] and 153/198 [77.3%], respectively) than after the first injection

(83/200 [41.5%] and 89/199 [44.7%], respectively), with no apparent differences observed between treatment groups.

The most common (> 20% of participants) solicited ARs after the second injection included the following ([Table 15](#)).

- Pain: 169/198 (85.4%) for 100 µg mRNA-1273, 155/195 (79.5%) for 50 µg mRNA-1273, and 15/194 (7.7%) for placebo
- Fatigue: 128/198 (64.6%) for 100 µg mRNA-1273, 104/195 (53.3%) for 50 µg mRNA-1273, and 41/194 (21.1%) for placebo.
- Headache: 104/198 (52.5%) for 100 µg mRNA-1273, 96/195 (49.2%) for 50 µg mRNA-1273, and 33/194 (17.0%) for placebo
- Myalgia: 104/198 (52.5%) for 100 µg mRNA-1273, 81/195 (41.5%) for 50 µg mRNA-1273, and 15/194 (7.7%) for placebo
- Arthralgia: 77/198 (38.9%) for 100 µg mRNA-1273, 68/195 (34.9%) for 50 µg mRNA-1273, and 13/194 (6.7%) for placebo
- Chills: 78/198 (39.4%) for 100 µg mRNA-1273 and 49/195 (25.1%) for 50 µg mRNA-1273, and 5/194 (2.6%) for placebo
- Nausea: 41/198 (20.7%) for 100 µg mRNA-1273, 25/195 (12.8%) for 50 µg mRNA-1273, and 2/194 (1.0%) for placebo

The incidence of pain at the injection site was comparable between the first and second injection for the 100 µg mRNA-1273 group, and increased after the second dose for the 50 µg mRNA-1273 group. For the 50 and 100 µg mRNA-1273 dose groups, the incidence of fatigue, headache, myalgia, arthralgia, nausea/vomiting, and chills were increased after the second injection ([Table 14](#) and [Table 15](#)).

More grade 3 ARs occurred after the second injection (52/393 [13.2%]) than after the first (7/400 [1.8%]) in the mRNA-1273 overall group ([Table 15](#) and [Table 14](#)), and the most common grade 3 ARs after the second injection were consistent with those reported after any injection (fatigue, myalgia, and headache; [Section 7.1.1.1](#)).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) in the incidences of any solicited ARs, local ARs, and systemic ARs after the second

injection ([Table 14.3.1.1.2](#)). In the mRNA-1273 groups, grade 3 solicited ARs were reported by 29/196 (14.8%) participants in Cohort 1 and 23/197 (11.7%) participants in Cohort 2 after the second injection.

Solicited local ARs were reported by 78/97 (80.4%), 89/99 (89.9%), and 10/94 (10.6%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 1, and by 78/98 (79.6%), 81/99 (81.8%), and 6/100 (6.0%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 2. The most commonly reported solicited local AR after the second injection was pain in the 50 µg (80.4%) and 100 µg (89.9%) mRNA-1273 and placebo (9.6%) groups in Cohort 1 and 50 µg (78.6%) and 100 µg (80.8%) mRNA-1273 and placebo (6.0%) groups in Cohort 2.

Solicited systemic ARs were reported by 69/97 (71.1%), 78/99 (78.8%), and 23/94 (24.5%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 1, and by 66/98 (67.3%), 75/99 (75.8%), and 35/100 (35.0%) participants in the 50 µg and 100 µg mRNA-1273 and placebo groups, respectively, in Cohort 2. The most commonly reported solicited local AR after the second injection was headache in the 50 µg (50.5%) and 100 µg (55.6%) mRNA-1273 and placebo (14.9%) groups in Cohort 1, and 50 µg (48.0%) and 100 µg (49.5%) mRNA-1273 and placebo (19.0%) groups in Cohort 2. Fatigue was also commonly reported in the 50 µg (45.4%) and 100 µg (65.7%) mRNA-1273 and placebo (20.2%) groups in Cohort 1, and 50 µg (61.2%) and 100 µg (63.6%) mRNA-1273 and placebo (22.0%) groups in Cohort 2. The incidences of myalgia, arthralgia, nausea/vomiting, and chills were also increased in Cohorts 1 and 2 after the second injection ([Table 14.3.1.1.1](#) and [14.3.1.1.2](#)).

Table 13: Summary of Solicited Adverse Reactions Within 7 Days After Any Injection by Grade (Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=200) n (%)	mRNA-1273			Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Solicited adverse reactions - N1	200	200	200		400
Any solicited adverse reactions	103 (51.5)	182 (91.0)	192 (96.0)		374 (93.5)
95% CI	44.3, 58.6	86.1, 94.6	92.3, 98.3		90.6, 95.7
Grade 1	72 (36.0)	95 (47.5)	69 (34.5)		164 (41.0)
Grade 2	21 (10.5)	61 (30.5)	90 (45.0)		151 (37.8)
Grade 3	6 (3.0)	25 (12.5)	32 (16.0)		57 (14.3)
Grade 4	0	0	0		0
Solicited local adverse reactions - N1	200	200	200		400
Any solicited local adverse reactions	38 (19.0)	171 (85.5)	185 (92.5)		356 (89.0)
95% CI	13.8, 25.1	79.8, 90.1	87.9, 95.7		85.5, 91.9
Grade 1	37 (18.5)	139 (69.5)	137 (68.5)		276 (69.0)
Grade 2	1 (0.5)	29 (14.5)	40 (20.0)		69 (17.3)
Grade 3	0	3 (1.5)	8 (4.0)		11 (2.8)
Grade 4	0	0	0		0
Solicited systemic adverse reactions - N1	200	200	200		400
Any solicited systemic adverse reactions	91 (45.5)	148 (74.0)	167 (83.5)		315 (78.8)
95% CI	38.5, 52.7	67.3, 79.9	77.6, 88.4		74.4, 82.7
Grade 1	60 (30.0)	66 (33.0)	61 (30.5)		127 (31.8)
Grade 2	21 (10.5)	58 (29.0)	79 (39.5)		137 (34.3)
Grade 3	6 (3.0)	23 (11.5)	26 (13.0)		49 (12.3)
Grade 4	0	0	0		0

Abbreviations: CI=confidence intervals; N1=number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

Source: [Table 14.3.1.1.3.](#)

Table 14: Summary of Solicited Adverse Reactions Within 7 Days After First Injection by Grade (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited adverse reactions - N1	199	200	200	400
Any solicited adverse reactions	77 (38.7)	142 (71.0)	176 (88.0)	318 (79.5)
95% CI	31.9, 45.8	64.2, 77.2	82.7, 92.2	75.2, 83.4
Grade 1	55 (27.6)	105 (52.5)	149 (74.5)	254 (63.5)
Grade 2	15 (7.5)	30 (15.0)	24 (12.0)	54 (13.5)
Grade 3	4 (2.0)	5 (2.5)	2 (1.0)	7 (1.8)
Grade 4	0	0	0	0
Solicited local adverse reactions - N1	199	200	200	400
Any solicited local adverse reactions	27 (13.6)	131 (65.5)	168 (84.0)	299 (74.8)
95% CI	9.1, 19.1	58.5, 72.1	78.2, 88.8	70.2, 78.9
Grade 1	26 (13.1)	124 (62.0)	157 (78.5)	281 (70.3)
Grade 2	1 (0.5)	6 (3.0)	10 (5.0)	16 (4.0)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0
Pain - N1	199	200	199	399
Any	21 (10.6)	131 (65.5)	166 (83.4)	297 (74.4)
Grade 1	21 (10.6)	125 (62.5)	155 (77.9)	280 (70.2)
Grade 2	0	5 (2.5)	10 (5.0)	15 (3.8)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0
Erythema (redness) - N1	199	200	199	399
Any	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Grade 1	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0

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Solicited Adverse Reaction Category Grade	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Swelling (hardness)- N1	199	200	200	400
Any	1 (0.5)	8 (4.0)	8 (4.0)	16 (4.0)
Grade 1	1 (0.5)	7 (3.5)	8 (4.0)	15 (3.8)
Grade 2	0	1 (0.5)	0	1 (0.3)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Lymphadenopathy - N1 ^a	199	200	199	399
Any	5 (2.5)	10 (5.0)	18 (9.0)	28 (7.0)
Grade 1	4 (2.0)	10 (5.0)	16 (8.0)	26 (6.5)
Grade 2	1 (0.5)	0	2 (1.0)	2 (0.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Solicited systemic adverse reactions - N1	199	200	199	399
Any solicited systemic adverse reactions	64 (32.2)	83 (41.5)	89 (44.7)	172 (43.1)
95% CI	25.7, 39.1	34.6, 48.7	37.7, 51.9	38.2, 48.1
Grade 1	42 (21.1)	50 (25.0)	69 (34.7)	119 (29.8)
Grade 2	15 (7.5)	26 (13.0)	18 (9.0)	44 (11.0)
Grade 3	4 (2.0)	4 (2.0)	1 (0.5)	5 (1.3)
Grade 4	0	0	0	0
Fever - N1	199	200	199	399
Any	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Headache - N1	199	200	199	399
Any	36 (18.1)	58 (29.0)	43 (21.6)	101 (25.3)
Grade 1	30 (15.1)	42 (21.0)	35 (17.6)	77 (19.3)
Grade 2	2 (1.0)	13 (6.5)	8 (4.0)	21 (5.3)
Grade 3	4 (2.0)	3 (1.5)	0	3 (0.8)

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Solicited Adverse Reaction Category Grade	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Grade 4	0	0	0	0
Fatigue - N1	199	200	199	399
Any	35 (17.6)	48 (24.0)	50 (25.1)	98 (24.6)
Grade 1	25 (12.6)	30 (15.0)	38 (19.1)	68 (17.0)
Grade 2	10 (5.0)	17 (8.5)	11 (5.5)	28 (7.0)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0
Myalgia - N1	199	200	199	399
Any	14 (7.0)	21 (10.5)	28 (14.1)	49 (12.3)
Grade 1	12 (6.0)	14 (7.0)	23 (11.6)	37 (9.3)
Grade 2	2 (1.0)	7 (3.5)	4 (2.0)	11 (2.8)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Arthralgia - N1	199	200	199	399
Any	10 (5.0)	18 (9.0)	18 (9.0)	36 (9.0)
Grade 1	7 (3.5)	14 (7.0)	15 (7.5)	29 (7.3)
Grade 2	3 (1.5)	4 (2.0)	2 (1.0)	6 (1.5)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Nausea/vomiting - N1	199	200	199	399
Any	10 (5.0)	11 (5.5)	6 (3.0)	17 (4.3)
Grade 1	5 (2.5)	10 (5.0)	5 (2.5)	15 (3.8)
Grade 2	5 (2.5)	1 (0.5)	0	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Chills - N1	199	200	199	399
Any	6 (3.0)	13 (6.5)	10 (5.0)	23 (5.8)
Grade 1	5 (2.5)	10 (5.0)	6 (3.0)	16 (4.0)
Grade 2	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	199	200	199	399
Any	5 (2.5)	6 (3.0)	5 (2.5)	11 (2.8)

Abbreviations: CI=confidence intervals; N1=number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

^a Lymphadenopathy=localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Source: [Table 14.3.1.1.1](#).

Table 15: Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Grade	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited adverse reactions - N1	194	195	198	393
Any solicited adverse reactions	66 (34.0)	171 (87.7)	178 (89.9)	349 (88.8)
95% CI	27.4, 41.2	82.2, 92.0	84.8, 93.7	85.3, 91.7
Grade 1	53 (27.3)	90 (46.2)	64 (32.3)	154 (39.2)
Grade 2	10 (5.2)	60 (30.8)	83 (41.9)	143 (36.4)
Grade 3	2 (1.0)	21 (10.8)	31 (15.7)	52 (13.2)
Grade 4	0	0	0	0
Solicited local adverse reactions - N1	194	195	198	393
Any solicited local adverse reactions	16 (8.2)	156 (80.0)	170 (85.9)	326 (83.0)
95% CI	4.8, 13.0	73.7, 85.4	80.2, 90.4	78.9, 86.5
Grade 1	16 (8.2)	127 (65.1)	129 (65.2)	256 (65.1)
Grade 2	0	27 (13.8)	34 (17.2)	61 (15.5)
Grade 3	0	2 (1.0)	7 (3.5)	9 (2.3)
Grade 4	0	0	0	0
Pain - N1	194	195	198	393
Any	15 (7.7)	155 (79.5)	169 (85.4)	324 (82.4)
Grade 1	15 (7.7)	131 (67.2)	140 (70.7)	271 (69.0)
Grade 2	0	22 (11.3)	28 (14.1)	50 (12.7)
Grade 3	0	2 (1.0)	1 (0.5)	3 (0.8)
Grade 4	0	0	0	0
Erythema (redness) - N1	194	195	198	393
Any	0	10 (5.1)	15 (7.6)	25 (6.4)
Grade 1	0	5 (2.6)	7 (3.5)	12 (3.1)
Grade 2	0	5 (2.6)	3 (1.5)	8 (2.0)
Grade 3	0	0	5 (2.5)	5 (1.3)
Grade 4	0	0	0	0

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Solicited Adverse Reaction Category Grade	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Swelling (hardness)- N1	194	195	198	393
Any	1 (0.5)	12 (6.2)	21 (10.6)	33 (8.4)
Grade 1	1 (0.5)	6 (3.1)	14 (7.1)	20 (5.1)
Grade 2	0	6 (3.1)	6 (3.0)	12 (3.1)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Lymphadenopathy - N1 ^a	194	195	198	393
Any	1 (0.5)	19 (9.7)	20 (10.1)	39 (9.9)
Grade 1	1 (0.5)	12 (6.2)	17 (8.6)	29 (7.4)
Grade 2	0	7 (3.6)	3 (1.5)	10 (2.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Solicited systemic adverse reactions - N1	194	195	198	393
Any solicited systemic adverse reactions	58 (29.9)	135 (69.2)	153 (77.3)	288 (73.3)
95% CI	23.5, 36.9	62.2, 75.6	70.8, 82.9	68.6, 77.6
Grade 1	45 (23.2)	55 (28.2)	56 (28.3)	111 (28.2)
Grade 2	10 (5.2)	58 (29.7)	72 (36.4)	130 (33.1)
Grade 3	2 (1.0)	20 (10.3)	25 (12.6)	45 (11.5)
Grade 4	0	0	0	0
Fever - N1	194	195	198	393
Any	1 (0.5)	12 (6.2)	26 (13.1)	38 (9.7)
Grade 1	1 (0.5)	7 (3.6)	19 (9.6)	26 (6.6)
Grade 2	0	3 (1.5)	3 (1.5)	6 (1.5)
Grade 3	0	2 (1.0)	4 (2.0)	6 (1.5)
Grade 4	0	0	0	0
Headache - N1	194	195	198	393
Any	33 (17.0)	96 (49.2)	104 (52.5)	200 (50.9)
Grade 1	33 (17.0)	65 (33.3)	56 (28.3)	121 (30.8)
Grade 2	0	22 (11.3)	39 (19.7)	61 (15.5)
Grade 3	0	9 (4.6)	9 (4.5)	18 (4.6)

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Solicited Adverse Reaction Category Grade	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Grade 4	0	0	0	0
Fatigue - N1	194	195	198	393
Any	41 (21.1)	104 (53.3)	128 (64.6)	232 (59.0)
Grade 1	33 (17.0)	44 (22.6)	44 (22.2)	88 (22.4)
Grade 2	6 (3.1)	49 (25.1)	66 (33.3)	115 (29.3)
Grade 3	2 (1.0)	11 (5.6)	18 (9.1)	29 (7.4)
Grade 4	0	0	0	0
Myalgia - N1	194	195	198	393
Any	15 (7.7)	81 (41.5)	104 (52.5)	185 (47.1)
Grade 1	12 (6.2)	36 (18.5)	35 (17.7)	71 (18.1)
Grade 2	3 (1.5)	35 (17.9)	54 (27.3)	89 (22.6)
Grade 3	0	10 (5.1)	15 (7.6)	25 (6.4)
Grade 4	0	0	0	0
Arthralgia - N1	194	195	198	393
Any	13 (6.7)	68 (34.9)	77 (38.9)	145 (36.9)
Grade 1	11 (5.7)	32 (16.4)	32 (16.2)	64 (16.3)
Grade 2	2 (1.0)	29 (14.9)	37 (18.7)	66 (16.8)
Grade 3	0	7 (3.6)	8 (4.0)	15 (3.8)
Grade 4	0	0	0	0
Nausea/vomiting - N1	194	195	198	393
Any	2 (1.0)	25 (12.8)	41 (20.7)	66 (16.8)
Grade 1	2 (1.0)	18 (9.2)	25 (12.6)	43 (10.9)
Grade 2	0	7 (3.6)	16 (8.1)	23 (5.9)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Chills - N1	194	195	198	393
Any	5 (2.6)	49 (25.1)	78 (39.4)	127 (32.3)
Grade 1	4 (2.1)	22 (11.3)	30 (15.2)	52 (13.2)
Grade 2	1 (0.5)	24 (12.3)	47 (23.7)	71 (18.1)
Grade 3	0	3 (1.5)	1 (0.5)	4 (1.0)
Grade 4	0	0	0	0

Solicited Adverse Reaction Category Grade	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Rash - N1	194	195	198	393
Any	1 (0.5)	10 (5.1)	6 (3.0)	16 (4.1)

Abbreviations: CI=confidence intervals; N1=number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

^a Lymphadenopathy=Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Source: [Table 14.3.1.1.2](#).

7.1.2 Unsolicited Adverse Events Reported as Solicited Adverse Reactions Persisting Beyond 7 Days or Assessed as Serious Adverse Event

The incidence of solicited ARs that were ongoing 7 days after injection and reported as TEAEs in the eCRF was comparable in the mRNA-1273 overall group (28/400 [7.0%]) and placebo (8/200 [4.0%]; [Table 14.3.1.20](#)). In both the 50 µg and 100 µg mRNA-1273 groups, 14/200 (7.0%) participants reported solicited ARs lasting > 7 days, with 31 TEAEs in the mRNA-1273 50 µg group and 24 TEAEs in the mRNA-1273 100 µg group. In the placebo group, 8 of 200 (4.0%) participants reported 13 solicited ARs that lasted > 7 days and were captured as TEAEs.

The majority of the solicited ARs ongoing 7 days after any injection and reported as TEAEs were reported by ≤ 3 participants in any one treatment group. In the mRNA-1273 overall group or placebo group, the highest incidence (> 1.0%) of solicited ARs ongoing 7 day after any injection (by decreasing incidence in the mRNA-1273 overall group) were fatigue (14/400 [3.5%] and 5/200 [2.5%], respectively), headache (11/400 [2.8%] and 1/200 [0.5%], respectively), and arthralgia and myalgia (both 7/400 [1.8%] and 2/200 [1.0%], respectively).

No solicited AR met the SAE criteria ([Table 14.3.1.20](#) and [Listing 16.2.7.8](#)).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for solicited ARs ongoing 7 days after any injection and reported as TEAEs for the mRNA-1273 50 µg and placebo groups ([Table 14.3.1.20](#)). For the mRNA-1273 100 µg group, the incidence of solicited ARs ongoing 7 days after any injection was numerically higher in Cohort 1 (10/100 [10%]) than Cohort 2 (4/100 [4.0%]).

7.1.3 Solicited Adverse Reactions by Day of Reporting

7.1.3.1 After Any Injection

In the mRNA-1273 overall and placebo groups, participants most often reported solicited ARs within the first 3 days after any injection ([Table 14.3.1.2.3](#)). For the mRNA-1273 overall group, solicited ARs were most commonly reported on Day 2 (354/400 [88.5%]), followed by Day 3 (269/400 [67.6%]), and Day 1 (259/400 [64.8%]). In the placebo group, solicited ARs were most commonly reported from Day 1 (47/200 [23.5%]) through Day 3 (40/197 [20.3%]).

In the mRNA-1273 overall group, both solicited local ARs and systemic ARs also were most commonly reported in the first 3 days after any injection, with the highest level of reporting on Day 2 after injection. After Day 2, the percentage of participants reporting solicited local and systemic ARs decreased daily through Day 7.

Analysis of day of reporting by severity grade within 7 days after any injection showed results for solicited ARs, local ARs, and systemic ARs consistent with those seen with all grades combined.

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for day of reporting solicited ARs within 7 days after any injection ([Table 14.3.1.2.3](#)).

7.1.3.2 After the First Injection

In the mRNA-1273 overall and placebo groups, participants most often reported solicited ARs in the first 3 days after the first injection ([Table 14.3.1.2.1](#)). For the mRNA-1273 overall group, solicited ARs were most commonly reported on Day 2 (273/396 [68.9%]), followed by Day 1 (181/399 [45.4%]), and Day 3 (167/391 [42.7%]).

In the mRNA-1273 groups, solicited local ARs were also most commonly reported in the first 3 days after the first injection, with the highest level of reporting on Day 2 (265/395 [67.1%] overall) and declining thereafter. Solicited local ARs persisting on Day 7 after the first injection were noted in the 100 μ g mRNA-1273 group only (5/194 [2.6%]), and included pain, lymphadenopathy, and swelling.

In the mRNA-1273 groups, solicited systemic ARs were also most commonly reported in the first 3 days after the first injection, with the highest level of reporting on Day 2 (84/395 [21.3%] overall) and declining thereafter. Solicited systemic ARs persisting on Day 7 after the first injection were noted in both the 50 μ g and 100 μ g mRNA-1273 groups (21/194 [10.8%] and 15/195 [7.7%], respectively), and included headache, fatigue, myalgia, and rash; arthralgia (50 μ g mRNA-1273 group only); and nausea/vomiting and chills (100 μ g mRNA-1273 group only).

Analysis of day of reporting by severity grade within 7 days after the first injection showed results for solicited ARs, local ARs, and systemic ARs consistent with those seen with all grades combined.

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for day of reporting solicited ARs within 7 days after the first injection (Table 14.3.1.2.1).

7.1.3.3 After the Second Injection

In the mRNA-1273 overall and placebo groups, participants most often reported solicited ARs in the first 3 days after the second injection (Table 14.3.1.2.2). For the mRNA-1273 overall group, solicited ARs were most commonly reported on Day 2 (329/391 [84.1%]), followed by Day 3 (231/376 [61.4%]), and Day 1 (207/389 [53.2%]).

In the mRNA-1273 groups, solicited local ARs were also most commonly reported in the first 3 days after the second injection, with the highest level of reporting on Day 2 (305/391 [78.0%] overall) and declining thereafter. Solicited local ARs persisting on Day 7 after the second injection were noted in both the 50 μ g and 100 μ g mRNA-1273 groups (4/190 [2.1%] and 8/196 [4.1%], respectively), and included pain, swelling (100 μ g mRNA-1273 group only), and lymphadenopathy (50 μ g mRNA-1273 group only).

In the mRNA-1273 groups, solicited systemic ARs were also most commonly reported in the first 3 days after the second injection, with the highest level of reporting on Day 2 (254/391 [65.0%] overall) and declining thereafter. Solicited systemic ARs persisting on Day 7 were noted in both the 50 μ g and 100 μ g mRNA-1273 groups (29/190 [15.3%] and 18/196 [9.2%], respectively), and included headache, fatigue, myalgia, arthralgia, and nausea/vomiting; chills (100 μ g mRNA-1273 group only); and rash (50 μ g mRNA-1273 group only).

Analysis of day of reporting by severity grade within 7 days after the second injection showed results for solicited ARs, local ARs, and systemic ARs consistent with those seen with all grades combined.

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for day of reporting solicited ARs within 7 days after the second injection (Table 14.3.1.2.2).

7.1.4 Solicited Adverse Reactions by Day of Onset

The onset of an individual solicited AR was defined as the time point (Day 1 to Day 7) after each injection at which the respective solicited AR first occurred.

7.1.4.1 After Any Injection

In the mRNA-1273 overall group, the onset of any solicited ARs most frequently occurred on Day 1 (60/400 [15.0%] 1 hour after vaccination [at the study site] and 199/400 [49.8%] after vaccination [at home]) or Day 2 (104/400 [26.0%]) after any injection ([Table 14.3.1.3.3](#)). Solicited local ARs had an onset after any injection that was highest on Day 1 after vaccination (at home) (191/400 [47.8%]) followed by Day 2 (110/400 [27.5%]), while solicited systemic ARs had the highest incidence for onset on Day 2 (157/400 [39.3%]), followed by Day 1 after vaccination (at home) (105/400 [26.3%]).

Less than 20% of participants in any treatment group reported any solicited ARs 1 hour after any injection on Day 1 (at the study site). The highest incidence for any solicited ARs at this time point was 19.5% (39/200) in the mRNA-1273 50 µg group, compared with 10.5% (21/200) in mRNA-1273 100 µg group, 15.0% (60/400) in the mRNA-1273 overall group, and 10.0% (20/200) in the placebo group. Solicited local and systemic ARs 1 hour after any injection were also highest in the mRNA-1273 50 µg group (28/200 [14.0%] and 19/200 [9.5%], respectively). In the mRNA-1273 overall group, more participants had an onset of solicited local ARs 1 hour after any injection on Day 1 than an onset of solicited systemic ARs (46/400 [11.5%] and 24/400 [6.0%], respectively), primarily due to the occurrence of pain (43/400 [10.8%]).

In the mRNA-1273 overall group, the onset for the most common solicited local AR (pain) and systemic ARs (fatigue, myalgia, headache, arthralgia, and chills) after any injection were consistent with the incidence by day of reporting ([Section 7.1.3.1](#)), with onset on Day 1 (191/400 [47.8%]) and Day 2 (111/400 [27.8%]) for pain and Day 2 for fatigue (147/400 [36.8%]), myalgia (133/400 [33.3%]), headache (122/400 [30.5%]), arthralgia (108/400 [27.0%]), and chills (94/400 [23.5%]).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for onset of solicited ARs within 7 days after any injection ([Table 14.3.1.3.3](#)).

7.1.4.2 After First Injection

In the mRNA-1273 overall group, the onset of any solicited ARs most frequently occurred on Day 1 after vaccination (at home) (146/400 [36.5%]) or Day 2 (114/400 [28.5%]) after the first injection ([Table 14.3.1.3.1](#)). Solicited local ARs had an onset after the first injection that was highest on Day 1 after vaccination (at home) (141/400 [35.3%]) followed by Day 2 (123/400 [30.8%]). The percentage of subjects with solicited systemic ARs with onset on Day 1 after injection (at home) and on Day 2 were comparable (54/399 [13.5%] and 55/399 [13.8%], respectively).

The percentage of participants with an onset of solicited ARs at 1 hour after the first injection on Day 1 (at the study site) in the mRNA-1273 overall or placebo groups was 35/400 (8.8%) and 12/199 (6.0%), respectively, for any solicited AR; 22/400 (5.5%) and 8/199 (4.0%), respectively, for solicited local ARs; and 17/399 (4.3%) and 5/199 (2.5%), respectively, for solicited systemic ARs. Pain was the most common solicited local AR at this time point (22/399 [5.5%] in the mRNA-1273 overall group and 7/199 [3.5%] in the placebo group).

In the mRNA-1273 groups and the placebo group, the day of onset for the most common solicited local AR (pain) and systemic ARs (headache and fatigue) after the first injection was consistent with the that reported for these ARs after any injection ([Section 7.1.4.1](#)).

Age Cohorts

No apparent differences were observed between Cohorts 1 and 2 for onset of solicited ARs within 7 days after the first injection ([Table 14.3.1.3.1](#)).

7.1.4.3 After Second Injection

In the mRNA-1273 overall group, the onset of any solicited ARs most frequently occurred on Day 1 after vaccination (at home) (175/393 [44.5%]) or Day 2 (131/393 [33.3%]) after the second injection ([Table 14.3.1.3.2](#)). Solicited local ARs had an onset after the second injection that was highest on Day 1 after vaccination (at home) (166/393 [42.2%]) followed by Day 2 (125/393 [31.8%]). Solicited systemic ARs had an onset after the second injection that was highest on Day 2 after vaccination (173/393 [44.0%]) followed by Day 1 (at home) (78/393 [19.8%]).

In the mRNA-1273 overall and placebo groups, the percentage of participants with an onset of solicited ARs, local ARs, and systemic ARs at 1 hour after the second injection at Day 1 (at the study site) was consistent with that seen after the first injection ([Section 7.1.4.2](#)).

In the mRNA-1273 overall group, the day of onset for the most common solicited local AR (pain) and systemic ARs (fatigue, headache, myalgia, arthralgia, and chills) after the second injection was consistent with that reported for these ARs after any injection ([Section 7.1.4.1](#)).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for onset of solicited ARs within 7 days after the second injection ([Table 14.3.1.3.2](#)).

7.1.5 Solicited Adverse Reactions by Number of Days Reporting

The mean (SD) number of days participants reported solicited ARs within 7 days after any injection was 3.9 (3.43) days for participants who received mRNA-1273 (overall) and 2.6 (2.61) days for those who received placebo ([Table 16](#)). The mean (SD) number of days reporting solicited local and systemic ARs were 2.9 (1.80) days and 3.1 (3.62) days, respectively, for the mRNA-1273 overall group and 2.0 (2.86) days and 2.4 (2.16) days, respectively, for the placebo group. No apparent differences were observed between 50 μg and 100 μg mRNA-1273 groups in the mean number of days reporting solicited local and systemic ARs after any injection.

In the mRNA-1273 groups, the mean number of days reporting solicited local ARs ranged from 1.3 to 4.4 days after the first injection and from 1.6 to 2.8 days after the second injection ([Table 17](#) and [Table 18](#)). The mean number of days reporting solicited systemic ARs ranged from 1.2 to 3.6 days after the first injection and from 1.2 to 2.5 days after the second injection.

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for the mean number of days reporting solicited AR, local ARs, and systemic ARs within 7 days after any injection, the first injection, and second injection ([Table 14.3.1.4.1](#), [Table 14.3.1.4.2](#), and [Table 14.3.1.4.3](#))

Table 16: Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection (Solicited Safety Set)

Solicited Adverse Reaction Category Statistic	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited adverse reactions				
n	103	182	192	374
Mean (SD)	2.6 (2.61)	3.8 (3.19)	4.0 (3.65)	3.9 (3.43)
Median	2.0	3.0	3.0	3.0
Min, Max	1, 16	1, 24	1, 33	1, 33
Solicited local adverse reactions				
n	38	171	185	356
Mean (SD)	2.0 (2.86)	2.7 (1.56)	3.0 (1.99)	2.9 (1.80)
Median	1.0	2.0	3.0	3.0
Min, Max	1, 16	1, 13	1, 20	1, 20
Pain				
n	32	171	183	354
Mean (SD)	1.6 (1.88)	2.6 (1.50)	2.8 (1.39)	2.7 (1.45)
Median	1.0	2.0	3.0	2.0
Min, Max	1, 11	1, 13	1, 7	1, 13
Erythema (redness)				
n	1	12	19	31
Mean (SD)	10.0 (NA)	2.0 (1.13)	1.8 (0.90)	1.9 (0.98)
Median	10.0	2.0	2.0	2.0
Min, Max	10, 10	1, 4	1, 4	1, 4
Swelling (hardness)				
n	2	16	25	41
Mean (SD)	8.5 (10.61)	2.5 (1.41)	3.2 (3.87)	2.9 (3.14)
Median	8.5	2.5	2.0	2.0
Min, Max	1, 16	1, 5	1, 18	1, 18
Lymphadenopathy ^a				
n	5	24	32	56
Mean (SD)	2.0 (1.00)	1.9 (1.30)	1.8 (1.33)	1.8 (1.30)
Median	2.0	1.5	1.0	1.0
Min, Max	1, 3	1, 6	1, 6	1, 6

Solicited systemic adverse reactions

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Solicited Adverse Reaction Category Statistic	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
n	91	148	167	315
Mean (SD)	2.4 (2.16)	3.3 (3.51)	3.0 (3.72)	3.1 (3.62)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 10	1, 24	1, 33	1, 33
Fever				
n	1	12	26	38
Mean (SD)	1.0 (NA)	1.2 (0.39)	1.3 (0.93)	1.3 (0.79)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5
Headache				
n	59	111	115	226
Mean (SD)	1.7 (1.47)	2.4 (2.09)	2.3 (2.34)	2.3 (2.22)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 10	1, 13	1, 18	1, 18
Fatigue				
n	61	113	138	251
Mean (SD)	2.1 (2.01)	2.7 (3.15)	2.4 (3.29)	2.6 (3.22)
Median	1.0	2.0	1.5	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Myalgia				
n	26	87	111	198
Mean (SD)	2.0 (1.78)	2.2 (2.07)	1.9 (1.34)	2.0 (1.70)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 7	1, 11	1, 7	1, 11
Arthralgia				
n	21	74	79	153
Mean (SD)	2.4 (2.44)	2.4 (3.15)	2.2 (3.04)	2.3 (3.09)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 9	1, 23	1, 24	1, 24
Nausea/vomiting				
n	11	31	43	74
Mean (SD)	1.3 (0.47)	1.4 (0.76)	1.5 (1.16)	1.5 (1.01)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6
Chills				

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Solicited Adverse Reaction Category Statistic	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
n	11	52	83	135
Mean (SD)	1.2 (0.40)	1.5 (0.94)	1.4 (0.90)	1.4 (0.91)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 6	1, 5	1, 6
Rash				
n	6	14	11	25
Mean (SD)	2.0 (2.00)	2.6 (2.28)	1.6 (1.03)	2.2 (1.86)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 6	1, 7	1, 4	1, 7

Abbreviations: n=number of exposed subjects who reported the event on any day within 7 days of the first injection; Max=maximum; Min=minimum; SD=standard deviation.

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

^a Lymphadenopathy=localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Source: [Table 14.3.1.4.3](#).

Table 17: Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection (First Injection Solicited Safety Set)

Solicited Adverse Reaction Category Statistic	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited adverse reactions				
n	77	142	176	318
Mean (SD)	2.2 (1.96)	3.1 (2.99)	2.8 (2.29)	2.9 (2.63)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 10	1, 24	1, 20	1, 24
Solicited local adverse reactions				
n	27	131	168	299
Mean (SD)	1.6 (1.82)	2.0 (0.93)	2.4 (1.84)	2.2 (1.52)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 10	1, 5	1, 20	1, 20
Pain				
n	21	131	166	297
Mean (SD)	1.1 (0.36)	2.0 (0.91)	2.2 (1.10)	2.1 (1.02)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 2	1, 4	1, 7	1, 7
Erythema (redness)				
n	1	5	5	10
Mean (SD)	10.0 (NA)	1.4 (0.89)	1.6 (0.89)	1.5 (0.85)
Median	10.0	1.0	1.0	1.0
Min, Max	10, 10	1, 3	1, 3	1, 3
Swelling (hardness)				
n	1	8	8	16
Mean (SD)	1.0 (NA)	1.5 (0.76)	4.4 (5.85)	2.9 (4.30)
Median	1.0	1.0	2.0	1.5
Min, Max	1, 1	1, 3	1, 18	1, 18
Lymphadenopathy ^a				
n	5	10	18	28
Mean (SD)	2.0 (1.00)	1.3 (0.48)	1.9 (1.64)	1.7 (1.36)
Median	2.0	1.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 6	1, 6

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Solicited Adverse Reaction Category Statistic	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited systemic adverse reactions				
n	64	83	89	172
Mean (SD)	2.1 (1.78)	3.1 (3.72)	2.2 (2.17)	2.6 (3.04)
Median	1.5	2.0	1.0	2.0
Min, Max	1, 9	1, 24	1, 14	1, 24
Fever				
n	0	0	1	1
Mean (SD)			1.0 (NA)	1.0 (NA)
Median			1.0	1.0
Min, Max			1, 1	1, 1
Headache				
n	36	58	43	101
Mean (SD)	1.6 (0.87)	2.0 (1.75)	1.8 (1.20)	1.9 (1.53)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 4	1, 10	1, 6	1, 10
Fatigue				
n	35	48	50	98
Mean (SD)	2.1 (1.89)	2.8 (3.42)	2.5 (2.65)	2.7 (3.04)
Median	2.0	1.0	1.0	1.0
Min, Max	1, 9	1, 13	1, 14	1, 14
Myalgia				
n	14	21	28	49
Mean (SD)	2.0 (1.66)	2.0 (2.04)	1.8 (1.06)	1.9 (1.54)
Median	1.0	1.0	1.5	1.0
Min, Max	1, 7	1, 9	1, 5	1, 9
Arthralgia				
n	10	18	18	36
Mean (SD)	2.6 (2.59)	3.6 (5.38)	1.7 (1.14)	2.6 (3.95)
Median	1.5	2.0	1.0	2.0
Min, Max	1, 9	1, 23	1, 5	1, 23
Nausea/vomiting				
n	10	11	6	17
Mean (SD)	1.2 (0.42)	1.2 (0.60)	1.5 (1.22)	1.3 (0.85)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 4	1, 4

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Solicited Adverse Reaction Category Statistic	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Chills				
n	6	13	10	23
Mean (SD)	1.0 (0.00)	1.3 (0.63)	1.6 (1.26)	1.4 (0.95)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 3	1, 5	1, 5
Rash				
n	5	6	5	11
Mean (SD)	2.2 (2.17)	3.3 (2.42)	1.2 (0.45)	2.4 (2.06)
Median	1.0	3.0	1.0	1.0
Min, Max	1, 6	1, 7	1, 2	1, 7

Abbreviations: n=number of exposed subjects who reported the event on any day within 7 days of the second injection; Max=maximum; Min=minimum; SD=standard deviation.

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

^a Lymphadenopathy=localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Source: [Table 14.3.1.4.1](#).

Table 18: Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection (Second Injection Solicited Safety Set)

Solicited Adverse Reaction Category Statistic	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited adverse reactions				
n	66	171	178	349
Mean (SD)	2.4 (2.63)	3.4 (2.56)	3.6 (3.50)	3.5 (3.07)
Median	1.0	3.0	3.0	3.0
Min, Max	1, 16	1, 19	1, 33	1, 33
Solicited local adverse reactions				
n	16	156	170	326
Mean (SD)	2.4 (3.77)	2.6 (1.62)	2.7 (1.62)	2.7 (1.61)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 16	1, 13	1, 10	1, 13
Pain				
n	15	155	169	324
Mean (SD)	2.1 (2.69)	2.6 (1.56)	2.6 (1.42)	2.6 (1.49)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 11	1, 13	1, 7	1, 13
Erythema (redness)				
n	0	10	15	25
Mean (SD)		2.1 (1.10)	1.9 (0.92)	2.0 (0.98)
Median		2.0	2.0	2.0
Min, Max		1, 4	1, 4	1, 4
Swelling (hardness)				
n	1	12	21	33
Mean (SD)	16.0 (NA)	2.8 (1.48)	2.8 (2.86)	2.8 (2.42)
Median	16.0	3.0	2.0	2.0
Min, Max	16, 16	1, 5	1, 10	1, 10
Lymphadenopathy ^a				
n	1	19	20	39
Mean (SD)	2.0 (NA)	2.1 (1.39)	1.6 (0.82)	1.8 (1.14)
Median	2.0	2.0	1.0	2.0
Min, Max	2, 2	1, 6	1, 4	1, 6

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Solicited Adverse Reaction Category Statistic	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited systemic adverse reactions				
n	58	135	153	288
Mean (SD)	2.3 (2.10)	2.9 (2.68)	2.9 (3.70)	2.9 (3.26)
Median	1.5	2.0	2.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Fever				
n	1	12	26	38
Mean (SD)	1.0 (NA)	1.2 (0.39)	1.3 (0.93)	1.3 (0.79)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5
Headache				
n	33	96	104	200
Mean (SD)	1.6 (1.80)	2.4 (2.14)	2.3 (2.42)	2.3 (2.29)
Median	1.0	1.0	2.0	2.0
Min, Max	1, 10	1, 13	1, 18	1, 18
Fatigue				
n	41	104	128	232
Mean (SD)	2.0 (1.79)	2.5 (2.63)	2.2 (3.14)	2.3 (2.92)
Median	1.0	2.0	1.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Myalgia				
n	15	81	104	185
Mean (SD)	1.8 (1.78)	2.2 (1.98)	1.8 (1.32)	2.0 (1.65)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 7	1, 11	1, 7	1, 11
Arthralgia				
n	13	68	77	145
Mean (SD)	2.1 (2.25)	2.1 (1.83)	2.1 (3.06)	2.1 (2.55)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 9	1, 9	1, 24	1, 24
Nausea/vomiting				
n	2	25	41	66
Mean (SD)	1.5 (0.71)	1.4 (0.76)	1.5 (1.12)	1.5 (1.00)
Median	1.5	1.0	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6

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Solicited Adverse Reaction Category Statistic	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Chills				
n	5	49	78	127
Mean (SD)	1.4 (0.55)	1.5 (0.94)	1.4 (0.83)	1.4 (0.87)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 6	1, 5	1, 6
Rash				
n	1	10	6	16
Mean (SD)	1.0 (NA)	2.1 (1.91)	2.0 (1.26)	2.1 (1.65)
Median	1.0	1.0	1.5	1.0
Min, Max	1, 1	1, 7	1, 4	1, 7

Abbreviations: n=number of exposed subjects who reported the event on any day within 7 days after any injection; Max=maximum; Min=minimum; SD=standard deviation.

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

^a Lymphadenopathy=localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Source: [Table 14.3.1.4.2](#).

7.1.5.1 Number of Days Reporting Solicited ARs by Time Window

When number of days of reporting was summarized by time windows after any injection, results in each group were consistent with the mean number of days reporting after any injection ([Section 7.1.3.1](#)). In the mRNA-1273 overall group, the highest percentage of participants reported solicited ARs that persisted for 1 to 2 days (137/400 [34.3%]) or 3 to 4 days (143/400 [35.8%]) after any injection, with a lower percentage of participants reporting solicited ARs that persisted for 5 to 6 days (49/400 [12.3%]) or ≥ 7 days (45/400 [11.3%]) ([Table 14.3.1.5.3](#)). In the placebo group, the highest percentage of participants reported solicited ARs that persisted for 1 to 2 days (71/200 [35.5%]), with a lower percentage of participants reporting solicited ARs that persisted for 3 to 4 days (19/200 [9.5%], 5 to 6 days (4/200 [2.0%]), or ≥ 7 days (9/200 [4.5%]). Similar trends were observed for solicited local ARs. For solicited systemic ARs, the highest percentage of participants reported solicited ARs that persisted for 1 to 2 days, with fewer participants reporting solicited systemic ARs persisting 3 to 4 days, 5 to 6 days, or ≥ 7 days. No notable differences in the number of days reporting solicited ARs by time window were noted between the mRNA-1273 dose groups.

After the first injection, the majority of participants reported solicited ARs persisting for 1 to 2 days ([Table 14.3.1.5.1](#)). After the second injection, the majority of participants reported solicited ARs persisting for 1 to 2 days or 3 to 4 days which was consistent with that seen after any injection ([Table 14.3.1.5.2](#)).

7.1.6 Rash and Lymphadenopathy Assessed by Healthcare Provider

As summarized in [Section 3.7.2.1](#), participants were instructed to contact the site within 24 hours for severe local or systemic AR, presence of any rash, or presence of axillary swelling ipsilateral to the injection, observed within 7 days after any injection in order to arrange an on-site assessment of the AR. During site follow-up, several participants indicated that they had either mistakenly indicated a rash event or reported local injection site reactions as rash in the eDiary. Such occurrences were either confirmed with the participant as an error and no HCP assessment was performed (ie, no grade assigned), or if they were confirmed as an error during the HCP assessment, the rash AR was assessed by the HCP as grade 0 (no rash) in the eCRF and in the safety database.

A total of 7 participants in the mRNA-1273 overall group submitted data for rash within 7 days after the first injection: 5 and 2 participants in the mRNA-1273 50 μ g and 100 μ g groups, respectively ([Table 19](#)). Thirteen participants in the mRNA-1273 overall group submitted data for lymphadenopathy within 7 days after the first injection: 6 and 7 participants in the

mRNA-1273 50 µg and 100 µg groups, respectively. Of these participants, the HCPs assessed 3/7 (42.9%) with rash and 3/13 (23.1%) with lymphadenopathy. In the placebo group, the HCP assessed 1/1 (100%) participant with rash and 1/2 (50.0%) participant with lymphadenopathy after the first injection.

Similar results were observed after the second injection ([Table 20](#)). Of the participants in the mRNA-1273 overall group who reported rash or lymphadenopathy, the HCPs assessed 3/6 (50.0%) with rash and 3/20 (15.0%) with lymphadenopathy. In the placebo group, no events were assessed as rash or lymphadenopathy by the HCP after the second injection.

Table 19: Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider Within 7 Days After First Injection (First Injection Solicited Safety Set)

Category Grade	Placebo (N=199) n (%)	mRNA-1273			Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Rash - N1	1	5	2		7
Any	1 (100)	2 (40.0)	1 (50.0)		3 (42.9)
Grade 1	1 (100)	2 (40.0)	1 (50.0)		3 (42.9)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Lymphadenopathy - N1	2	6	7		13
Any	1 (50.0)	1 (16.7)	2 (28.6)		3 (23.1)

Abbreviations: N1=number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Source: [Table 14.3.1.6.1.](#)

Table 20: Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider Within 7 Days After Second Injection (Second Injection Solicited Safety Set)

Category Grade	Placebo (N=194) n (%)	mRNA-1273			Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)		
Rash - N1	1	6	0		6
Any	0	3 (50.0)	0		3 (50.0)
Grade 1	0	3 (50.0)	0		3 (50.0)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Lymphadenopathy - N1	0	10	10		20
Any	0	1 (10.0)	2 (20.0)		3 (15.0)

Abbreviation: N1=number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Source: [Table 14.3.1.6.2.](#)

7.1.7 Medication Use for Solicited Adverse Reactions of Pain and Fever

To further characterize potential reactogenicity of mRNA-1273, 2 ad hoc analyses were performed for participant use of medications to prevent or treat pain or fever. The first analysis was based on participant-recorded use in the eDiary, wherein participants entered responses in the eDiary to questions about use of medications to treat or prevent pain or fever. The second analysis was based on participant-reported use of analgesic/antipyretic medications as recorded by site staff in the prior/concomitant medications and/or vaccination eCRF.

Medication use for pain or fever based on eDiary entries was summarized after any injection, the first injection, and the second injection for the following time intervals: within 7 days, any use, and use beyond 7 days (ie, use either started before Day 7 and continued after Day 7 or use started after Day 7).

After any injection, medication taken to treat or prevent pain and fever was reported by 79/200 (39.5%) and 103/200 (51.5%) participants in the 50 µg and 100 µg mRNA-1273 groups, respectively, and 29/200 (14.5%) participants in the placebo group (Table 14.1.4.4.2.3), and use occurred primarily within 7 days after any injection (Table 14.1.4.4.1.3).

After the first injection, medication taken to treat or prevent pain and fever was reported by 30/200 (15%) participants each in the 50 µg and 100 µg mRNA-1273 groups and 21/199 (10.6%) participants in the placebo group (Table 14.1.4.4.2.1), and use occurred primarily within 7 days after injection (Table 14.1.4.4.1.1). Medication use increased after the second injection in the 50 µg and 100 µg mRNA-1273 groups (69/195 [35.4%] and 97/198 [49.0%], respectively), while no notable difference was observed after the second injection for the placebo group (13/194 [6.7%]; Table 14.1.4.4.2.2). As observed after the first injection, medication use occurred primarily within 7 days after the second injection (Table 14.1.4.4.1.2).

Medication use beyond 7 days after any injection was low in the mRNA-1273 overall group (6/400 [1.5%]) and in the placebo group (2/200 [1.0%]; Table 14.1.4.4.3.3), with similar results noted after the first and second injections (Table 14.1.4.4.3.1 and Table 14.1.4.4.3.2).

Analgesic/antipyretic use based on recorded use on the concomitant page of the eCRF was summarized for the following time intervals after the first and second injection: ≥ Day 1 (Table 14.1.4.3.1.1 and Table 14.1.4.3.1.2), within 1 week (Table 14.1.4.3.2.1 and Table 14.1.4.3.2.2), and within 2 weeks (Table 14.1.4.3.3.1 and Table 14.1.4.3.3.2). Additional time intervals summarized after the second injection were analgesic/antipyretic use starting on

≥ Day 8 ([Table 14.1.4.3.4.1](#)), or any use on Day 8 or afterwards (ie, use started before Day 8 and continued after Day 8 or use started after Day 8; [Table 14.1.4.3.4.2](#)), analgesic/antipyretic use starting on ≥ Day 15 ([Table 14.1.4.3.5.1](#)), or any use on Day 15 or afterwards (ie, use started before Day 15 and continued after Day 15 or use started after Day 15; [Table 14.1.4.3.5.2](#)). The results of these analyses were consistent with the medication use for pain or fever based on eDiary entries.

7.2 Unsolicited Adverse Events

7.2.1 Overview of Unsolicited Adverse Events

The incidence of unsolicited TEAEs up to 28 days after any IP administration was comparable between the mRNA-1273 overall group (113/400 [28.3%]) and the placebo group (51/200 [25.5%]), with no dose-dependent increase observed in the mRNA-1273 groups (mRNA-1273 50 µg: 57/200 [28.5%] and mRNA-1273 100 µg: 56/200 [28.0%]; [Table 21](#)). Treatment-related TEAEs were more commonly reported by participants who received mRNA-1273 (43/400 [10.8%]) than by those who received placebo (13/200 [6.5%]).

No serious TEAEs (including fatal TEAEs) occurred up to 28 days after any IP administration; one participant (mRNA-1273 50 µg) had a serious TEAE of pneumonia that occurred > 28 days after any IP administration, which was considered not related to IP ([Section 7.3.2](#)).

The incidence of MAAEs was low in the mRNA-1273 overall group (39/400 [9.8%]) and the placebo group (17/200 [8.5%]; [Section 7.3.3.3](#)). Few participants in any group had MAAEs considered related to IP; the highest incidence was in the mRNA-1273 100 µg group (5/200 [2.5%]).

No unsolicited TEAE led to IP discontinuation up to 28 days after any IP administration ([Table 21](#)); however, 1 participant in the 50 µg mRNA-1273 group discontinued IP due to other reasons (positive COVID-19 test) on Day 6, which was erroneously not captured as a TEAE that led to IP discontinuation ([Section 7.3.3.1](#)). One participant each in the mRNA-1273 50 µg and placebo groups had a TEAE that led to IP discontinuation that occurred > 28 days after any IP administration ([Section 7.3.3.1](#)). No unsolicited TEAE led to study discontinuation up to 28 days after any IP administration ([Table 21](#)) or through Day 57 ([Table 14.3.1.15.2](#)).

The incidence of unsolicited severe TEAEs up to 28 days after any IP administration regardless of relationship was low in each group (12/400 [3.0%] in the mRNA-1273 overall group and 2/200 [2.0%] in the placebo group; [Section 7.3.3.2](#)). For the mRNA-1273 and placebo groups, approximately half of the reported unsolicited severe TEAEs were considered related to IP.

The TEAE profile from Day 1 to Day 57 was comparable to results up to Day 28 after IP administration, with 7 additional participants who received mRNA-1273 (50 or 100 µg) and 4 additional participants who received placebo experiencing TEAEs; none of which were considered related to IP ([Table 14.3.1.7.2](#)).

Age Cohorts

There were no notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for unsolicited TEAEs in the mRNA-1273 overall group (53/200 [26.5%]) and 60/200 [30.0%], respectively; [Table 14.3.1.7.1](#)). For the mRNA-1273 100 µg group, the incidence of unsolicited treatment-related TEAEs was numerically higher in Cohort 1 (18/100 [18.0%]) than in Cohort 2 (9/100 [9.0%]). Additionally, within Cohort 1, more participants in the mRNA-1273 100 µg group (18/100 [18.0%]) reported treatment-related unsolicited TEAEs than participants in the mRNA-1273 50 µg group (7/100 [7.0%]) and the placebo group (6/100 [6.0%]).

Table 21: Summary of Unsolicited TEAEs up to 28 Days After Any Vaccination (Safety Set)

	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Unsolicited TEAEs regardless of relationship to study vaccination				
All	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically attended	17 (8.5)	22 (11.0)	17 (8.5)	39 (9.8)
Leading to discontinuation from study vaccine	0	0	0	0
Leading to study discontinuation	0	0	0	0
Severe	4 (2.0)	7 (3.5)	5 (2.5)	12 (3.0)
Unsolicited TEAEs related to study vaccination				
All	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically attended	1 (0.5)	1 (0.5)	5 (2.5)	6 (1.5)
Leading to discontinuation from study vaccine	0	0	0	0
Leading to study discontinuation	0	0	0	0
Severe	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)

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.

Percentages are based on the number of safety subjects.

Source: [Table 14.3.1.7.1](#).

7.2.2 Most Common Unsolicited Adverse Events

The percentage of participants with unsolicited TEAEs up to 28 days after any IP administration was comparable between the mRNA-1273 overall (113/400 [28.3%]) and placebo groups (51/200 [25.5%]; [Table 22](#)). No dose-dependent increase in TEAEs was observed between the 50 µg and 100 µg mRNA-1273 groups.

In the mRNA-1273 overall and placebo groups, the unsolicited TEAE incidence in each SOC was < 10%. The SOCs with the highest incidence of unsolicited TEAEs (incidence > 5%) in the mRNA-1273 overall or placebo groups were nervous system disorders (24/400 [6.0%] and 6/200 [3.0%], respectively), musculoskeletal and connective tissue disorders (28/400 [7.0%] and 8/200 [4.0%], respectively), and general disorders and administration site conditions (34/400 [8.5%] and 10/200 [5.0%], respectively; [Table 22](#)).

The incidence of the most common unsolicited TEAEs was comparable between the mRNA-1273 overall and placebo groups. The common unsolicited TEAEs with the highest incidence ($\geq 2\%$) in the mRNA-1273 overall group or placebo group (by decreasing incidence in the mRNA-1273 overall group) were headache (15/400 [3.8%] and 5/200 [2.5%], respectively), fatigue (14/400 [3.5%] and 6/200 [3.0%], respectively), arthralgia (9/400 [2.3%] and 4/200 [2.0%], respectively), and myalgia (8/400 [2.0%] and 3/200 [1.5%], respectively; [Table 22](#)). These TEAEs reflected the solicited ARs that persisted for > 7 days after injection ([Section 7.1.2](#)).

Two participants each in the mRNA-1273 50 µg group and placebo group had unsolicited TEAEs of COVID-19 infection up to 28 days after any IP administration ([Table 22](#)); 3 additional participants in the placebo group had unsolicited TEAEs of COVID-19 infection > 28 days after any IP administration ([Table 14.3.1.8.2](#)). Additional details are provided in [Section 7.3.3.6](#) and [Section 8.3.1](#).

Within the general disorders and administration site conditions SOC, the common injection site PTs (injection site pain, injection site erythema, injection site induration, and injection site swelling; [Table 22](#)), as well as less common PTs (injection site bruising, injection site mass, or injection site pruritus; [Table 14.3.1.8.1](#)), had an incidence of $\leq 2.0\%$ in any one mRNA-1273 group (50 µg, 100 µg, or overall). Most of the injection site TEAEs were considered treatment related ([Section 7.2.4](#)).

The incidence of the most common unsolicited TEAEs from Day 1 to Day 57 was comparable to results up to Day 28 after IP administration for participants who received mRNA-1273 or placebo ([Table 14.3.1.8.2](#)).

Age Cohorts

For the most common TEAEs, no notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed across groups ([Table 14.3.1.8.1](#)).

Table 22: Participant Incidence of Common Unsolicited TEAE up to 28 Days After Any Vaccination (2% or More in Any Treatment Group Based on Preferred Term) by System Organ Class and Preferred Term (Safety Set)

System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Number of subjects reporting unsolicited adverse events	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Number of unsolicited adverse events	76	104	90	194
Infections and infestations	9 (4.5)	7 (3.5)	7 (3.5)	14 (3.5)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
COVID-19	2 (1.0)	2 (1.0)	0	2 (0.5)
Immune system disorders	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Nervous system disorders	6 (3.0)	12 (6.0)	12 (6.0)	24 (6.0)
Headache	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Respiratory, thoracic and mediastinal disorders	5 (2.5)	3 (1.5)	3 (1.5)	6 (1.5)
Oropharyngeal pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Cough	2 (1.0)	0	0	0
Skin and subcutaneous tissue disorders	8 (4.0)	11 (5.5)	6 (3.0)	17 (4.3)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Musculoskeletal and connective tissue disorders	8 (4.0)	16 (8.0)	12 (6.0)	28 (7.0)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
General disorders and administration site conditions	10 (5.0)	17 (8.5)	17 (8.5)	34 (8.5)

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System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Fatigue	6 (3.0)	11 (5.5)	3 (1.5)	14 (3.5)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Investigations	5 (2.5)	2 (1.0)	3 (1.5)	5 (1.3)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Injury, poisoning and procedural complications	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Skin laceration	2 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0.

Source: [Table 14.3.1.8.1.](#)

7.2.3 Unsolicited Adverse Events by Maximum Intensity

Most unsolicited TEAEs reported up to 28 days after any injection in the mRNA-1273 overall and placebo groups were mild or moderate in severity ([Table 23](#)). Few participants reported severe unsolicited TEAEs up to 28 days after any injection: 12/400 (3.0%) participants in the mRNA-1273 overall group and 4/200 (2.0%) participants in the placebo group. No severe COVID-19 TEAEs were reported from Day 1 through Day 57 ([Table 14.3.1.16.2](#)). Severe unsolicited TEAEs are summarized further in [Section 7.3.3.2](#). Severity of TEAEs was comparable in the mRNA-1273 50 and 100 µg groups.

The incidence of mild, moderate, and severe unsolicited TEAEs from Day 1 through Day 57 was comparable to results up to Day 28 after IP administration for participants who received mRNA-1273 or placebo ([Table 14.3.1.10.2](#)).

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed for the severity of TEAEs across groups ([Table 14.3.1.10.1](#)).

Table 23: Participant Incidence of Unsolicited TEAE by Severity up to 28 Days After Any Vaccination (Safety Set)

System Organ Class Preferred Term Severity	Placebo (N=200) n (%)	mRNA-1273			Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)		
Number of subjects reporting unsolicited adverse events	51 (25.5)	57 (28.5)	56 (28.0)		113 (28.3)
Mild	40 (20.0)	38 (19.0)	38 (19.0)		76 (19.0)
Moderate	7 (3.5)	12 (6.0)	13 (6.5)		25 (6.3)
Severe	4 (2.0)	7 (3.5)	5 (2.5)		12 (3.0)
Number of unsolicited adverse events	76	104	90		194
Mild	61	82	72		154
Moderate	11	13	13		26
Severe	4	9	5		14

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Source: [Table 14.3.1.10.1.](#)

7.2.4 Unsolicited Adverse Events by Relationship to Investigational Product

More participants reported treatment-related unsolicited TEAEs in the mRNA-1273 overall group (43/400 [10.8%]) than in the placebo group (13/200 [6.5%]), and participants reported a greater number of events in the mRNA-1273 overall group than in the placebo group (79 and 18, respectively; [Table 24](#)).

The treatment-related TEAEs with the highest incidence (> 1%) in mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were fatigue (13/400 [3.3%] and 6/200 [3.0%], respectively), headache (11/400 [2.8%] and 1/200 [0.5%], respectively), arthralgia (7/400 [1.8%] and 4/200 [2.0%], respectively), myalgia (7/400 [1.8%] and 2/200 [1.0%], respectively), and injection site pain (5/400 [1.3%] and 1/200 [0.5%], respectively). In many instances, these TEAEs reflected the solicited ARs that persisted for > 7 days after injection ([Section 7.1.2](#)).

Few participants had severe unsolicited treatment-related TEAEs: 6/400 (1.5%) participants in the mRNA-1273 overall group and 2/200 (1.0%) participants in the placebo group ([Table 14.3.1.12.1](#)). Unsolicited severe TEAEs are summarized further in [Section 7.3.3.2](#).

The incidence of treatment-related TEAEs was numerically higher in the mRNA-1273 100 µg group compared with the 50 µg group, (27/200 [13.5%] versus 16/200 [8.0%], respectively). The higher incidence of treatment-related TEAEs reported by participants who received mRNA-1273 at 100 µg compared with 50 µg was attributed to a greater frequency of injection site reactions (eg, injection site pain, erythema, induration) reported as unsolicited events per criteria described in [Section 3.7.2.1](#) ([Table 24](#)).

The incidence of treatment-related unsolicited TEAEs from Day 1 to Day 57 was comparable to results up to Day 28 after IP administration ([Table 14.3.1.11.2](#)).

Age Cohorts

No apparent differences were observed between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) for unsolicited treatment-related TEAEs for the mRNA-1273 50 µg and placebo groups ([Table 14.3.1.11.1](#)). For the mRNA-1273 100 µg group, the incidence of unsolicited treatment-related TEAEs was numerically higher in Cohort 1 (18/100 [18.0%]) than in Cohort 2 (9/100 [9.0%]). Additionally, within Cohort 1, more participants in the mRNA-1273 100 µg

group (18/100 [18.0%]) reported treatment-related unsolicited TEAEs than participants in the mRNA-1273 50 µg group (7/100 [7.0%]) and the placebo group (6/100 [6.0%]).

Table 24: Participant Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days After Any Vaccination (Safety Set)

System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects reporting unsolicited adverse events	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Number of unsolicited adverse events	18	33	46	79
Infections and infestations	0	0	1 (0.5)	1 (0.3)
Gastroenteritis	0	0	1 (0.5)	1 (0.3)
Nervous system disorders	1 (0.5)	5 (2.5)	8 (4.0)	13 (3.3)
Headache	1 (0.5)	5 (2.5)	6 (3.0)	11 (2.8)
Dizziness	0	0	1 (0.5)	1 (0.3)
Paraesthesia	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	0	2 (1.0)	2 (0.5)
Oropharyngeal pain	0	0	1 (0.5)	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Gastrointestinal disorders	0	0	4 (2.0)	4 (1.0)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Nausea	0	0	1 (0.5)	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Skin and subcutaneous tissue disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Pruritus	0	1 (0.5)	0	1 (0.3)
Angioedema	1 (0.5)	0	0	0

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System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Musculoskeletal and connective tissue disorders	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
Arthralgia	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Musculoskeletal pain	1 (0.5)	0	0	0
General disorders and administration site conditions	8 (4.0)	12 (6.0)	15 (7.5)	27 (6.8)
Fatigue	6 (3.0)	10 (5.0)	3 (1.5)	13 (3.3)
Injection site pain	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

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Source: [Table 14.3.1.11.1.](#)

7.3 Deaths, Other Serious Adverse Events, and Other Significant Unsolicited Adverse Events

7.3.1 Deaths

At the time of database lock for the primary analysis, no participants died during the study ([Table 7](#)).

7.3.2 Other Serious Adverse Events

One SAE was reported up to Day 57 in this study ([Table 14.3.1.13.2](#)). A 65-year-old participant in the mRNA-1273 50 µg group reported a serious severe TEAE of pneumonia on Day 33 that resulted in a 5-day hospitalization ([Listing 16.2.7.8](#)). Administration of the second injection was initially delayed because of the participant's hospitalization ([Listing 16.2.5.1](#)). Over the course of the SAE, the participant's SARS-CoV-2 tests were negative ([Listing 16.2.6.3](#)). The serious TEAE was considered not related to the IP or any study procedure and ultimately resulted in discontinuation of the IP. The event was considered resolved on Day 58. As of the time of database lock for the primary analysis, the participant was continuing in the study.

A case narrative for this participant is provided in [Section 15](#).

7.3.3 Other Clinically Meaningful Unsolicited Adverse Events

7.3.3.1 Unsolicited Adverse Events Leading to Discontinuation From IP or From the Study

Two participants discontinued the IP due to an unsolicited TEAE (1 each in the mRNA-1273 50 µg and placebo groups) ([Listing 16.2.7.9](#)). In addition, as detailed in [Section 5.1](#), one participant in the mRNA-1273 100 µg group was summarized in study disposition as having discontinued IP due to AEs, but IP discontinuation was due to three grade 3 solicited ARs. One participant in the 50 µg mRNA-1273 group discontinued IP due to other reasons (positive COVID-19 test) on Day 6, which was erroneously not captured as a TEAE that led to IP discontinuation.

The participant in the mRNA-1273 50 µg who discontinued the IP reported a serious TEAE of pneumonia (onset Day 33); the event for this participant is summarized in [Section 7.3.2](#). The participant in the placebo group discontinued the IP due to a moderate TEAE of COVID-19 infection (onset Day 32). The event was considered not related to the IP or study procedures and was considered resolved on Day 49. As of the time of database lock for the primary analysis, both participants were continuing in the study.

No participants reported unsolicited TEAEs leading to discontinuation from the study up to 28 days after any IP administration or through Day 57 ([Table 14.3.1.15.1](#) and [Table 14.3.1.15.2](#)).

Case narratives for participants who discontinued the IP due to an unsolicited TEAE or other reasons (positive COVID-19 test) are provided in [Section 15](#).

7.3.3.2 Unsolicited Severe Adverse Events

Up to 28 days after any IP administration, 12/400 (3.0%) participants who received mRNA-1273 reported 14 unsolicited severe TEAEs ([Table 14.3.1.16.1](#)). Of these, 6/400 (1.5%) participants had treatment-related severe TEAEs ([Table 14.3.1.17.1](#)). In the placebo group 4/200 (2.0%) participants reported 4 unsolicited severe TEAEs, with 2 (1.0%) participants having treatment-related severe TEAEs. No severe COVID-19 TEAEs were reported from Day 1 through Day 57 ([Table 14.3.1.16.2](#)).

Most unsolicited severe TEAEs were reported by one participant each in either the mRNA-1273 overall or placebo groups ([Table 14.3.1.16.1](#)). The unsolicited severe TEAEs with the highest incidence ($\geq 0.5\%$) in the mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were fatigue (2/400 [0.5%] and 2/200 [1.0%], respectively), blood pressure increased (2/400 [0.5%] and 1/200 [0.5%], respectively), arthralgia (2/400 [0.5%] and 0, respectively), and allergy to arthropod sting (0 and 1/200 [0.5%], respectively).

The treatment-related unsolicited severe TEAEs in the mRNA-1273 100 µg group were headache and rhinorrhea (each 1/200 [0.5%]), and in the mRNA-1273 50 µg group were arthralgia and fatigue (each 2/200 [1.0%]) and axillary pain and pain (each 1/200 [0.5%]; [Table 14.3.1.17.1](#)). In the placebo group, the only treatment-related severe TEAE was fatigue (2/200 [1.0%]).

The incidence of severe unsolicited TEAEs (unrelated and related) from Day 1 to Day 57 was comparable to results up to Day 28 after IP administration, with one additional participant in the mRNA-1273 50 µg group who experienced a serious severe TEAE of pneumonia, as detailed in [Section 7.3.2](#) ([Table 14.3.1.16.2](#) and [Table 14.3.1.17.2](#)).

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed for incidence of unsolicited severe TEAEs by treatment group ([Table 14.3.1.16.1](#)).

7.3.3.3 Medically Attended Adverse Events

The incidence of MAAEs up to 28 days after any injection was comparable in the mRNA-1273 overall group (39/400 [9.8%]) and placebo group (17/200 [8.5%]; [Table 25](#)).

Most MAAEs were reported by one participant each in either the mRNA-1273 overall or placebo groups. The MAAEs with the incidence > 0.5% in the mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were contact dermatitis (4/400 [1.0%] and 1/200 [0.5%], respectively), urinary tract infection (3/400 [0.8%] and 1/200 [0.5%], respectively), headache (3/400 [0.8%] and 0, respectively), and skin laceration (0 and 2/100 [1.0%], respectively).

The incidence of MAAEs from Day 1 to Day 57 was comparable to results up to Day 28 after injection ([Table 14.3.1.18.2](#)).

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed for the incidence of MAAEs by treatment group ([Table 14.3.1.18.1](#)).

Table 25: Participant Incidence of Unsolicited Medically Attended TEAE (Reported in 1% Participants in Any Treatment Group) by System Organ Class and Preferred Term up to 28 Days After Any Vaccination (Safety Set)

System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects reporting unsolicited adverse events	17 (8.5)	22 (11.0)	17 (8.5)	39 (9.8)
Number of unsolicited adverse events	22	28	21	49
Infections and infestations	6 (3.0)	5 (2.5)	5 (2.5)	10 (2.5)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
COVID-19	1 (0.5)	2 (1.0)	0	2 (0.5)
Nervous system disorders	0	3 (1.5)	3 (1.5)	6 (1.5)
Headache	0	1 (0.5)	2 (1.0)	3 (0.8)
Skin and subcutaneous tissue disorders	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Dermatitis contact	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Rash	0	2 (1.0)	0	2 (0.5)
Musculoskeletal and connective tissue disorders	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
Arthralgia	0	0	2 (1.0)	2 (0.5)
General disorders and administration site conditions	0	2 (1.0)	3 (1.5)	5 (1.3)
Axillary pain	0	0	2 (1.0)	2 (0.5)

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System Organ Class Preferred Term	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Skin laceration	2 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Source: [Table 14.3.1.18.1](#).

7.3.3.4 Adverse Events of Special Interest

Ad hoc analyses for AEs of special interest were performed by searching the database using SMQs. The SMQs for this study included vasculitis, hypersensitivity, arthritis, angioedema, peripheral neuropathy, demyelination, and convulsions; the SMQs are provided in [Appendix 16.1.13](#).

No participants had AEs of special interest in the SMQs of vasculitis ([Table 14.3.1.22.1](#)), peripheral neuropathy ([Table 14.3.1.22.5](#)), demyelination ([Table 14.3.1.22.6](#)), or convulsions ([Table 14.3.1.22.7](#)).

One participant reported an AE that was captured in the arthritis SMQ. Specifically, 1/200 (0.5%) participant in the mRNA-1273 100 µg group had a TEAE of gout ([Table 14.3.1.22.3](#)).

The incidence of hypersensitivity was comparable between the mRNA-1273 overall group (11/400 [2.8%]) and placebo group (6/200 [3.0%]; [Table 14.3.1.22.2](#)). More participants in the mRNA-1273 50 µg group (9/200 [4.5%]) reported hypersensitivity TEAEs than in the mRNA-1273 100 µg (2/200 [1.0%]). The following hypersensitivity TEAEs were reported:

- Angioedema: 1/200 (0.5%) participant in placebo group (also captured as an AE of special interest of angioedema; [Table 14.3.1.22.4](#))
- Dermatitis: 1/200 (0.5%) participant in mRNA-1273 50 µg group
- Contact dermatitis: 5/200 (2.5%) participants in mRNA-1273 50 µg group, 2/200 (1.0%) participants in the mRNA-1273 100 µg group, and 3/100 (1.5%) participants in the placebo group
- Rash: 3/200 (1.5%) participants in mRNA-1273 50 µg group and 2/200 (1.0%) participants in the placebo group

Only the angioedema AE of special interest in the placebo group was considered related to IP administration ([Table 14.3.1.12.2](#)).

7.3.3.5 SARS-CoV-2 Exposure and Symptoms

At Day 1, none of the participants who received mRNA-1273 (50 or 100 µg) or who received placebo had close contact with a person having SARS-CoV-2 infection or COVID-19 ([Table 14.2.3.2.1](#)). Across the remaining visits (Day 8 to Day 57), the number of participants exposed in the mRNA-1273 overall group ranged from 1/400 (0.3%) to 4/400 (1.0%) participants, with an overall mean length of exposure at any visit that ranged from 1.5 to

4.0 days. Results in the mRNA-1273 50 µg group ranged from 1/200 (0.5%) and 2/200 (1.0%) participants exposed, with an overall mean length of exposure ranging from 1.0 to 4.0 days. In the mRNA-1273 100 µg group, no participants had exposure at Day 8 and Day 15; for the remaining postbaseline visits until Day 57, a range of 1/200 (0.5%) and 2/200 (1.0%) participants were exposed with an overall mean length of exposure ranging from 1.7 to 5.0 days. The number of participants exposed in the placebo group ranged from 0 to 5 of 200 (2.5%) participants, with an overall mean length of exposure at any visit that ranged from 1 to 7.0 days, with no exposure on Day 8.

Due to the low number of participants in the mRNA-1273 overall or placebo groups who had close contact with a person having SARS-CoV-2 infection or COVID-19, no pattern for common symptoms was evident ([Table 14.2.3.2.1](#)). Overall, the mean time from SARS-CoV-2 infection or COVID-19 exposure to first symptoms was 9.0 days in participants who received mRNA-1273 (overall) and 5.3 days in participants who received placebo ([Table 26](#)).

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed for SARS-CoV-2 exposure and symptoms ([Table 14.2.3.2.1](#) and [Table 14.2.3.2.2](#)).

Table 26: Summary of Time From SARS-CoV-2 or COVID-19 Exposure to First Symptoms (Safety Set)

	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Time from exposure to first symptoms (Days)				
n	3	2	1	3
Mean (SD)	5.3 (5.13)	9.0 (5.66)	9.0 (NA)	9.0 (4.00)
Median	4.0	9.0	9.0	9.0
Min, Max	1, 11	5, 13	9, 9	5, 13

Abbreviations: COVID-19=coronavirus disease 2019; Max=maximum; Min=minimum; SD=standard deviation.

Time from exposure to the first symptoms is defined as the time between the date of the first symptom and the last exposure date prior to the first symptom.

Source: [Table 14.2.3.2.2.](#)

7.3.3.6 Solicited Adverse Reactions and Unsolicited Adverse Events for Participants Detected With SARS-CoV-2 or COVID-19

SARS-CoV-2 infection or COVID-19 was detected in 2 participants in the mRNA-1273 50 µg group, one each in Cohorts 1 and 2, and 5 participants in the placebo group, 3 in Cohort 1 and 2 in Cohort 2 ([Listing 16.2.6.3](#) and [Listing 16.2.6.6](#)). Additional details for SARS-CoV-2 and COVID-19 test results are provided in [Section 8.3.1](#).

Few participants detected with SARS-CoV-2 infection or COVID-19 had solicited ARs ([Listing 16.2.7.1.2](#)). One participant in the placebo group (Cohort 1) had grade 1 fatigue on Day 5 after the second injection. Both participants in the mRNA-1273 50 µg group had solicited ARs: one participant (Cohort 1) had grade 1 pain on Days 1 and 2 after the first injection and Day 2 after the second injection; and the other participant (Cohort 2) had erythema on Day 1 and pain on Day 2 after the first injection.

All participants who had SARS-CoV-2 infection or COVID-19 had unsolicited TEAEs of COVID-19 reported, with one participant in the placebo group also having unsolicited TEAEs of cough and sinus headache ([Listing 16.2.7.12](#)). The participants in the mRNA-1273 50 µg group had mild COVID-19 TEAEs while in the placebo group, 3 participants had mild and 2 participants had moderate COVID-19 TEAEs. All events resolved and all were considered not related to IP. One participant who received mRNA-1273 50 µg did not receive the second injection because of the positive COVID-19 result ([Listing 16.2.1.1](#)), and one participant who received placebo discontinued the IP after the first injection due to the COVID-19 TEAE ([Section 7.3.3.1](#)).

7.4 Clinical Laboratory Evaluation

Baseline hematology, chemistry, and coagulation tests were performed for all participants and postbaseline tests were performed only for Cohort 2 (≥ 55 years; see [Section 3.7.2.5](#)).

7.4.1 Clinical Laboratory Values Over Time in Cohort 2

Overall, no treatment-related, dose-related, or clinically relevant trends in change from baseline to Day 29 and Day 57 were observed for the hematology, coagulation, and chemistry laboratory test results of participants in Cohort 2 ([Table 14.3.2.1](#)).

7.4.2 Evaluation of Individual Laboratory Parameters in Cohort 2

7.4.2.1 Individual Participant Changes by Treatment Group in Cohort 2

The majority of Cohort 2 participants had baseline and worst postbaseline values for chemistry, hematology, and coagulation parameters of grade 0 or 1 ([Table 14.3.2.3](#)).

Few Cohort 2 participants in the mRNA-1273 overall or placebo groups had individual shifts from baseline to a worst postbaseline result of grade 3 or higher in chemistry, hematology, and coagulation ([Table 14.3.2.3](#)). The following overall results were noted:

- The incidence of shifts from baseline to grade 3 for decreased hemoglobin was comparable between the mRNA-1273 overall group (7/200 [3.5%]) and the placebo group (2/100 [2.0%]). In the mRNA-1273 50 and 100 µg groups, 5/100 (5.0%) participants and 2/100 (2.0%) participants, respectively, had hemoglobin shifts from baseline to grade 3. No participant in any group shifted to grade 4 decreased hemoglobin.
- Other than hemoglobin, no other chemistry, hematology, or coagulation shifts from baseline to grade 3 or higher were observed in the mRNA-1273 100 µg group.
- In the mRNA-1273 50 µg group, other shifts from baseline to grade 3 were decreased platelets, increased alkaline phosphatase, and increased activated partial thromboplastin time (each 1/100 [1.0%]). One (1.0%) participant in the mRNA-1273 50 µg group had increased prothrombin time that shifted from grade 0 at baseline to postbaseline grade 4.

7.4.2.2 Individual Clinically Meaningful Abnormalities by Treatment Group in Cohort 2

For hematology, coagulation, and chemistry laboratory test results, the following abnormalities of grade 3 or higher were reported for participants in Cohort 2 ([Table 14.3.2.2](#)):

- **mRNA-1273 50 µg group**
 - Grade 3 decreased hemoglobin: 2/97 (2.1%) participants at Day 29 and 3/94 (3.2%) participants at Day 57
 - Grade 3 decreased platelets: 1/96 (1.0%) participant at Day 29 and 1/94 (1.1%) at Day 57
 - Grade 3 increased alkaline phosphatase: 1/98 (1.0%) participant at Day 29
 - Grade 3 increased activated partial thromboplastin time: 1/88 (1.1%) participant at Day 57
 - Grade 4 increased prothrombin time; 1/92 (1.1%) participant at Day 29

- **mRNA-1273 100 µg group**
 - Grade 3 decreased hemoglobin: 1/94 (1.1%) participant at Day 29 and Day 57
- **Placebo**
 - Grade 3 decreased hemoglobin: 1/94 (1.1%) participant at Day 29 and 1/99 (1.0%) at Day 57

7.5 Vital Signs and Other Observations Related to Safety

7.5.1 Vital Signs

Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed after dosing and through Day 57 were comparable to those observed at baseline, with no notable trends or differences across groups ([Table 14.3.3.1](#)).

Few Cohort 2 participants in the mRNA-1273 overall or placebo groups had individual shifts from baseline to vital signs toxicity of grade 3 or higher ([Table 14.3.3.2](#)). The following overall results were noted:

- The incidence of shifts from baseline to worst postbaseline grade 3 diastolic hypertension was comparable between the mRNA-1273 overall group (1/400 [0.3%]) and the placebo group (1/200 [0.5%]). None of the grade 3 events occurred on the day of dosing (Day 1 or Day 29). In the mRNA-1273 100 µg group, grade 3 diastolic hypertension was observed on Day 36 and Day 43 (each 1/200 [0.5%]). Grade 3 diastolic hypertension was not observed in the mRNA-1273 50 µg group.
- The incidence of shifts from baseline to worst postbaseline grade 3 systolic hypertension was comparable between the mRNA-1273 overall group (8/400 [2.0%]) and the placebo group (5/200 [2.5%]). Grade 3 systolic hypertension 1-hour post dose on Day 1 was observed in 2/400 (0.5%) participants in the mRNA-1273 overall group and in 3/200 (1.5%) participants in the placebo group. On Day 29, grade 3 systolic hypertension 1-hour post dose was observed for 2/400 (0.5%) participants in the mRNA-1273 overall group and for no participants in the placebo group.
- The incidence of shifts from baseline to worst postbaseline grade 3 bradycardia was comparable between the mRNA-1273 overall group (5/400 [1.3%]) and the placebo group (5/200 [2.5%]). Grade 3 bradycardia 1-hour post dose on Day 1 and Day 29 was observed for 2/400 (0.5%) participants in the mRNA-1273 overall group and for 3/200 (1.5%) participants in the placebo group.

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed in vital sign measurements by treatment group ([Table 14.3.3.2](#)).

7.5.2 Vital Signs Reported as Adverse Events

Vital signs reported as TEAEs up to 28 days after any IP administration included the following ([Table 14.3.1.8.1](#)):

- **mRNA-1273 50 μ g group**
 - Hypertension: 1/200 (0.5%) participant
 - Increased blood pressure: 1/200 (0.5%) participant
- **mRNA-1273 100 μ g group**
 - Diastolic hypertension: 1/200 (0.5%) participant
 - Increased blood pressure: 1/200 (0.5%) participant
 - Increased diastolic blood pressure: 1/200 (0.5%) participant
- **Placebo**
 - Increased blood pressure: 2/200 (1.0%) participants
 - Cardiac murmur: 1/200 (0.5%) participant
 - Decreased heart rate: 2/200 (1.0%) participants

Age Cohorts

No notable differences between Cohort 1 (≥ 18 to < 55 years) and Cohort 2 (≥ 55 years) were observed for the incidence of vital signs reported as TEAEs by treatment group ([Table 14.3.1.8.1](#)).

7.6 Pregnancies

As of the date of the data cutoff for this primary analysis CSR, no pregnancies were reported ([Listing 16.2.8.5](#)).

7.7 Safety Conclusions

In this primary analysis, the mRNA-1273 vaccine, administered as 2 doses (50 µg or 100 µg) 28 days apart, demonstrated an acceptable safety profile in the participant population enrolled in this study in both age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).

The following are the key safety and reactogenicity findings supporting the safety conclusion:

Solicited Adverse Reactions

- More participants reported any solicited ARs within 7 days of any injection in the mRNA-1273 overall group (93.5%) than in the placebo group (51.5%).
- The incidence of solicited local ARs and systemic ARs within 7 days of any injection were both higher for participants who received mRNA-1273 (overall; 89.0% and 78.8%, respectively) than for those who received placebo (19.0% and 45.5%, respectively).
- The incidence of solicited local ARs within 7 days after injection was comparable after the first and second injections for the mRNA-1273 overall group (74.8% versus 83.0%). In the mRNA-1273 overall group, the incidence of solicited systemic ARs was numerically higher after the second injection than after the first injection (73.3% and 43.1%, respectively).
- Across all treatment groups, the majority of solicited ARs were grade 1 or grade 2; no grade 4 solicited ARs were reported. More grade 3 solicited ARs were reported in the mRNA-1273 overall group (14.3%) than in the placebo group (3.0%). In the mRNA-1273 overall group, most grade 3 solicited ARs occurred after the second injection and the most common solicited ARs were fatigue, myalgia, and headache.
- In the mRNA-1273 overall group, the most common solicited local AR was pain: 74.4% after the first injection and 82.4% after the second injection.
- The most common solicited systemic ARs in the mRNA-1273 overall group were headache (25.3%) and fatigue (24.6%) after the first injection and fatigue (59.0%), headache (50.9%), myalgia (47.1%), arthralgia (36.9%), and chills (32.3%) after the second injection.
- There was a dose-dependent increase in pain between the mRNA-1273 50 µg and 100 µg groups after the first injection (65.5% and 83.4%, respectively).
- Fever, fatigue, myalgia, arthralgia, nausea/vomiting, and chills showed a dose-dependent increase between the mRNA-1273 50 µg and 100 µg groups after the second injection but not after the first injection.

- After the first injection, the incidence of any solicited ARs and solicited local ARs was (88.0% and 84.0%, respectively) in the mRNA-1273 100 µg group and (71.0% and 65.5%, respectively) in mRNA-1273 50 µg group.
- In the mRNA-1273 overall group, the incidence of any solicited ARs, solicited local ARs, and solicited systemic ARs after the first injection were 85.0%, 80.0%, and 49.0%, respectively, in Cohort 1 (≥ 18 to < 55 years) and 74.0%, 69.5%, and 37.2%, respectively, in Cohort 2 (≥ 55 years).
- In the mRNA-1273 overall group, the incidence of any solicited ARs, solicited local ARs, and solicited systemic ARs after the second injection was 90.8%, 85.2%, and 75.0%, respectively, in Cohort 1 (≥ 18 to < 55 years) and 86.8%, 80.7%, and 71.6%, respectively, in Cohort 2 (≥ 55 years).
- In the mRNA-1273 overall and placebo groups, participants most often reported solicited local ARs and systemic ARs within the first 3 days after any injection, with an onset of each on Day 1 or Day 2 after any injection in both groups. The mean number of days solicited local ARs and systemic ARs were reported within the 7 days after any injection was 2.9 and 3.1 days, respectively, in the mRNA-1273 overall group and 2.0 and 2.4 days, respectively, in the placebo group.
- The incidence of solicited ARs that were ongoing 7 days after any injection and reported as TEAEs in the mRNA-1273 overall group was 28/400 (7.0%) and that in the placebo group was 8/200 (4.0%); no solicited AR met the SAE criteria. In the mRNA-1273 overall group or placebo group, the highest incidence ($> 1.0\%$) of solicited ARs ongoing 7 day after any injection and reported as TEAEs (by decreasing incidence in the mRNA-1273 overall group) were fatigue (3.5% and 2.5%, respectively), headache (2.8% and 0.5%, respectively), and arthralgia and myalgia (both 1.8% and 1.0%, respectively).
- One participant in the mRNA-1273 100 µg group discontinued vaccination due to three grade 3 solicited ARs (fatigue, myalgia, and arthralgia).
- Ad hoc analysis of medication use for pain or fever, which was based on patient-reported use in Diary entries (after any, first, or second injection), demonstrated that more participants reported medication use in the mRNA-1273 groups (50 µg, 100 µg) than the placebo group (39.5%, 51.5%, and 14.5%, respectively) after any injection.

Unsolicited TEAEs

- The incidence of unsolicited TEAEs up to 28 days after any IP administration was comparable between the mRNA-1273 overall group (28.3%) and the placebo group (25.5%), with no dose-dependent increase with mRNA-1273 dose (50 and 100 µg both approximately 28%).
- The incidence of the most common unsolicited TEAEs was comparable between the mRNA-1273 overall group and placebo group. The common TEAEs with the highest incidence ($\geq 2\%$) in the mRNA-1273 overall group or placebo group (by decreasing incidence in the mRNA-1273 overall group) were headache (3.8% and 2.5%, respectively), fatigue (3.5% and 3.0%, respectively), arthralgia (2.3% and 2.0%, respectively), and myalgia (2.0% and 1.5%, respectively).
- Most unsolicited TEAEs reported up to 28 days after any injection in both the mRNA-1273 overall and placebo groups were mild or moderate in severity. Few participants reported severe unsolicited TEAEs: 3.0% in the mRNA-1273 overall group and 2.0% in the placebo group, and approximately half of the reported severe unsolicited TEAEs in the each treatment group were considered related to IP.
- More participants reported treatment-related unsolicited TEAEs in the mRNA-1273 overall group (10.8%) than in the placebo group (6.5%). The treatment-related TEAEs with the highest incidence ($> 1\%$) in mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were fatigue (3.3% and 3.0%, respectively), headache (2.8% and 0.5%, respectively), arthralgia (1.8% and 2.0%, respectively), myalgia (1.8% and 1.0%, respectively), and injection site pain (1.3% and 0.5%, respectively). No treatment-related SAEs were reported through Day 57.
- Of the 7 participants with confirmed SARS CoV 2 infection, 3 participants were symptomatic (2 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group) and 4 participants remained asymptomatic (3 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group). No cases of asymptomatic SARS-CoV-2 infection or symptomatic COVID-19 were reported in the 100-µg group. All participants with SARS-CoV-2 infection or COVID-19 reported TEAEs of COVID-19; none were severe, all resolved, and none were considered related to the IP.
- No deaths occurred up to the data cutoff for this primary analysis and one participant (mRNA-1273 50 µg) had a serious TEAE (pneumonia), which occurred > 28 days after any IP administration and was considered not related to IP.
- Due to positive COVID-19 on Day 6, one participant in the mRNA-1273 50 µg group discontinued IP administration. One participant each in the mRNA-1273 50 µg and

placebo groups had a TEAE that led to IP discontinuation that occurred > 28 days after any IP administration; both TEAE were considered not related to IP.

- No unsolicited TEAE led to study discontinuation from Day 1 through Day 57.
- The incidence of MAAEs up to 28 days after any injection was comparable in the mRNA-1273 overall group (9.8%) and placebo group (8.5%). Few participants in any treatment group had MAAEs considered related to IP.
- As identified from ad hoc analysis based on an SMQ search of the database, the incidence of hypersensitivity was comparable between the mRNA-1273 overall group (2.8%) and placebo group (3.0%). No participants had AEs of special interest in the SMQs of vasculitis, peripheral neuropathy, demyelination, or convulsions. One participant in the mRNA-1273 100 µg group had an AE of special interest in the arthritis SMQ (gout).
- No treatment-related, dose-related, or clinically relevant trends in changes from baseline from Day 1 through Day 57 were observed for the hematology, coagulation, and chemistry laboratory test results of participants in Cohort 2.
- Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed from Day 1 and through Day 57 were similar to those observed at baseline, with no notable trends or differences between any of the treatment groups.
- The only notable difference by age cohorts was for treatment-related unsolicited TEAEs in the mRNA-1273 100 µg group, with a higher incidence in Cohort 1 (18.0%) than in Cohort 2 (9.0%). In addition, in Cohort 1, more participants in the mRNA-1273 100 µg group reported treatment-related unsolicited TEAEs than participants in the mRNA-1273 50 µg and placebo groups (18.0%, 7.0%, and 6.0%, respectively).

8 Immunogenicity Results

The results for the primary and secondary immunogenicity endpoints are presented through Day 57. The number of participants in the FAS and PP Sets did not differ by > 10% (Section 4.2.3); thus, supportive analyses of immunogenicity results based on the FAS were not required, as specified in the protocol.

8.1 SARS-CoV-2-Specific bAb

The baseline GM level of VAC58 spike IgG antibodies, as measured by ELISA specific to the SARS-CoV-2 spike protein, was approximately 6 µg/mL in each treatment group. The GMTs remained unchanged over time in the placebo group (Table 27).

Both mRNA-1273 doses induced increases in the levels of anti-SARS-CoV-2-spike IgG bAb from baseline by Day 29 (28 days after the first injection). Anti-SARS-CoV-2-spike IgG bAb levels peaked at Day 43 (14 days after the second injection) to GM level (95% CI) of 169.460 (156.251, 183.786) µg/mL in the mRNA-1273 50 µg group and 198.134 (182.865, 214.678) µg/mL in the mRNA-1273 100 µg group. Elevated levels of anti-SARS-CoV-2-spike IgG bAb persisted through Day 57 (28 days after the second injection) with GM levels (95% CI) of 123.892 (113.072, 135.748) µg/mL in the mRNA-1273 50 µg group and 147.415 (134.466, 161.612) µg/mL in the mRNA-1273 100 µg group (Table 27, Figure 4, and Figure 5).

The GMFRs (95% CI) trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (4.29 [3.87, 4.76] and 3.36 [3.05, 3.69], respectively), Day 43 (33.51 [30.37, 36.96] and 27.46 [24.86, 30.33], respectively) and Day 57 (25.04 [22.51, 27.86] and 20.39 [18.31, 22.70], respectively) (Table 27).

In Cohort 1, the GMFRs (95% CI) were generally higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (5.26 [4.57, 6.06] and 3.65 [3.20, 4.16], respectively), Day 43 (38.47 [34.54, 42.85] and 26.82 [23.46, 30.67], respectively), and Day 57 (29.13 [25.68, 33.03] and 20.70 [17.92, 23.90], respectively). No apparent trend was observed between the two mRNA-1273 doses in Cohort 2 (Table 14.2.1.1.1, Figure 6, and Figure 7).

The GM level of VAC58 NP IgG antibodies at each postbaseline visit was similar to baseline levels in each mRNA-1273 groups (baseline approximately 11 AU/mL), with a GMFR < 1 in all groups (Table 14.2.1.1.1 and Figure 14.2.3.1), indicating that the binding and neutralizing antibody results reflect an immunological response to the vaccine.

Analysis of VAC58 spike IgG using the ANCOVA model showed results of GM levels, GMFRs, and corresponding CIs consistent with those presented above ([Table 14.2.1.2.1](#)).

Sensitivity analysis of the bAb levels using an adjusted PP Set based on a more rigid visit window for Day 29 (-3/+7 window; detailed in [Section 4.2.3.1](#)) provided results similar to those for the unadjusted PP Set ([Table 14.2.1.1.3](#) and [Table 14.2.1.2.3](#)).

Table 27: Summary of Binding Antibody Levels (Per-Protocol Set for SARS-CoV-2-Specific bAb)

Timepoint Statistic	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Antibody: VAC58 spike IgG antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)				
Baseline				
n ^a	186	185	189	374
GM level	5.952	6.078	5.875	5.975
95% CI ^b	5.592, 6.335	5.646, 6.543	5.485, 6.293	5.682, 6.282
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 106.00	1.95, 106.00
Day 29				
n ^c	184	184	189	373
GM level	5.803	20.324	25.229	22.677
95% CI ^b	5.420, 6.213	18.601, 22.207	22.777, 27.944	21.179, 24.281
Median	5.900	20.200	25.600	22.000
Min, Max	1.95, 40.40	4.10, 106.50	4.30, 431.60	4.10, 431.60
GM fold-rise	0.98	3.36	4.29	3.80
95% CI ^b	0.95, 1.01	3.05, 3.69	3.87, 4.76	3.54, 4.08
Day 43				
n ^c	180	175	181	356
GM level	5.735	169.460	198.134	183.478
95% CI ^b	5.361, 6.135	156.251, 183.786	182.865, 214.678	173.252, 194.309
Median	5.900	186.300	204.300	197.550
Min, Max	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM fold-rise	0.97	27.46	33.51	30.38
95% CI ^b	0.95, 1.00	24.86, 30.33	30.37, 36.96	28.32, 32.59

Timepoint Statistic	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n ^c	175	176	177	353
GM level	5.861	123.892	147.415	135.176
95% CI ^b	5.461, 6.291	113.072, 135.748	134.466, 161.612	126.651, 144.275
Median	5.900	136.000	166.100	149.600
Min, Max	1.95, 62.50	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM fold-rise	0.98	20.39	25.04	22.60
95% CI ^b	0.94, 1.03	18.31, 22.70	22.51, 27.86	20.94, 24.39

Abbreviations: bAb=binding antibody; CI=confidence interval; GM=geometric mean; IgG=immunoglobulin G; LLOQ=lower limit of quantification;
Max=maximum; Min=minimum; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19;
ULOQ=upper limit of quantification.

Antibody values reported as below the LLOQ are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the ULOQ are converted to the ULOQ.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

^a Number of subjects with nonmissing baseline.

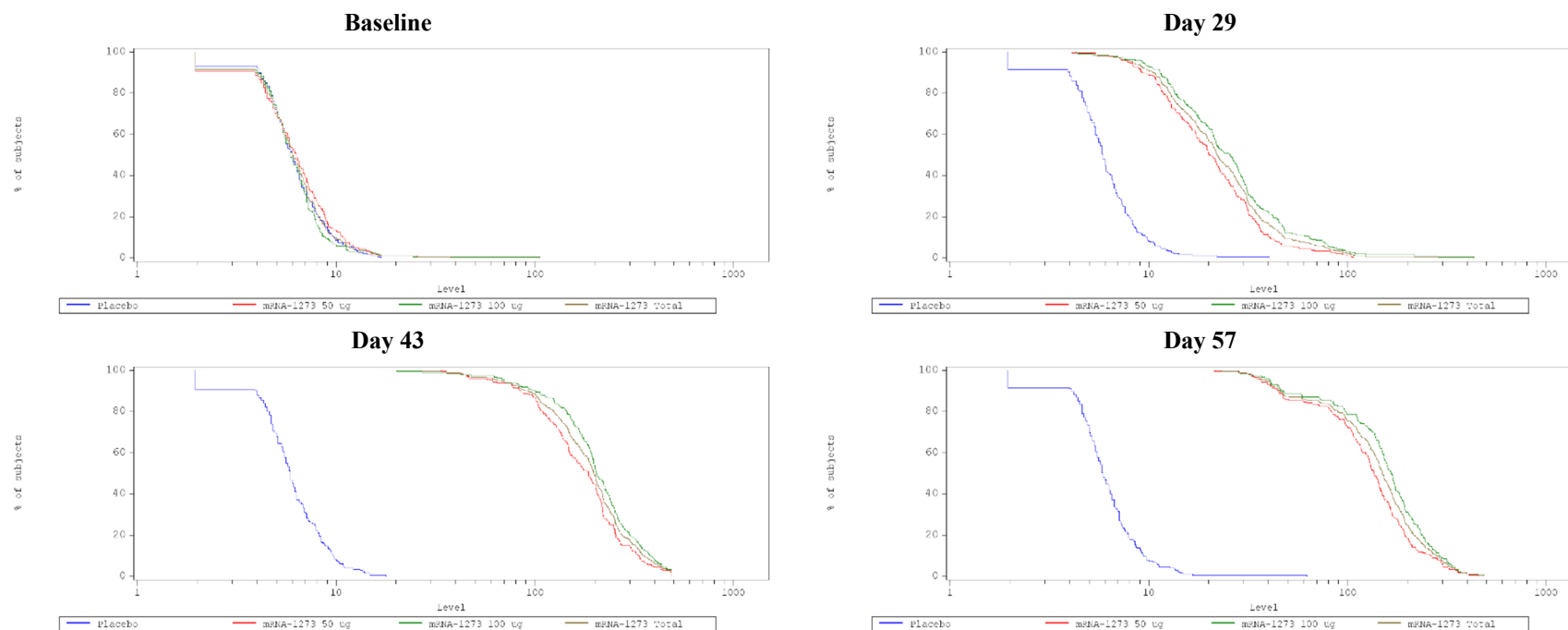
^b 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.

^c Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

Source: [Table 14.2.1.1.1.](#)

Figure 4: Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels (Per-Protocol Set for SARS-CoV-2-Specific bAb)

VAC58 Spike IgG Antibody (μg/mL) (LLOQ: 3.9, ULOQ: 487)



Abbreviations: bAb=binding antibody; IgG=immunoglobulin G; LLOQ=lower limit of quantification; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

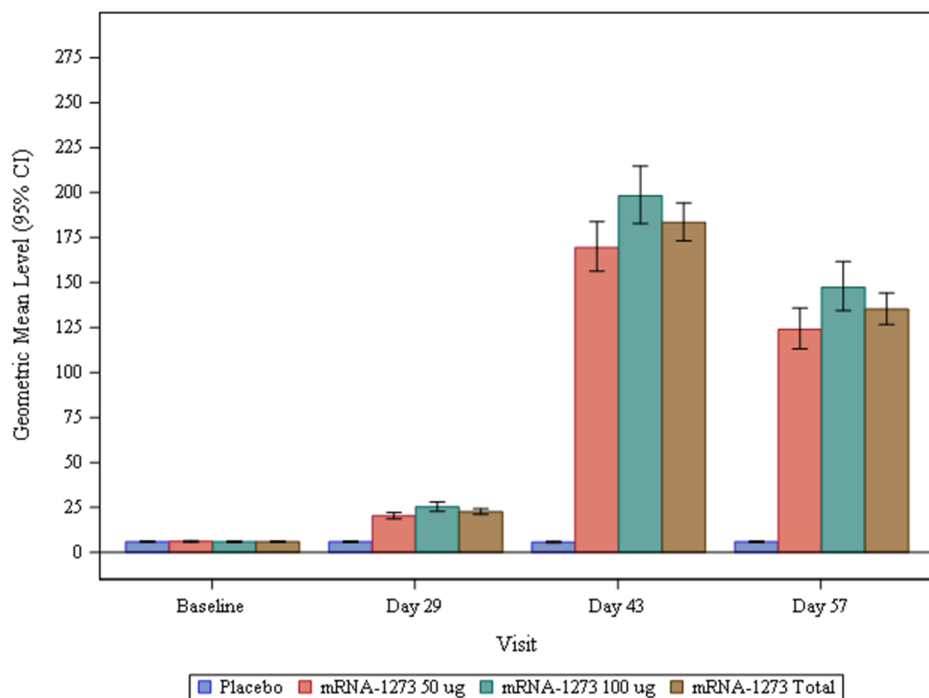
Note: Percentages were based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with nonmissing data at each visit.

Antibody values reported as below the LLOQ were replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the ULOQ were converted to the ULOQ.

Source: [Figure 14.2.3.1](#).

Figure 5: Geometric Mean Levels of Binding Antibody Immunogenicity Results (Per-Protocol Set for SARS-CoV-2-specific bAb)

VAC58 Spike IgG Antibody ($\mu\text{g/mL}$) (LLOQ: 3.9, ULOQ: 487)



Abbreviations: bAb=binding antibody; CI=confidence interval; IgG=immunoglobulin G; LLOQ=lower limit of quantification; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

Antibody values reported as below the LLOQ are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the ULOQ are converted to the ULOQ.

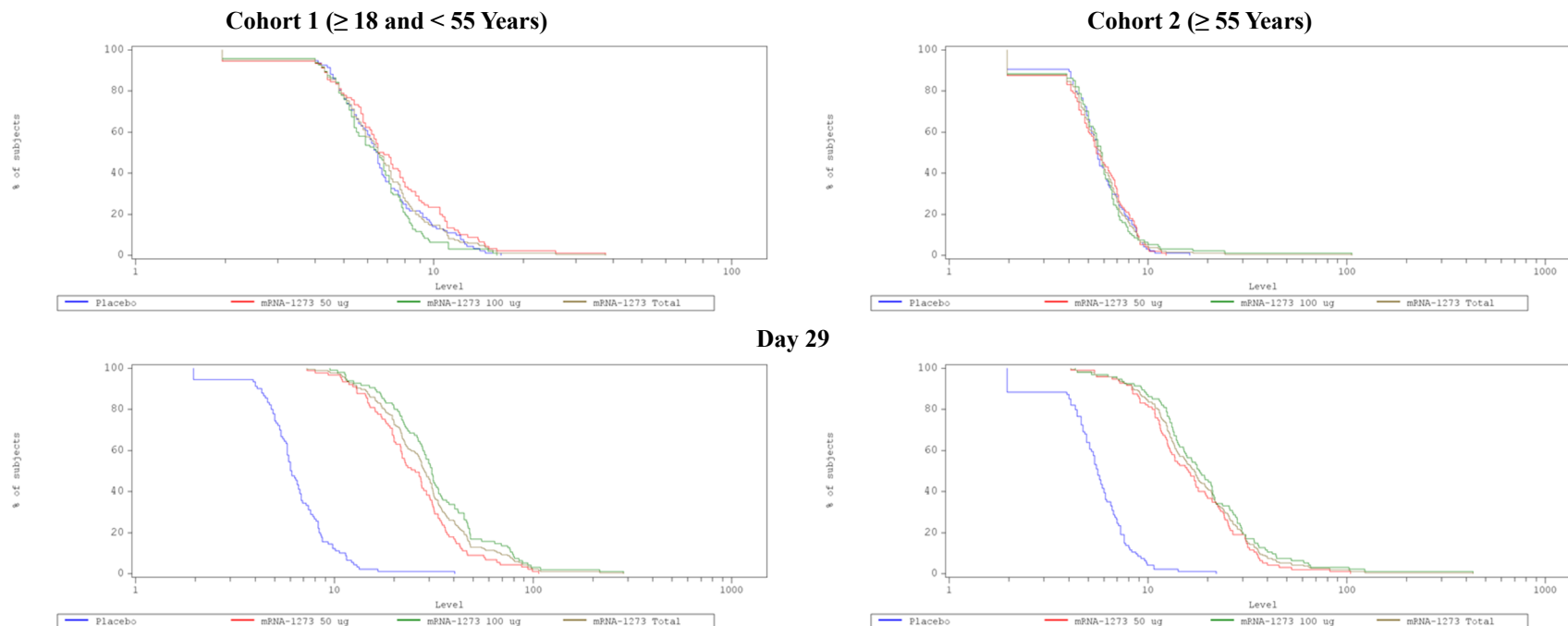
Confidence intervals are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

Source: [Figure 14.2.1.1.](#)

Figure 6: Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels by Age Cohort (Per-Protocol Set for SARS-CoV-2-specific bAb)

VAC58 Spike IgG Antibody ($\mu\text{g/mL}$) (LLOQ: 3.9, ULOQ: 487)

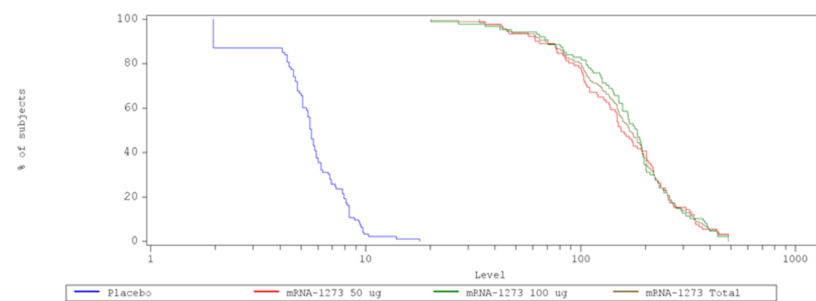
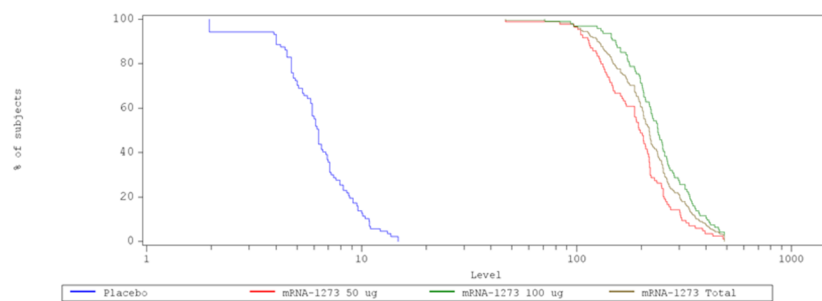
Baseline



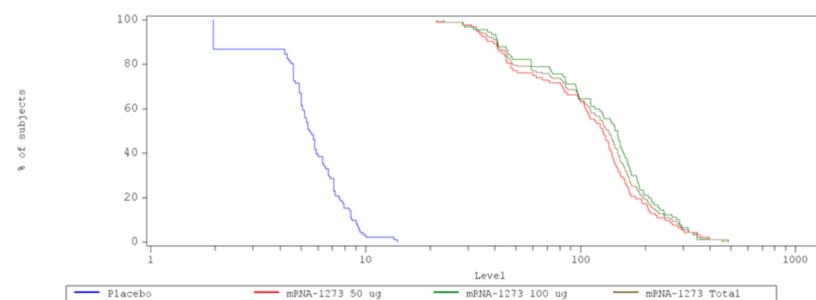
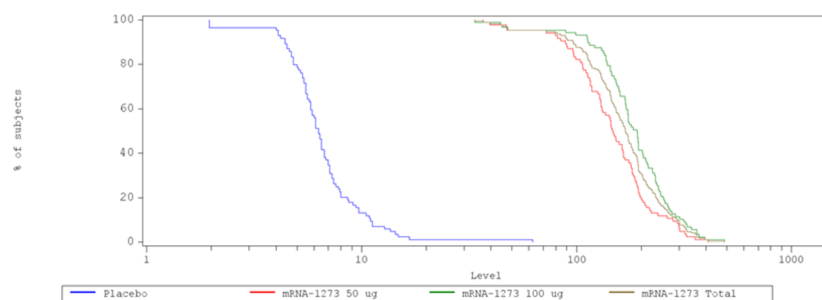
Cohort 1 (≥ 18 and < 55 Years)

Cohort 2 (≥ 55 Years)

Day 43



Day 57



Abbreviations: bAb=binding antibody; IgG=immunoglobulin G; LLOQ=lower limit of quantification; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

Note: Percentages were based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with nonmissing data at each visit.

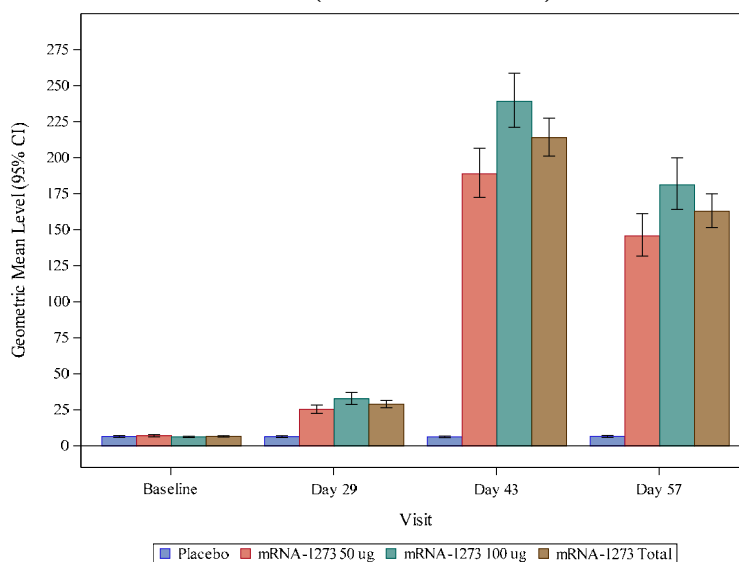
Antibody values reported as below the LLOQ were replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the ULOQ were converted to the ULOQ.

Source: [Figure 14.2.3.1](#).

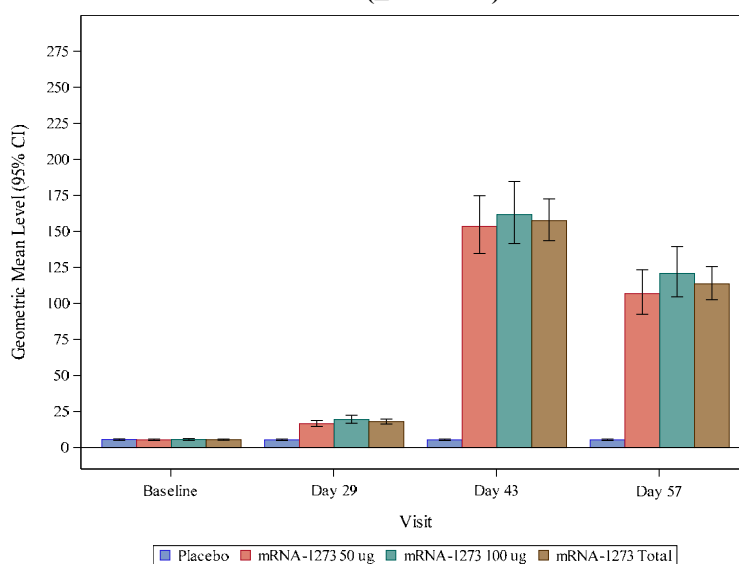
Figure 7: Geometric Mean Levels of Binding Antibody Immunogenicity Results by Age Cohort (Per-Protocol Set for SARS-CoV-2-Specific bAb)

VAC58 Spike IgG Antibody ($\mu\text{g/mL}$) (LLOQ: 3.9, ULOQ: 487)

Cohort 1 (≥ 18 and < 55 Years)



Cohort 2 (≥ 55 Years)



Abbreviations: bAb=binding antibody; CI=confidence interval; IgG=immunoglobulin G; LLOQ=lower limit of quantification; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

Antibody values reported as below the LLOQ are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the ULOQ are converted to the ULOQ.

Confidence intervals are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

Source: [Figure 14.2.1.1](#).

8.2 SARS-CoV-2-Specific nAb and Seroconversion

The titer for SARS-CoV-2-specific nAb and seroconversion after 2 doses of mRNA-1273 were the secondary immunogenicity endpoints ([Section 2](#)).

Unless otherwise indicated, SARS-CoV-2-specific nAb and seroconversion results are presented in this section for the primary analysis set, PP Set for SARS-CoV-2-specific nAb from the First Lot, as defined in [Section 5.2](#). Additionally, due to high assay repeat frequency, results are missing for 30 samples at the time of this report. Ideally, results from these samples should have been included in the primary analysis because they were collected before the Day 57 visit. However, the analysis laboratory was not able to provide these missing results because of required additional re-testing that could not be performed in time for inclusion in the primary analysis. Data from these 30 samples will be included in the EOS CSR.

Importantly, a large proportion of the serum samples at Day 43 and Day 57 had nAb titers that reached the assay's ULOQ (1280 for MN endpoint titer and 2031.87 for MN₅₀).

8.2.1 MN Endpoint Titer

The baseline GMT values for MN endpoint titer was approximately 20 in each treatment group ([Table 28](#)). The GMTs remained unchanged over time in the placebo group.

Both mRNA-1273 doses induced increases in MN endpoint titers from baseline by Day 29 (28 days after the first injection). The MN endpoint titers peaked at Day 43 (14 days after the second injection) to GMT (95% CI) of 1144.7 (1094.4, 1197.2) in the mRNA-1273 50 µg group and 1179.4 (1130.5, 1230.5) in the mRNA-1273 100 µg group. Elevated MN endpoint titers persisted through Day 57 (28 days after the second injection) with GMTs (95% CI) of 1091.0 (1035.5, 1149.5) in the mRNA-1273 50 µg group and 1095.8 (1038.8, 1155.9) in the mRNA-1273 100 µg group ([Table 28](#), [Figure 8](#), and [Figure 9](#)).

No apparent difference in GMFRs (95% CI) was observed between the mRNA-1273 50 µg group and the mRNA-100 µg group at Day 29 (5.59 [4.65, 6.71] and 7.46 [6.32, 8.81], respectively), Day 43 (56.23 [53.29, 59.34] and 58.97 [56.52, 61.52], respectively), and Day 57 (53.65 [50.54, 56.95] and 54.79 [51.94, 57.80], respectively) ([Table 28](#)).

In both mRNA-1273 50 µg and 100 µg groups, the GMT and GMFR of MN endpoint titer values at Day 29 were numerically higher in Cohort 1 than in Cohort 2, while no apparent difference was observed between Cohort 1 and Cohort 2 at Day 43 or Day 57 ([Table 14.2.2.1.1.1](#), [Figure 10](#) and [Figure 12](#)).

Based on the MN endpoint titers, the seroconversion rate was 78.0% (131/168 participants) in the mRNA-1273 50 µg group and 88.9% (160/180 participants) in the mRNA-1273 100 µg group at Day 29. At Day 43 and Day 57, seroconversion criteria were met for 100% of participants in both mRNA-1273 dose groups ([Table 28](#)).

8.2.2 MN₅₀ Titer

The baseline GMT values for MN₅₀ antibody titer was approximately 46 in each treatment group. The GMTs remained unchanged over time in the placebo group ([Table 28](#)).

Both mRNA-1273 doses induced increases in MN₅₀ from baseline by Day 29 (28 days after the first injection). The MN₅₀ peaked at Day 43 (14 days after the second injection) to GMTs (95% CI) of 1774.345 (1691.196, 1861.582) in the mRNA-1273 50 µg group and 1813.420 (1730.358, 1900.471) in the mRNA-1273 100 µg group. Elevated MN₅₀ titers persisted through Day 57 (28 days after the second injection) with GMTs (95% CI) of 1639.612 (1550.751, 1733.564) in the mRNA-1273 50 µg group and 1655.087 (1563.172, 1752.405) in the mRNA-1273 100 µg group ([Table 28](#), [Figure 8](#), and [Figure 9](#)).

No apparent difference in GMFRs (95% CI) was observed between the mRNA-1273 50 µg group and the mRNA-100 µg group at Day 29 (3.75 [3.16, 4.45] and 4.97 [4.23, 5.85], respectively), Day 43 (38.59 [36.68, 40.60] and 39.81 [37.99, 41.72], respectively), and Day 57 (35.68 [33.67, 37.81] and 36.34 [4.32, 38.47], respectively) ([Table 28](#)).

In both mRNA-1273 dose groups, the GMT and GMFR of MN₅₀ titer values at Day 29 were numerically higher in Cohort 1 than in Cohort 2, while no apparent difference was observed between Cohort 1 and Cohort 2 on Day 43 and Day 57 ([Table 14.2.2.1.1.1](#), [Figure 11](#), and [Figure 12](#)).

Based on the MN₅₀ titers, the seroconversion rates were 65.5% (110/168 participants) in the mRNA-1273 50 µg group and 76.7% (138/180 participants) in the mRNA-1273 100 µg group at Day 29. At Day 43 and Day 57, seroconversion criteria were met for 100% of participants in both mRNA-1273 dose groups ([Table 28](#)).

8.2.3 Additional and Supportive Analyses

Analysis of nAb and seroconversion using the ANCOVA model showed results of GMTs, GMFRs, and corresponding CIs consistent with those presented in [Section 8.2.1](#) and [Section 8.2.2](#) ([Table 14.2.2.1.1](#)).

Sensitivity analysis of the MN endpoint and MN₅₀ titers using an adjusted PP Set based on a more rigid visit window for Day 29 (-3/+7 window; detailed in [Section 4.2.3.1](#)) demonstrated results similar to those for the unadjusted primary analysis PP Set ([Table 14.2.2.1.1.1](#) and [Table 14.2.2.1.3.1](#)).

Although numerical differences were observed between the SARS-CoV-2-specific nAb titer results for the PP Set for SARS-CoV-2-specific nAb from the All Lot and from the First Lot, the results were similar between the analysis sets ([Table 14.2.2.1.1.1](#), [Table 14.2.2.1.1.2](#), [Table 14.2.2.2.1.1](#), and [Table 14.2.2.2.1.2](#)).

Table 28: Summary of Neutralizing Antibody Titers (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)

Timepoint Data Category Statistic	mRNA-1273			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Antibody: MN endpoint titer				
Baseline				
n ^a	181	179	186	365
GMT	20.0	20.3	20.0	20.1
95% CI ^b	NE, NE	19.9, 20.7	NE, NE	19.9, 20.3
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120
Day 29				
n ^c	178	168	180	348
GMT	21.0	113.4	149.3	130.8
95% CI ^b	19.7, 22.3	94.6, 136.0	126.5, 176.2	115.6, 147.9
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.05	5.59	7.46	6.49
95% CI ^b	0.99, 1.11	4.65, 6.71	6.32, 8.81	5.74, 7.34
Seroconversion^d				
n ^e (%)	3 (1.7)	131 (78.0)	160 (88.9)	291 (83.6)
95% CI ^f	0.3, 4.8	70.9, 84.0	83.4, 93.1	79.3, 87.4
>=2-fold increase from baseline^g				
n ^e (%)	3 (1.7)	132 (78.6)	160 (88.9)	292 (83.9)
95% CI ^f	0.3, 4.8	71.6, 84.5	83.4, 93.1	79.6, 87.6
>=3-fold increase from baseline^g				
n ^e (%)	2 (1.1)	119 (70.8)	146 (81.1)	265 (76.1)
95% CI ^f	0.1, 4.0	63.3, 77.6	74.6, 86.5	71.3, 80.5
>=4-fold increase from baseline^g				
n ^e (%)	2 (1.1)	110 (65.5)	130 (72.2)	240 (69.0)
95% CI ^f	0.1, 4.0	57.8, 72.6	65.1, 78.6	63.8, 73.8

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Timepoint Data Category Statistic	mRNA-1273			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 43				
n ^c	175	141	150	291
GMT	20.4	1144.7	1179.4	1162.4
95% CI ^b	19.6, 21.4	1094.4, 1197.2	1130.5, 1230.5	1127.3, 1198.7
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR	1.02	56.23	58.97	57.63
95% CI ^b	0.98, 1.07	53.29, 59.34	56.52, 61.52	55.71, 59.62
Seroconversion ^d				
n ^c (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold increase from baseline ^g				
n ^c (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold increase from baseline ^g				
n ^c (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold increase from baseline ^g				
n ^c (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
Day 57				
n ^c	171	150	152	302
GMT	21.2	1091.0	1095.8	1093.4
95% CI ^b	19.8, 22.6	1035.5, 1149.5	1038.8, 1155.9	1053.5, 1134.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR	1.06	53.65	54.79	54.22
95% CI ^b	0.99, 1.13	50.54, 56.95	51.94, 57.80	52.11, 56.42

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Timepoint Data Category Statistic	mRNA-1273			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Seroconversion ^d				
n ^e (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold increase from baseline ^g				
n ^e (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold increase from baseline ^g				
n ^e (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold increase from baseline ^g				
n ^e (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
Antibody: MN50				
Baseline				
n ^a	181	179	186	365
GMT	45.550	45.886	45.550	45.714
95% CI ^b	NE, NE	45.225, 46.556	NE, NE	45.392, 46.040
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71
Day 29				
n ^c	178	168	180	348
GMT	47.321	172.202	226.487	198.423
95% CI ^b	44.875, 49.900	145.249, 204.156	192.585, 266.358	176.386, 223.214
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.75	4.97	4.34
95% CI ^b	0.99, 1.10	3.16, 4.45	4.23, 5.85	3.86, 4.88
Seroconversion ^d				
n ^e (%)	2 (1.1)	110 (65.5)	138 (76.7)	248 (71.3)
95% CI ^f	0.1, 4.0	57.8, 72.6	69.8, 82.6	66.2, 76.0

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Timepoint Data Category Statistic	mRNA-1273			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
>=2-fold increase from baseline ^g				
n ^e (%)	2 (1.1)	110 (65.5)	138 (76.7)	248 (71.3)
95% CI ^f	0.1, 4.0	57.8, 72.6	69.8, 82.6	66.2, 76.0
>=3-fold increase from baseline ^g				
n ^e (%)	2 (1.1)	98 (58.3)	127 (70.6)	225 (64.7)
95% CI ^f	0.1, 4.0	50.5, 65.9	63.3, 77.1	59.4, 69.7
>=4-fold increase from baseline ^g				
n ^e (%)	2 (1.1)	84 (50.0)	106 (58.9)	190 (54.6)
95% CI ^f	0.1, 4.0	42.2, 57.8	51.3, 66.2	49.2, 59.9
Day 43				
n ^e	175	141	150	291
GMT	46.442	1774.345	1813.420	1794.381
95% CI ^b	44.698, 48.255	1691.196, 1861.582	1730.358, 1900.471	1735.500, 1855.259
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.02	38.59	39.81	39.22
95% CI ^b	0.98, 1.06	36.68, 40.60	37.99, 41.72	37.89, 40.58
Seroconversion ^d				
n ^e (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold increase from baseline ^g				
n ^e (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold increase from baseline ^g				
n ^e (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold increase from baseline ^g				
n ^e (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI ^f	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0

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Timepoint Data Category Statistic	mRNA-1273			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 57				
n ^c	171	150	152	302
GMT	47.808	1639.612	1655.087	1647.382
95% CI ^b	45.240, 50.522	1550.751, 1733.564	1563.172, 1752.405	1583.283, 1714.076
Median	45.550	1810.193	2031.870	1810.193
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.05	35.68	36.34	36.01
95% CI ^b	0.99, 1.11	33.67, 37.81	34.32, 38.47	34.58, 37.50
Seroconversion ^d				
n ^c (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold increase from baseline ^g				
n ^c (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold increase from baseline ^g				
n ^c (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold increase from baseline ^g				
n ^c (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI ^f	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0

Abbreviations: CI=confidence interval; GMFR=geometric mean fold-rise (postbaseline vs baseline titers); GMT=geometric mean titer; LLOQ=lower limit of quantification; Max=maximum; Min=minimum; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

Antibody values reported as below the LLOQ are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the ULOQ are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit (n^c).

^a Number of subjects with nonmissing baseline.

^b 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

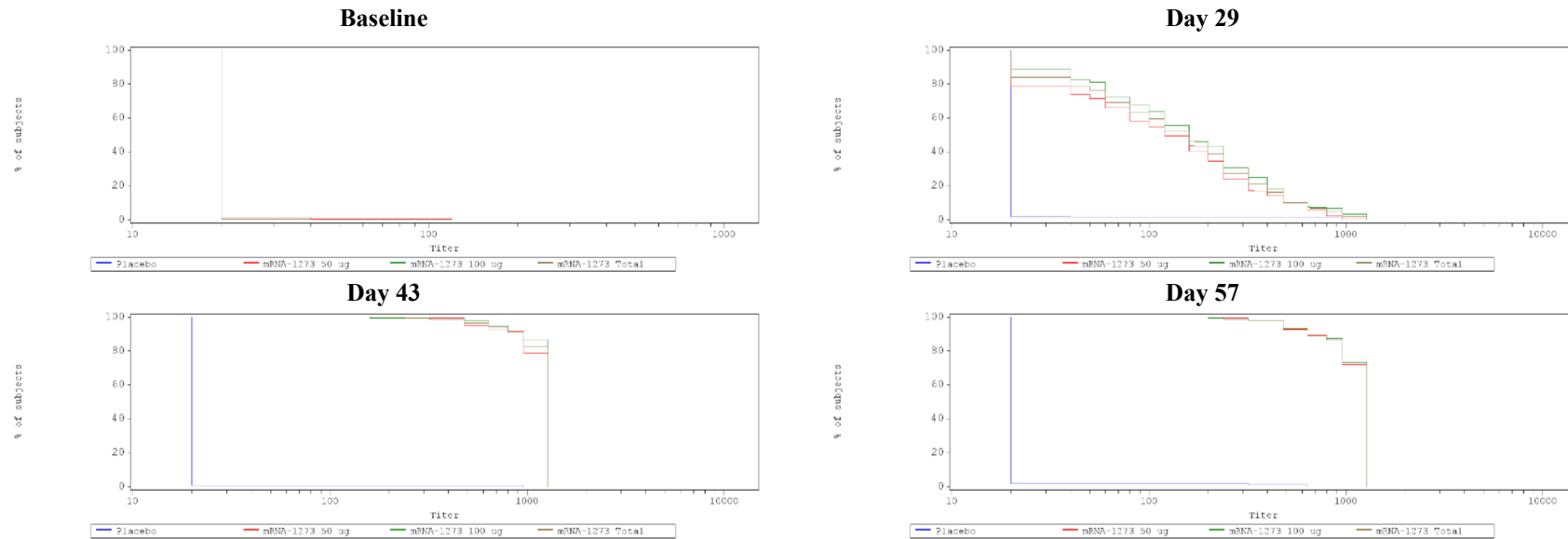
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- ^c Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.
- ^d Seroconversion at participant level is defined as a change of nAb titer from below the LLOQ to equal to or above LLOQ, or a 4-times or higher ratio in participants with pre-existing nAb titers.
- ^e Number of subjects in the corresponding category at the corresponding time point.
- ^f 95% CI is calculated using the Clopper-Pearson method.
- ^g $\geq$ z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

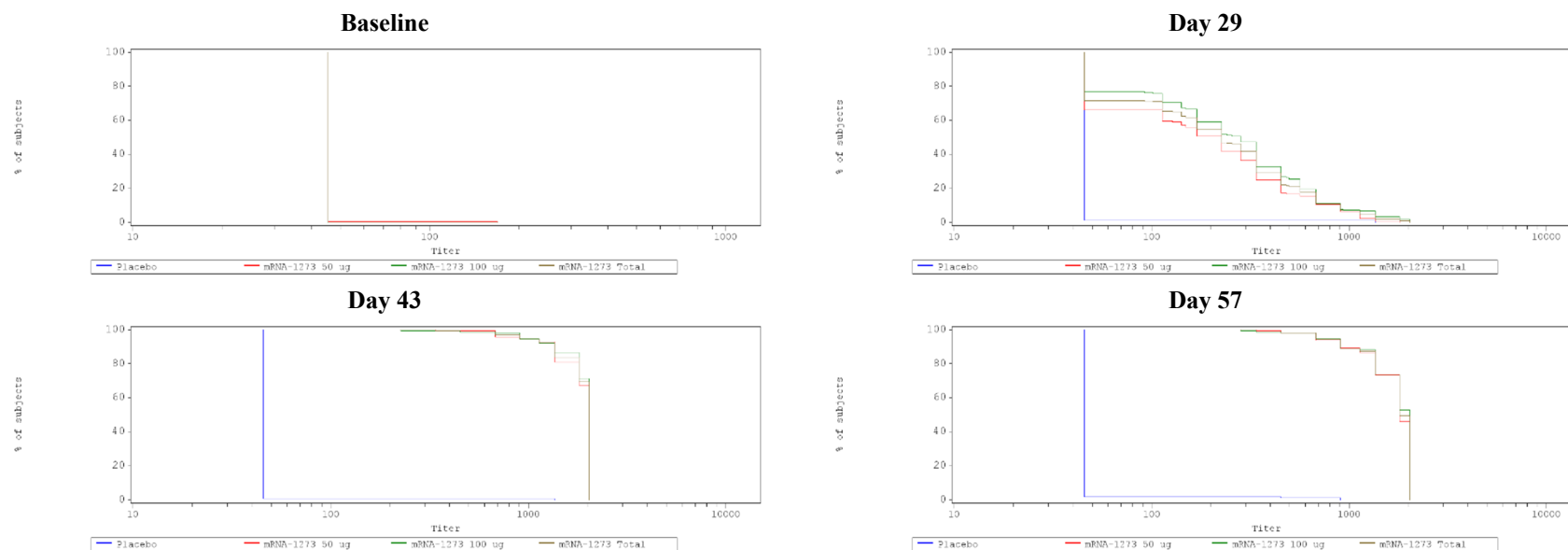
Source: [Table 14.2.2.1.1.1.](#)

Figure 8: Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)

Antibody: MN Endpoint Titer



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Antibody: MN₅₀

Abbreviations: MN=microneutralization; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

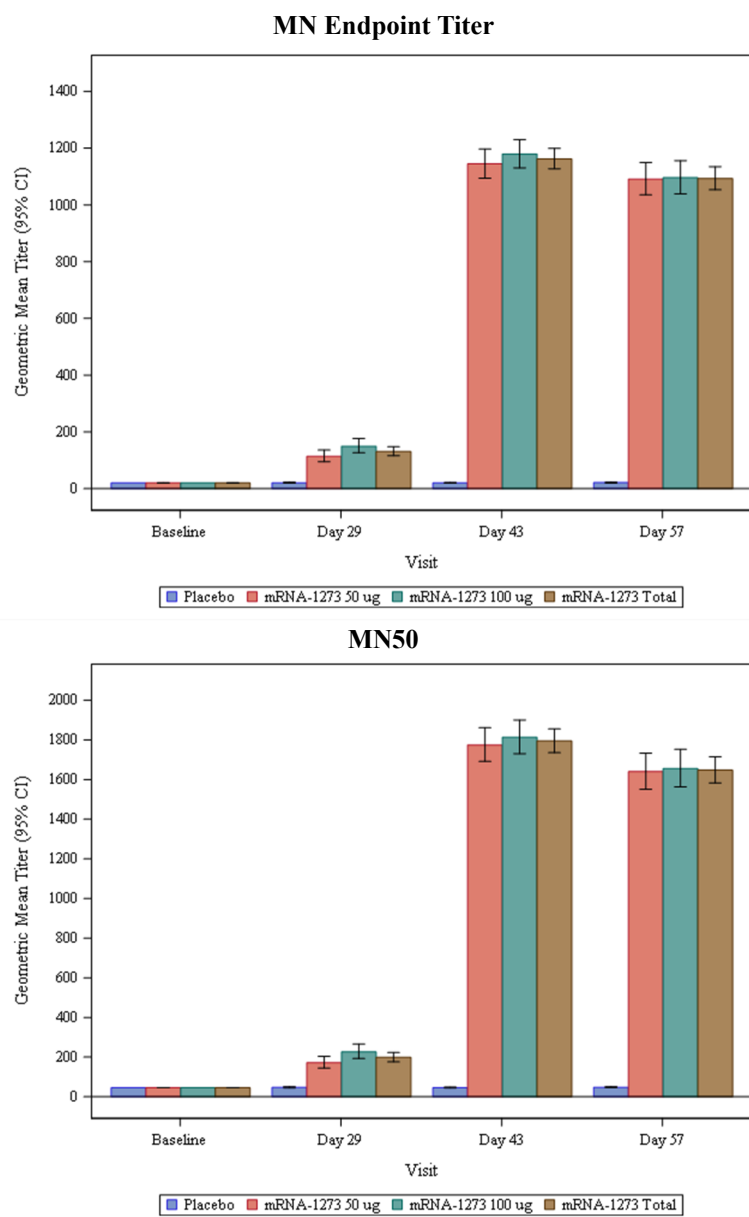
Note: Percentages were based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with nonmissing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the upper limit of quantification (ULOQ) were converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

Source: [Figure 14.2.6.1.1](#).

Figure 9: Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)



Abbreviations: CI=confidence interval; MN=microneutralization; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

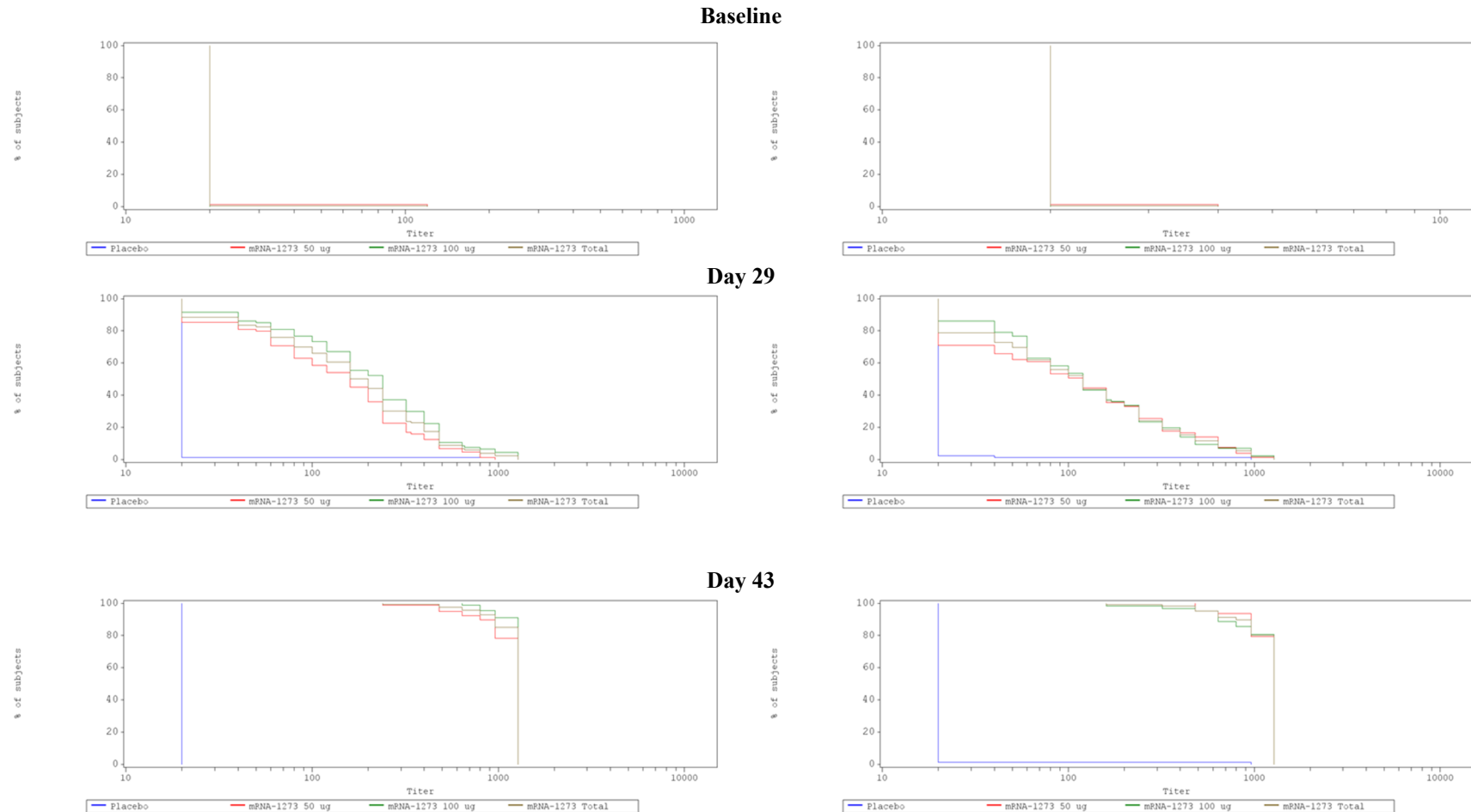
Source: [Figure 14.2.4.1.1.](#)

Figure 10: Reverse Cumulative Distribution Function of MN Endpoint Titer Results by Age Cohort (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)

Antibody: MN Endpoint Titer

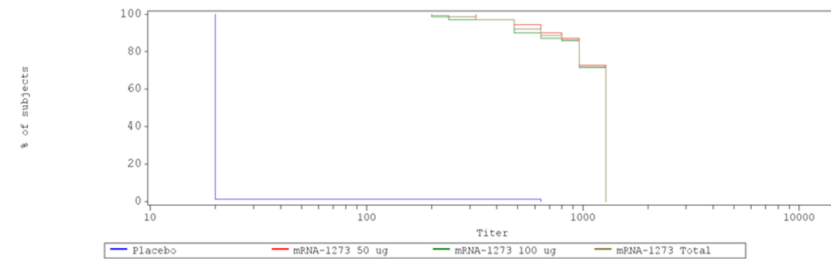
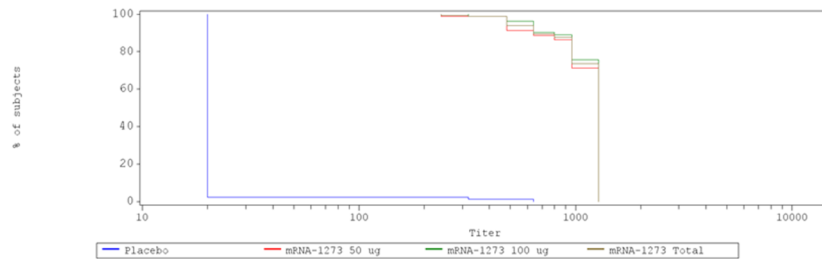
Cohort 1 (≥ 18 and < 55 Years)

Cohort 2 (≥ 55 Years)



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Day 57



Abbreviations: MN=microneutralization; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

Note: Percentages were based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with nonmissing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the upper limit of quantification (ULOQ) were converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280.

Source: [Figure 14.2.6.1.1.](#)

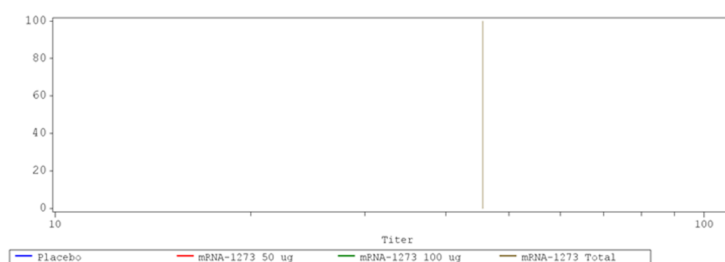
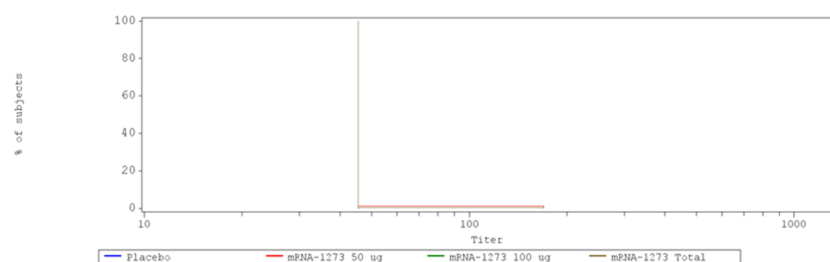
Figure 11: Reverse Cumulative Distribution Function of MN₅₀ Antibody Titer Results by Age Cohort (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)

Antibody: MN50

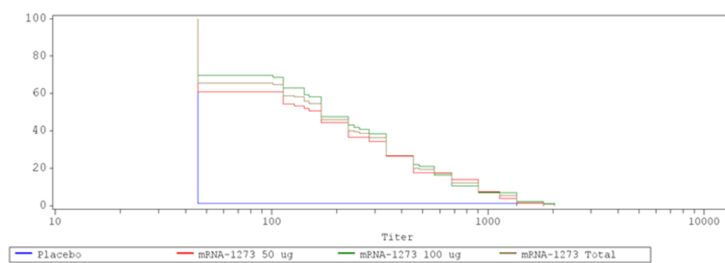
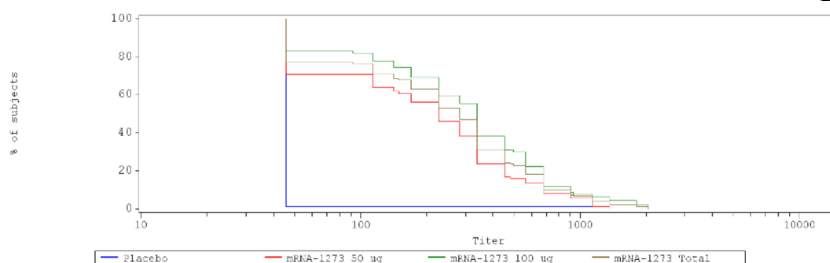
Cohort 1 (≥ 18 and < 55 Years)

Cohort 2 (≥ 55 Years)

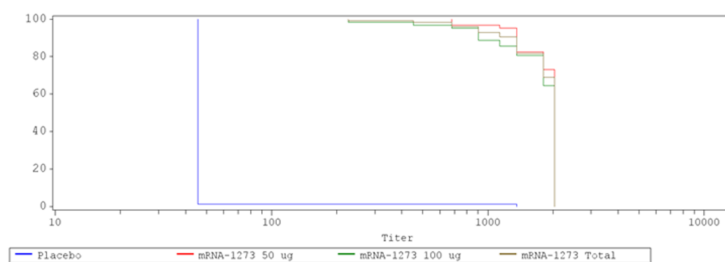
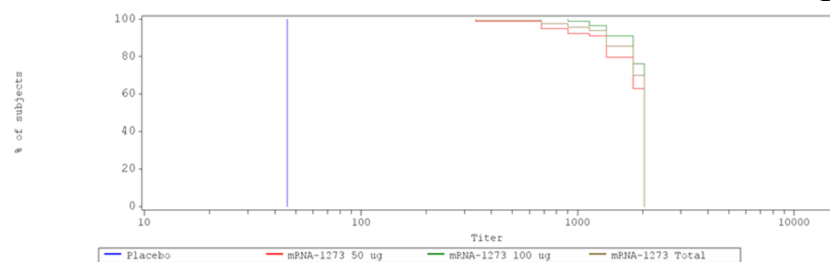
Baseline



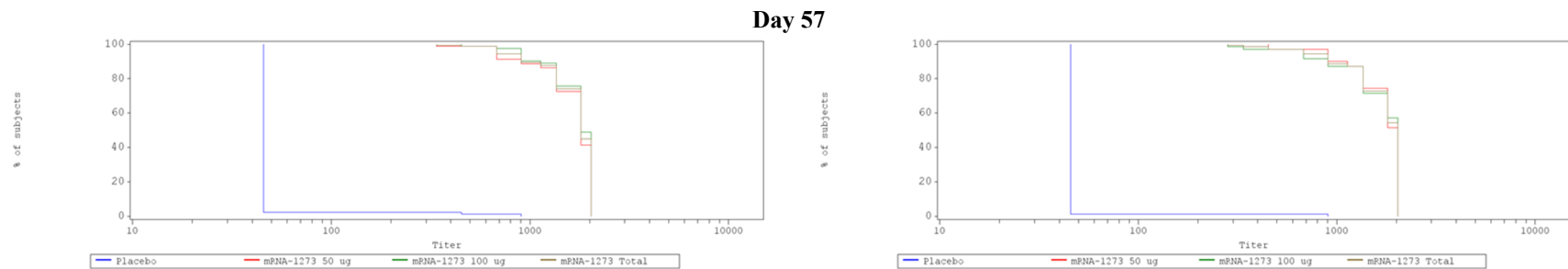
Day 29



Day 43



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Abbreviations: MN=microneutralization; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

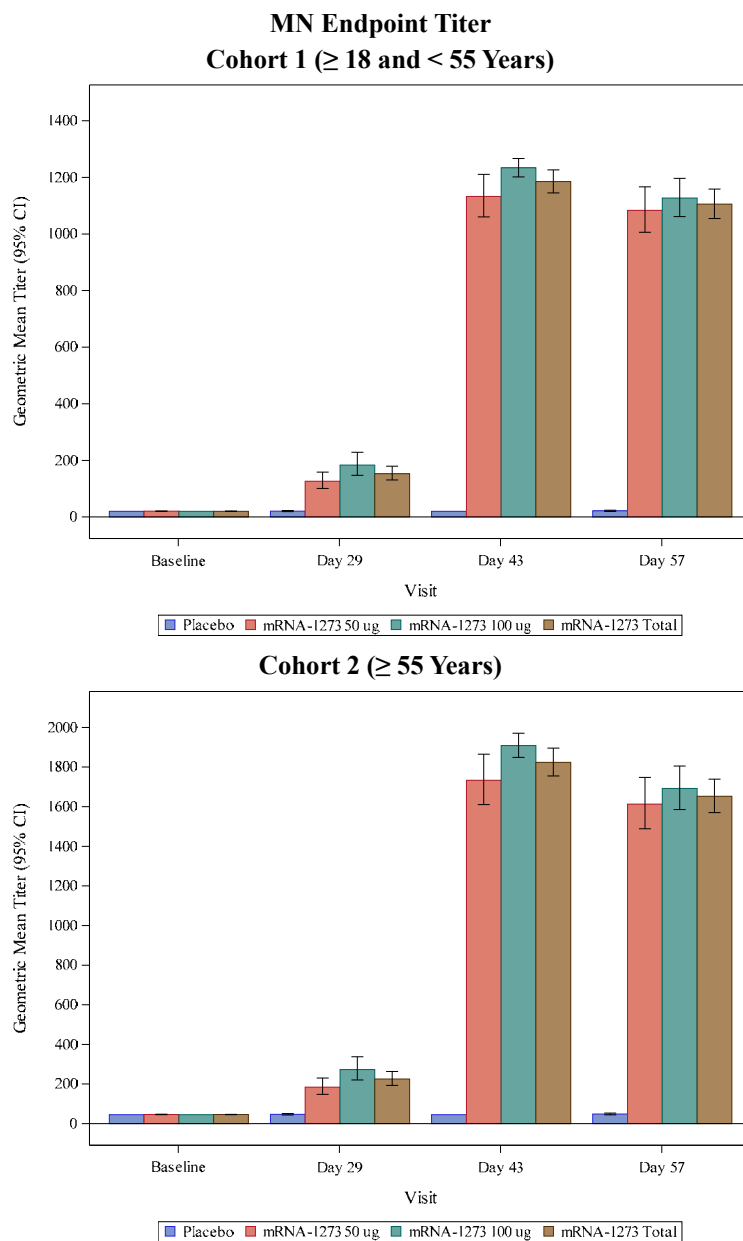
Note: Percentages were based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with nonmissing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that were greater than the upper limit of quantification (ULOQ) were converted to the ULOQ.

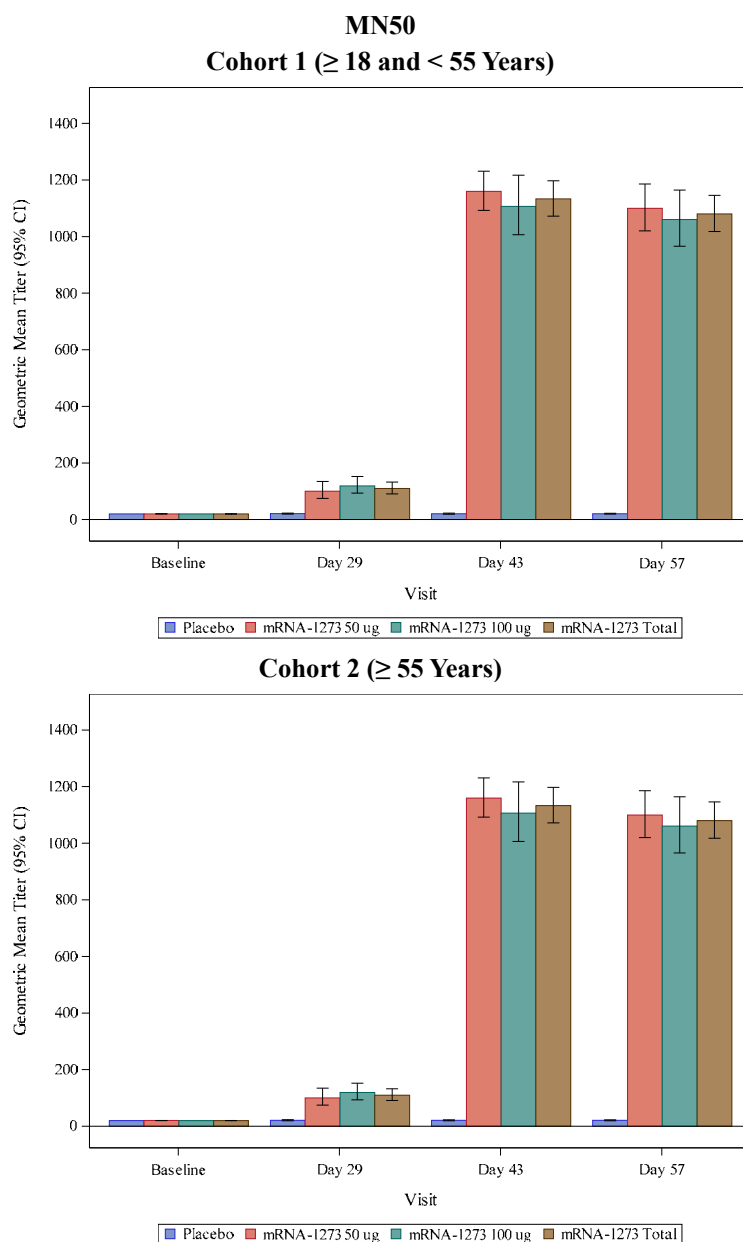
For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

Source: [Figure 14.2.6.1.1](#).

Figure 12: Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results by Age Cohorts (Per-Protocol Set for SARS-CoV-2-Specific nAb From First Lot)



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Abbreviations: CI=confidence interval; MN=microneutralization; nAb=neutralizing antibody; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

Source: [Figure 14.2.4.1.1.](#)

8.3 Other Immunogenicity Results

8.3.1 Serum bAb and nAb for Participants With SARS-CoV-2 Infection or COVID-19

A total of 7 participants (5 participants in the placebo group and 2 participants in the mRNA-1273 50 µg group) had SARS-CoV-2 infection confirmed by a positive RT-PCR test result ([Listing 16.2.6.3](#)) or a positive COVID-19 local diagnostic test result ([Listing 16.2.6.6](#)). Notably, 1 participant in the mRNA-1273 50 µg group was positive for COVID-19 at Day 10, before the second injection.

Of the 7 participants with confirmed SARS-CoV-2 infection, 3 participants were symptomatic (2 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group) and 4 participants remained asymptomatic (3 participants in the placebo group and 1 participant in the mRNA-1273 50 µg group). No participants in the mRNA-1273 100 µg group had SARS-CoV-2 infection confirmed by a positive RT-PCR test result or a positive COVID-19 local diagnostic test result ([Table 29](#)).

Of the 7 participants with confirmed SARS-CoV-2 infection, 1 participant (placebo group) had an increase in postbaseline VAC58 NP IgG antibody levels greater than 4 times the antibody level at baseline (4.5 AU/mL at Day 1 [baseline] and 241.6 AU/mL at Day 57); 5 participants (3 participants in the placebo group and 2 participants in the mRNA-1273 50 µg group) did not have a ratio of postbaseline/baseline VAC58 NP IgG antibody levels ≥ 4 ([Listing 16.2.6.1.1](#)). Postbaseline VAC58 NP IgG antibody levels were not available for 1 of the 7 participants with confirmed SARS-CoV-2 infection. The levels of bAb to SARS-CoV-2 spike and nAb for 6 of the 7 participants with confirmed SARS-CoV-2 infection are presented graphically in [Figure 13](#) and [Figure 14](#), respectively. Results were not included for the participant in the placebo group with SARS-CoV-2 detected by RT-PCR at Day 29 because antibody levels and titers were only available for Day 1 ([Listing 16.2.6.1.2](#) and [Listing 16.2.6.2.2](#)).

Overall, antibody responses elicited by mRNA-1273 vaccination were not impaired in participants with SARS-CoV-2 infection or COVID-19. ([Figure 13](#) and [Figure 14](#)).

Table 29: Summary of SARS-CoV-2 Test by RT-PCR (Safety Set)

	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Overall ^a				
n ^b	200 (100)	200 (100)	200 (100)	400 (100)
Detected	4 (2.0)	1 (0.5)	0	1 (0.3)
Not detected	196 (98.0)	199 (99.5)	200 (100)	399 (99.8)
Baseline				
n ^b	199 (99.5)	200 (100)	200 (100)	400 (100)
Detected	0	0	0	0
Not detected	199 (99.5)	200 (100)	200 (100)	400 (100)
Day 29				
n ^b	196 (98.0)	193 (96.5)	199 (99.5)	392 (98.0)
Detected	2 (1.0)	0	0	0
Not detected	194 (97.0)	193 (96.5)	199 (99.5)	392 (98.0)
Day 57				
n ^b	195 (97.5)	193 (96.5)	199 (99.5)	392 (98.0)
Detected	2 (1.0)	1 (0.5)	0	1 (0.3)
Not detected	193 (96.5)	192 (96.0)	199 (99.5)	391 (97.8)

Abbreviations: RT-PCR=reverse transcription polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

This table is based on SARS-CoV-2 test performed by Viracor lab. Percentages are based on the number of safety subjects.

^a Subjects are counted under Detected if the subjects have at least one result reported as Detected at any visit.

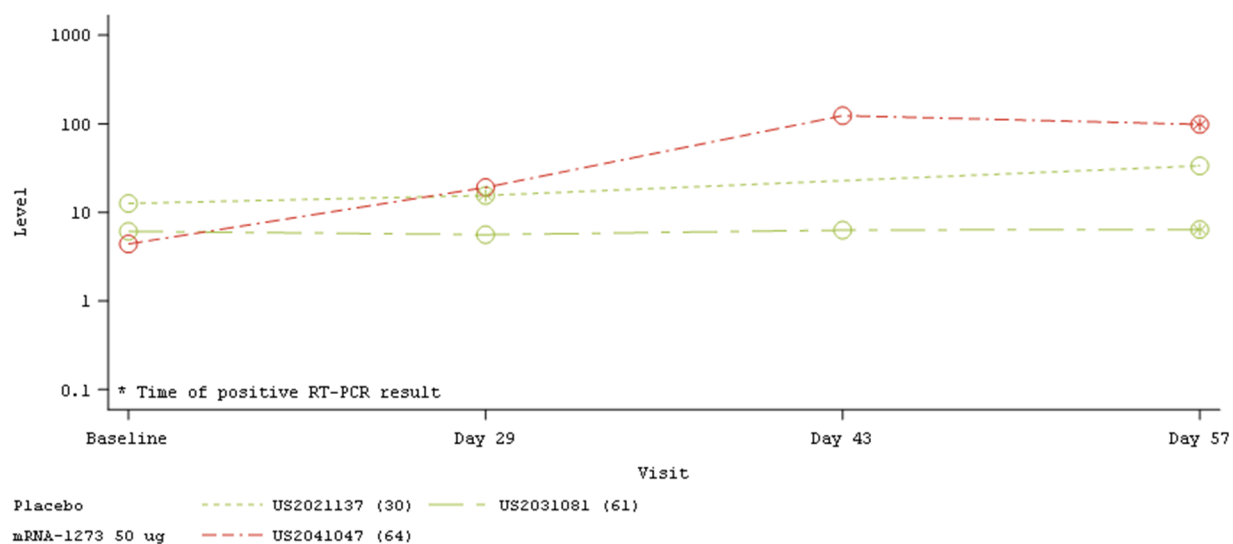
^b Number of subjects provided RT-PCR sample.

Source: [Table 14.2.3.1.](#)

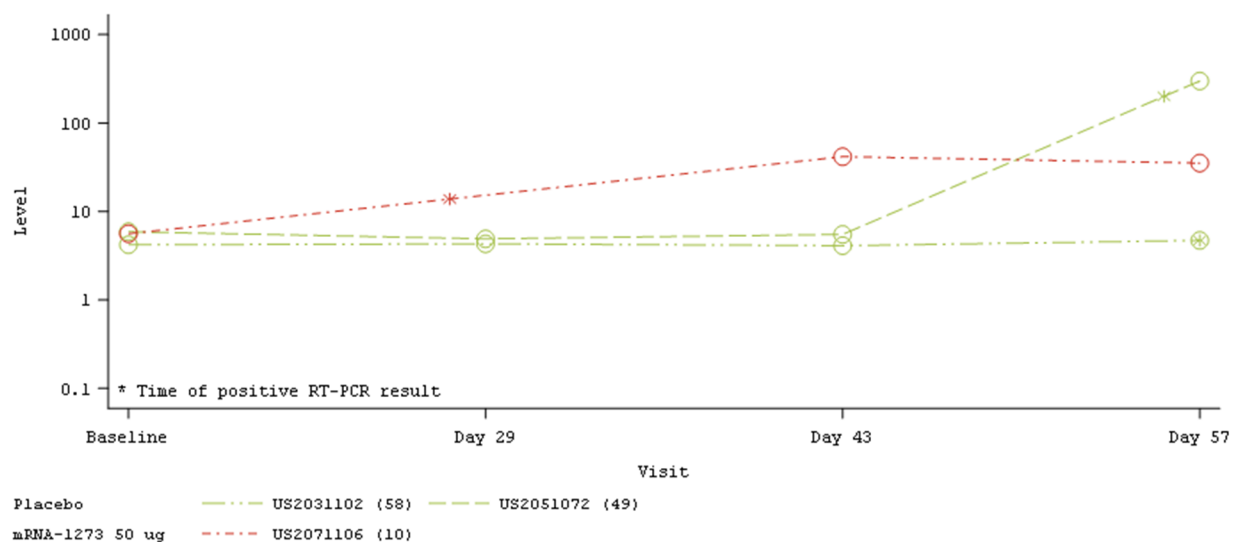
Figure 13: Individual VAC58 Spike IgG Antibody Levels Over Time for Participants With A Positive RT-PCR Swab (Full Analysis Set for SARS-CoV-2-Specific bAb)

Antibody: VAC58 Spike IgG Antibody (µg/mL) (LLOQ: 3.9, ULOQ: 487)

Cohort 1 (Age ≥ 18 and < 55 Years)



Cohort 2 (Age ≥ 55 Years)

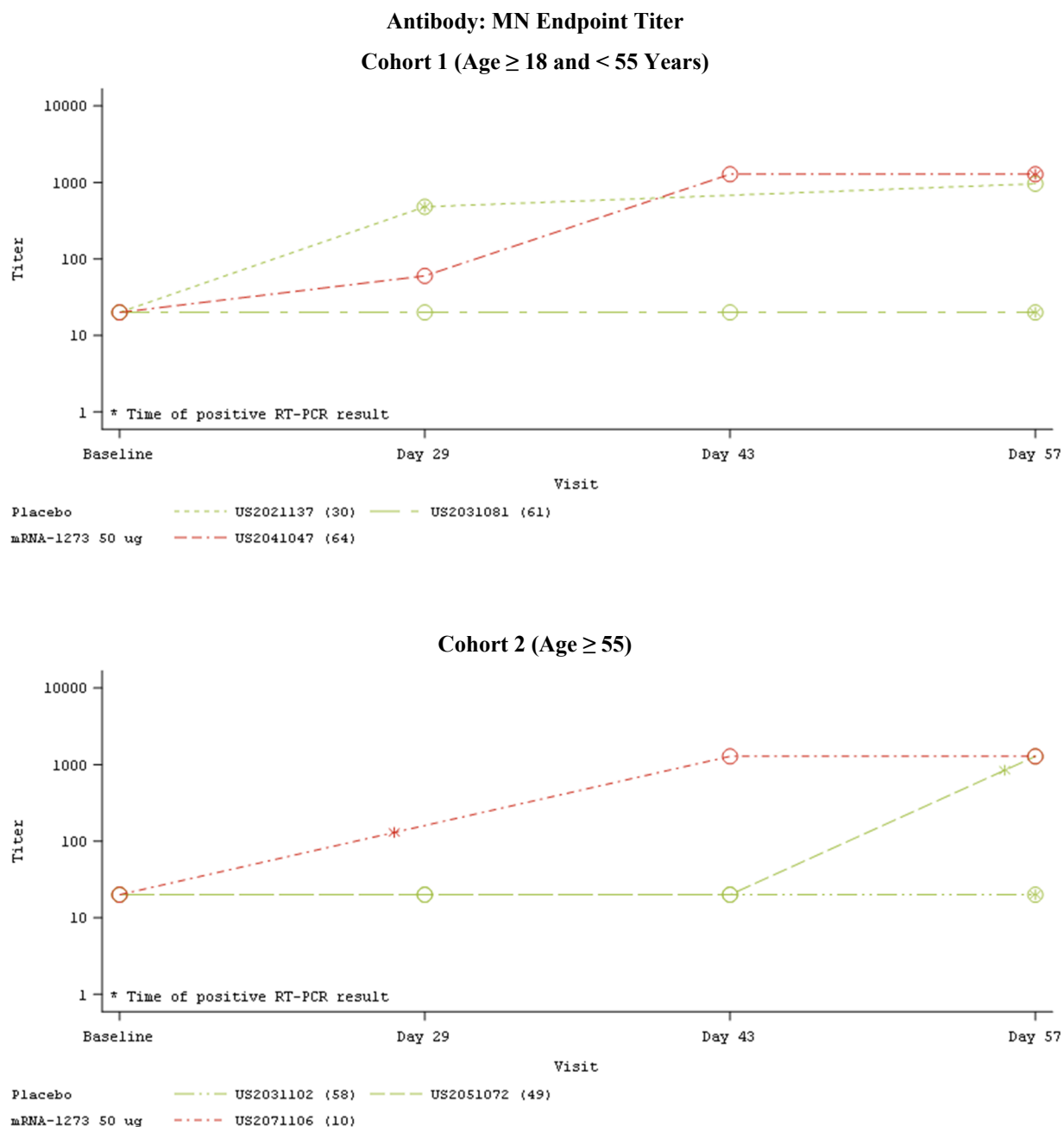


Abbreviations: bAb=binding antibody; COVID-19=coronavirus disease 2019; IgG=immunoglobulin G; LLOQ=lower limit of quantification; RT-PCR=reverse transcription polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19; ULOQ=upper limit of quantification.

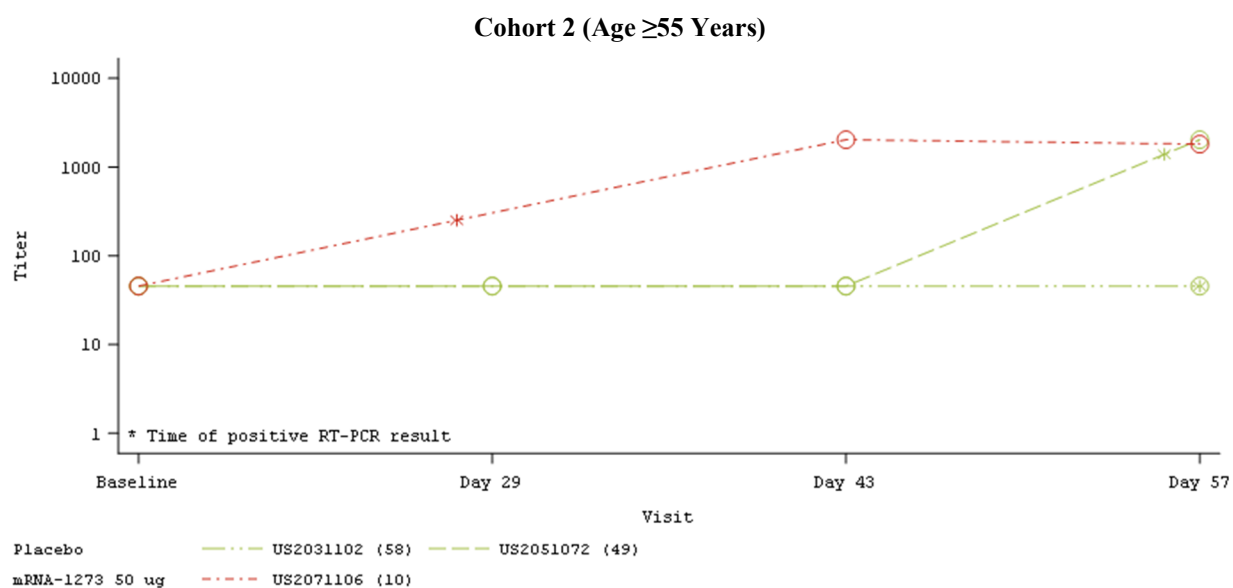
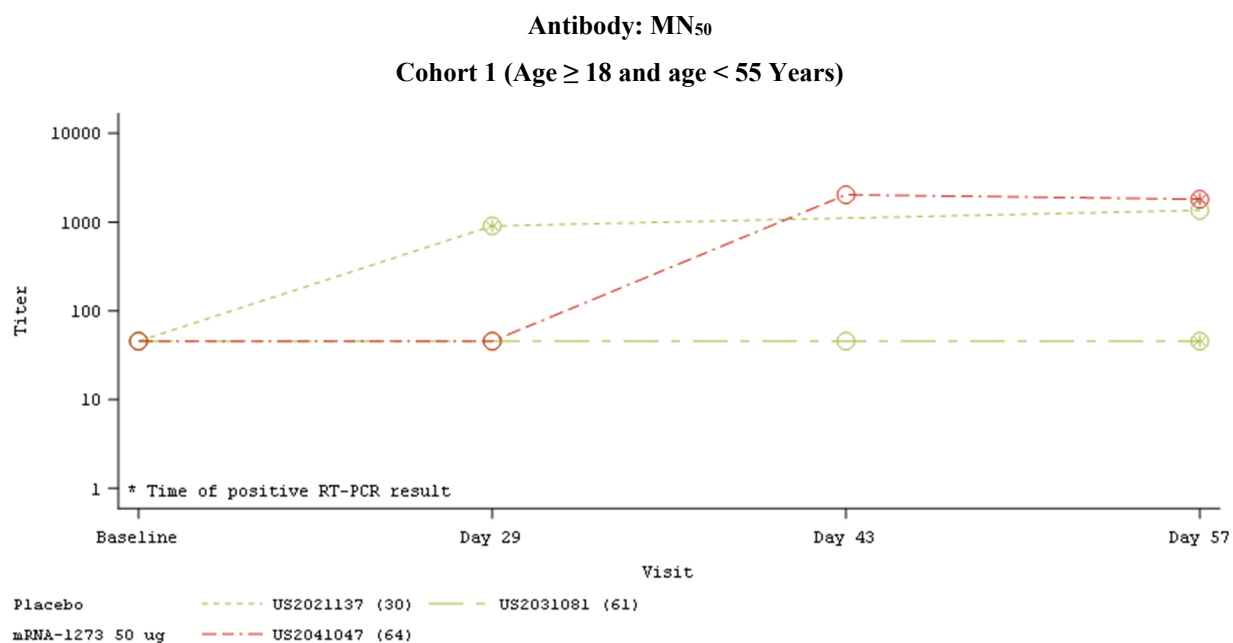
Antibody values reported as below the LLOQ are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification ULOQ are converted to the ULOQ.

Source: [Figure 14.2.7.1.](#)

Figure 14: Individual MN Endpoint Titers and MN₅₀ Titers Over Time for Participants With A Positive RT-PCR Swab (Full Analysis Set for SARS-CoV-2-Specific nAb from the First Lot)



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Abbreviations: COVID-19=coronavirus disease 2019; MN=microneutralization; nAb=neutralizing antibody; RT-PCR=reverse transcriptase polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus that causes COVID-19.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN₅₀: LLOQ=91.10 and ULOQ=2031.87.

Source: [Figure 14.2.7.2.1.](#)

8.4 Drug Dose, Drug Concentration, and Relationships to Response

Not applicable.

8.5 Drug-Drug and Drug-Disease Interaction

Not applicable.

8.6 By-Participant Displays

Not applicable.

8.7 Immunogenicity Conclusions

In this primary analysis, mRNA-1273 50 µg and 100 µg both induced anti-SARS-CoV-2 spike bAbs and nAbs at Day 29 (28 days after the first injection) that peaked at Day 43 and persisted through Day 57 (14 and 28 days, respectively, after the second injection), with generally comparable immunogenicity demonstrated in each age cohort.

The following are the key findings supporting the immunogenicity conclusions:

- The GMFRs (95% CI) of VAC58 spike IgG antibodies at Day 29 were 4.29 (3.87, 4.76) in the mRNA-1273 100 µg group and 3.36 (3.05, 3.69) in the mRNA-1273 50 µg group, and were 33.51 (30.37, 36.96) in the mRNA-1273 100 µg group compared with 27.46 (24.86, 30.33) in the mRNA-1273 50 µg group at Day 43.
- In both mRNA-1273 50 and 100 µg groups, the GMFR in VAC58 spike IgG antibody levels were > 27 at Day 43 and > 20 at Day 57.
- The GMFRs (95% CI) of VAC58 spike IgG antibodies trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (4.29 [3.87, 4.76] and 3.36 [3.05, 3.69], respectively), Day 43 (33.51 [30.37, 36.96] and 27.46 [24.86, 30.33], respectively) and Day 57 (25.04 [22.51, 27.86] and 20.39 [18.31, 22.70], respectively). In Cohort 1, the GMFRs (95% CI) were generally higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at Day 29 (5.26 [4.57, 6.06] and 3.65 [3.20, 4.16], respectively), Day 43 (38.47 [34.54, 42.85] and 26.82 [23.46, 30.67], respectively), and Day 57 (29.13 [25.68, 33.03] and 20.70 [17.92, 23.90], respectively). No apparent trend was observed between the two mRNA-1273 doses in Cohort 2.
- Both mRNA-1273 doses induced nAb responses, assessed by MN endpoint titers and MN₅₀ at each postbaseline visit. While no formal statistical testing was done, nAb

responses were generally comparable in participants who received the mRNA-1273 100 µg and the 50 µg dose at all time points.

- At Day 29 (28 days after the first injection), the MN endpoint GMFRs (95% CI) were 5.59 (4.65, 6.71) in the mRNA-1273 50 µg group and 7.46 (6.32, 8.81) in the mRNA-1273 100 µg group. At both Day 43 and Day 57, the GMFR was > 53 in each mRNA-1273 dose group.
- At Day 29 (28 days after the first injection), the MN₅₀ GMFRs (95% CI) were 3.75 (3.16, 4.45) in the mRNA-1273 50 µg group and 4.97 (4.23, 5.85) in the mRNA-1273 100 µg group. At both Day 43 and Day 57, the GMFR was > 35 in each mRNA-1273 dose group.
- At Day 29, the seroconversion rates based on the MN endpoint titers and MN₅₀ titers were 78.0% and 65.5%, respectively, in the mRNA-1273 50 µg group and 88.9% and 76.7%, respectively, in the mRNA-1273 100 µg group.
- At Day 43 and Day 57, 100% of participants met seroconversion criteria based on MN endpoint titers and MN₅₀ titers in both mRNA-1273 dose groups.
- Generally, no apparent difference in MN endpoint titers and MN₅₀ titers was observed between Cohort 1 and Cohort 2.

9 Pharmacokinetic Results

Not applicable.

10 Pharmacodynamic Results

Not applicable.

11 Biomarker Analysis Results

Not applicable.

12 Study Conclusions

This study was designed to evaluate the safety, reactogenicity, and immunogenicity of mRNA-1273 vaccine, administered in 2 doses (50 µg or 100 µg) 28 days apart.

- mRNA-1273 demonstrated an acceptable safety profile in the participant population enrolled in this study at both dose levels in two age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).
- Vaccination with mRNA-1273 resulted in significant immune responses to SARS-CoV-2 in participants 18 years and older at both dose levels, confirming the selection of the 100-µg dose that was brought forward in the pivotal Phase 3 (COVE) study.

This report is based on the primary analysis through Day 57. The full study analyses will be presented in the EOS CSR. The 13-month EOS assessment of this study and the ongoing Phase 3 (COVE) study may provide additional longer-term data on the safety and effectiveness of mRNA-1273 vaccine.

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14.2 Efficacy Data

Not applicable.

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Table 14.1.1.1
Subject Disposition
Randomized Set

	Overall				
	mRNA-1273				Overall (N=600) n (%)
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
Number of Subjects					
Received First Injection	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
Received Second Injection	194 (97.0)	195 (97.5)	198 (99.0)	393 (98.3)	587 (97.8)
Discontinued Study Vaccine	6 (3.0)	5 (2.5)	2 (1.0)	7 (1.8)	13 (2.2)
Reason for Discontinuation of Study Vaccine					
Adverse Event (COVID-19 Infection)	1 (0.5)	0	0	0	1 (0.2)
Adverse Event (Other)	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Death	0	0	0	0	0
Lost to Follow-Up	3 (1.5)	2 (1.0)	0	2 (0.5)	5 (0.8)
Physician Decision	0	0	0	0	0
Pregnancy	0	0	0	0	0
Protocol Deviation	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0
Withdrawal of Consent (COVID-19 Non-Infection Related)	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Withdrawal of Consent (Other)	0	0	0	0	0
Other	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)	4 (0.7)

Percentages are based on the number of randomized subjects.

[1] Study Completion is defined as a subject who completed 12 months of follow up after the last injection received.

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Table 14.1.1.1
Subject Disposition
Randomized Set

	Overall				
	mRNA-1273				Overall (N=600) n (%)
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
Completed Study [1]	0	0	0	0	0
Discontinued from Study	4 (2.0)	5 (2.5)	1 (0.5)	6 (1.5)	10 (1.7)
Reason for Discontinuation of Study					
Adverse Event (COVID-19 Infection)	0	0	0	0	0
Adverse Event (Other)	0	0	0	0	0
Death	0	0	0	0	0
Lost to Follow-Up	4 (2.0)	4 (2.0)	1 (0.5)	5 (1.3)	9 (1.5)
Physician Decision	0	0	0	0	0
Pregnancy	0	0	0	0	0
Protocol Deviation	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0
Withdrawal of Consent (COVID-19 Non-Infection Related)	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Withdrawal of Consent (Other)	0	0	0	0	0
Other	0	0	0	0	0

Percentages are based on the number of randomized subjects.

[1] Study Completion is defined as a subject who completed 12 months of follow up after the last injection received.

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Table 14.1.1.1
Subject Disposition
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Overall (N=300) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Overall (N=300) n (%)
Number of Subjects										
Received First Injection	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)
Received Second Injection	94 (94.0)	97 (97.0)	99 (99.0)	196 (98.0)	290 (96.7)	100 (100)	98 (98.0)	99 (99.0)	197 (98.5)	297 (99.0)
Discontinued Study Vaccine	6 (6.0)	3 (3.0)	1 (1.0)	4 (2.0)	10 (3.3)	0	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.0)
Reason for Discontinuation of Study Vaccine										
Adverse Event (COVID-19 Infection)	1 (1.0)	0	0	0	1 (0.3)	0	0	0	0	0
Adverse Event (Other)	0	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)
Death	0	0	0	0	0	0	0	0	0	0
Lost to Follow-Up	3 (3.0)	2 (2.0)	0	2 (1.0)	5 (1.7)	0	0	0	0	0
Physician Decision	0	0	0	0	0	0	0	0	0	0
Pregnancy	0	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	0	0	0	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0	0
Withdrawal of Consent (COVID-19 Non-Infection Related)	0	1 (1.0)	0	1 (0.5)	1 (0.3)	0	0	0	0	0
Withdrawal of Consent (Other)	0	0	0	0	0	0	0	0	0	0
Other	2 (2.0)	0	1 (1.0)	1 (0.5)	3 (1.0)	0	1 (1.0)	0	1 (0.5)	1 (0.3)

Percentages are based on the number of randomized subjects.

[1] Study Completion is defined as a subject who completed 12 months of follow up after the last injection received.

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Table 14.1.1.1
Subject Disposition
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273			Overall (N=300)	Placebo (N=100)	mRNA-1273			Overall (N=300)
		50 µg	100 µg	Total			50 µg	100 µg	Total	
		n (%)	n (%)	n (%)			n (%)	n (%)	n (%)	
Completed Study [1]	0	0	0	0	0	0	0	0	0	0
Discontinued from Study	4	4	0	4	8	0	1	1	2	2
	(4.0)	(4.0)		(2.0)	(2.7)		(1.0)	(1.0)	(1.0)	(0.7)
Reason for Discontinuation of Study										
Adverse Event (COVID-19 Infection)	0	0	0	0	0	0	0	0	0	0
Adverse Event (Other)	0	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0	0
Lost to Follow-Up	4	3	0	3	7	0	1	1	2	2
	(4.0)	(3.0)		(1.5)	(2.3)		(1.0)	(1.0)	(1.0)	(0.7)
Physician Decision	0	0	0	0	0	0	0	0	0	0
Pregnancy	0	0	0	0	0	0	0	0	0	0
Protocol Deviation	0	0	0	0	0	0	0	0	0	0
Study Terminated by Sponsor	0	0	0	0	0	0	0	0	0	0
Withdrawal of Consent (COVID-19	0	1	0	1	1	0	0	0	0	0
Non-Infection Related)		(1.0)		(0.5)	(0.3)					
Withdrawal of Consent (Other)	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of randomized subjects.

[1] Study Completion is defined as a subject who completed 12 months of follow up after the last injection received.

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Table 14.1.1.2
Number of Subjects Randomized by Site
Randomized Set

Site Number	Overall				
	mRNA-1273				Overall (N=600) n (%)
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
US201	30 (15.0)	25 (12.5)	24 (12.0)	49 (12.3)	79 (13.2)
US202	31 (15.5)	23 (11.5)	31 (15.5)	54 (13.5)	85 (14.2)
US203	31 (15.5)	25 (12.5)	23 (11.5)	48 (12.0)	79 (13.2)
US204	28 (14.0)	41 (20.5)	28 (14.0)	69 (17.3)	97 (16.2)
US205	13 (6.5)	35 (17.5)	32 (16.0)	67 (16.8)	80 (13.3)
US206	12 (6.0)	12 (6.0)	9 (4.5)	21 (5.3)	33 (5.5)
US207	28 (14.0)	20 (10.0)	24 (12.0)	44 (11.0)	72 (12.0)
US208	27 (13.5)	19 (9.5)	29 (14.5)	48 (12.0)	75 (12.5)

Percentages are based on the number of randomized subjects.

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Table 14.1.1.2
Number of Subjects Randomized by Site
Randomized Set

Site Number	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
US201	13 (13.0)	14 (14.0)	12 (12.0)	26 (13.0)	39 (13.0)	17 (17.0)	11 (11.0)	12 (12.0)	23 (11.5)	40 (13.3)
US202	18 (18.0)	8 (8.0)	16 (16.0)	24 (12.0)	42 (14.0)	13 (13.0)	15 (15.0)	15 (15.0)	30 (15.0)	43 (14.3)
US203	17 (17.0)	13 (13.0)	17 (17.0)	30 (15.0)	47 (15.7)	14 (14.0)	12 (12.0)	6 (6.0)	18 (9.0)	32 (10.7)
US204	18 (18.0)	25 (25.0)	13 (13.0)	38 (19.0)	56 (18.7)	10 (10.0)	16 (16.0)	15 (15.0)	31 (15.5)	41 (13.7)
US205	4 (4.0)	16 (16.0)	15 (15.0)	31 (15.5)	35 (11.7)	9 (9.0)	19 (19.0)	17 (17.0)	36 (18.0)	45 (15.0)
US206	7 (7.0)	7 (7.0)	6 (6.0)	13 (6.5)	20 (6.7)	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	13 (4.3)
US207	15 (15.0)	11 (11.0)	13 (13.0)	24 (12.0)	39 (13.0)	13 (13.0)	9 (9.0)	11 (11.0)	20 (10.0)	33 (11.0)
US208	8 (8.0)	6 (6.0)	8 (8.0)	14 (7.0)	22 (7.3)	19 (19.0)	13 (13.0)	21 (21.0)	34 (17.0)	53 (17.7)

Percentages are based on the number of randomized subjects.

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Table 14.1.1.3
Reasons for Screen Failure Subjects
Subjects Screened

	Subjects Screened (N=1090) n (%)
Number of Screen Failure Subjects	490 (45.0)
Reason for Screen Failure [1]	
Cohort Full	62 (12.7)
Inclusion/Exclusion	418 (85.3)
Withdrew Consent	6 (1.2)
Other	4 (0.8)

Percentages are based on the number of subjects screened.

[1] Percentages are based on the number of screen failure subjects.

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Table 14.1.1.4
Major Protocol Deviations
Randomized Set

Deviation Type	Placebo (N=200) n (%)	Overall mRNA-1273			Overall (N=600) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
Concomitant Medication	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Exclusion Criteria	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)	10 (1.7)
ICF Process/Timing	2 (1.0)	3 (1.5)	6 (3.0)	9 (2.3)	11 (1.8)
Inclusion Criteria	1 (0.5)	0	0	0	1 (0.2)
Informed Consent	3 (1.5)	1 (0.5)	0	1 (0.3)	4 (0.7)
Inv Record Keeping Source Docs	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
Missing Endpoint Assessments	10 (5.0)	12 (6.0)	9 (4.5)	21 (5.3)	31 (5.2)
Study Procedures/Assessments	6 (3.0)	1 (0.5)	9 (4.5)	10 (2.5)	16 (2.7)
Study Treatment Admin/Dispense	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)	8 (1.3)
Study Treatment Compliance	1 (0.5)	0	0	0	1 (0.2)
Visit Scheduling	17 (8.5)	28 (14.0)	25 (12.5)	53 (13.3)	70 (11.7)

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Table 14.1.1.4
Major Protocol Deviations
Randomized Set

Deviation Type	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273			Overall (N=300)	Placebo (N=100)	mRNA-1273			Overall (N=300)
		50 µg (N=100)	100 µg (N=100)	Total (N=200)			50 µg (N=100)	100 µg (N=100)	Total (N=200)	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Concomitant Medication	0	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)
Exclusion Criteria	1 (1.0)	0	2 (2.0)	2 (1.0)	3 (1.0)	2 (2.0)	2 (2.0)	3 (3.0)	5 (2.5)	7 (2.3)
ICF Process/Timing	0	0	3 (3.0)	3 (1.5)	3 (1.0)	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)	8 (2.7)
Inclusion Criteria	0	0	0	0	0	1 (1.0)	0	0	0	1 (0.3)
Informed Consent	2 (2.0)	1 (1.0)	0	1 (0.5)	3 (1.0)	1 (1.0)	0	0	0	1 (0.3)
Inv Record Keeping Source Docs	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	4 (1.3)	2 (2.0)	0	1 (1.0)	1 (0.5)	3 (1.0)
Missing Endpoint Assessments	9 (9.0)	9 (9.0)	5 (5.0)	14 (7.0)	23 (7.7)	1 (1.0)	3 (3.0)	4 (4.0)	7 (3.5)	8 (2.7)
Study Procedures/Assessments	4 (4.0)	1 (1.0)	5 (5.0)	6 (3.0)	10 (3.3)	2 (2.0)	0	4 (4.0)	4 (2.0)	6 (2.0)
Study Treatment Admin/Dispense	2 (2.0)	2 (2.0)	3 (3.0)	5 (2.5)	7 (2.3)	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Study Treatment Compliance	0	0	0	0	0	1 (1.0)	0	0	0	1 (0.3)
Visit Scheduling	10 (10.0)	20 (20.0)	13 (13.0)	33 (16.5)	43 (14.3)	7 (7.0)	8 (8.0)	12 (12.0)	20 (10.0)	27 (9.0)

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Overall				
	mRNA-1273				Overall (N=600) n (%)
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	
Safety Set	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
Solicited Safety Set	200 (100)	200 (100)	200 (100)	400 (100)	600 (100)
First Injection Solicited	199 (99.5)	200 (100)	200 (100)	400 (100)	599 (99.8)
Safety Set					
Second Injection Solicited	194 (97.0)	195 (97.5)	198 (99.0)	393 (98.3)	587 (97.8)
Safety Set					
Full Analysis Set [1]					
Full Analysis Set for	196 (98.0)	198 (99.0)	197 (98.5)	395 (98.8)	591 (98.5)
SARS-CoV-2-specific bAb					
Day 29	194 (97.0)	196 (98.0)	195 (97.5)	391 (97.8)	585 (97.5)
Day 57	196 (98.0)	194 (97.0)	197 (98.5)	391 (97.8)	587 (97.8)
Full Analysis Set for	191 (95.5)	192 (96.0)	195 (97.5)	387 (96.8)	578 (96.3)
SARS-CoV-2-specific nAb					
from the First Lot					
Day 29	188 (94.0)	180 (90.0)	187 (93.5)	367 (91.8)	555 (92.5)
Day 57	191 (95.5)	167 (83.5)	170 (85.0)	337 (84.3)	528 (88.0)
Full Analysis Set for	196 (98.0)	198 (99.0)	198 (99.0)	396 (99.0)	592 (98.7)
SARS-CoV-2-specific nAb					
from All Lots					
Day 29	194 (97.0)	191 (95.5)	192 (96.0)	383 (95.8)	577 (96.2)
Day 57	196 (98.0)	186 (93.0)	192 (96.0)	378 (94.5)	574 (95.7)

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Overall				
	mRNA-1273				
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
	n (%)	n (%)	n (%)	n (%)	n (%)
Per-Protocol (PP) Set [2]					
PP Set for SARS-CoV-2-specific bAb	186 (93.0)	185 (92.5)	189 (94.5)	374 (93.5)	560 (93.3)
Day 29	184 (92.0)	184 (92.0)	189 (94.5)	373 (93.3)	557 (92.8)
Day 57	175 (87.5)	176 (88.0)	177 (88.5)	353 (88.3)	528 (88.0)
PP Set for SARS-CoV-2-specific nAb from the First Lot	181 (90.5)	179 (89.5)	186 (93.0)	365 (91.3)	546 (91.0)
Day 29	178 (89.0)	168 (84.0)	180 (90.0)	348 (87.0)	526 (87.7)
Day 57	171 (85.5)	150 (75.0)	152 (76.0)	302 (75.5)	473 (78.8)
PP Set for SARS-CoV-2-specific nAb from All Lots	186 (93.0)	185 (92.5)	189 (94.5)	374 (93.5)	560 (93.3)
Day 29	184 (92.0)	179 (89.5)	185 (92.5)	364 (91.0)	548 (91.3)
Day 57	175 (87.5)	168 (84.0)	171 (85.5)	339 (84.8)	514 (85.7)

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Safety Set	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)
Solicited Safety Set	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)
First Injection Solicited	100	100	100	200	300	99	100	100	200	299
Safety Set	(100)	(100)	(100)	(100)	(100)	(99.0)	(100)	(100)	(100)	(99.7)
Second Injection Solicited	94	97	99	196	290	100	98	99	197	297
Safety Set	(94.0)	(97.0)	(99.0)	(98.0)	(96.7)	(100)	(98.0)	(99.0)	(98.5)	(99.0)

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Full Analysis Set [1]										
Full Analysis Set for	96	98	99	197	293	100	100	98	198	298
SARS-CoV-2-specific bAb	(96.0)	(98.0)	(99.0)	(98.5)	(97.7)	(100)	(100)	(98.0)	(99.0)	(99.3)
Day 29	94	97	98	195	289	100	99	97	196	296
	(94.0)	(97.0)	(98.0)	(97.5)	(96.3)	(100)	(99.0)	(97.0)	(98.0)	(98.7)
Day 57	96	95	99	194	290	100	99	98	197	297
	(96.0)	(95.0)	(99.0)	(97.0)	(96.7)	(100)	(99.0)	(98.0)	(98.5)	(99.0)
Full Analysis Set for	96	98	100	198	294	95	94	95	189	284
SARS-CoV-2-specific nAb	(96.0)	(98.0)	(100)	(99.0)	(98.0)	(95.0)	(94.0)	(95.0)	(94.5)	(94.7)
from the First Lot										
Day 29	94	97	98	195	289	94	83	89	172	266
	(94.0)	(97.0)	(98.0)	(97.5)	(96.3)	(94.0)	(83.0)	(89.0)	(86.0)	(88.7)
Day 57	96	91	94	185	281	95	76	76	152	247
	(96.0)	(91.0)	(94.0)	(92.5)	(93.7)	(95.0)	(76.0)	(76.0)	(76.0)	(82.3)
Full Analysis Set for	96	98	100	198	294	100	100	98	198	298
SARS-CoV-2-specific nAb	(96.0)	(98.0)	(100)	(99.0)	(98.0)	(100)	(100)	(98.0)	(99.0)	(99.3)
from All Lots										
Day 29	94	97	98	195	289	100	94	94	188	288
	(94.0)	(97.0)	(98.0)	(97.5)	(96.3)	(100)	(94.0)	(94.0)	(94.0)	(96.0)
Day 57	96	95	99	194	290	100	91	93	184	284
	(96.0)	(95.0)	(99.0)	(97.0)	(96.7)	(100)	(91.0)	(93.0)	(92.0)	(94.7)

Notes are listed on last page.

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Per-Protocol (PP) Set [2]										
PP Set for	92	90	95	185	277	94	95	94	189	283
SARS-CoV-2-specific bAb	(92.0)	(90.0)	(95.0)	(92.5)	(92.3)	(94.0)	(95.0)	(94.0)	(94.5)	(94.3)
Day 29	90	89	95	184	274	94	95	94	189	283
	(90.0)	(89.0)	(95.0)	(92.0)	(91.3)	(94.0)	(95.0)	(94.0)	(94.5)	(94.3)
Day 57	84	84	87	171	255	91	92	90	182	273
	(84.0)	(84.0)	(87.0)	(85.5)	(85.0)	(91.0)	(92.0)	(90.0)	(91.0)	(91.0)
PP Set for	92	90	95	185	277	89	89	91	180	269
SARS-CoV-2-specific nAb	(92.0)	(90.0)	(95.0)	(92.5)	(92.3)	(89.0)	(89.0)	(91.0)	(90.0)	(89.7)
from the First Lot										
Day 29	90	89	94	183	273	88	79	86	165	253
	(90.0)	(89.0)	(94.0)	(91.5)	(91.0)	(88.0)	(79.0)	(86.0)	(82.5)	(84.3)
Day 57	84	80	82	162	246	87	70	70	140	227
	(84.0)	(80.0)	(82.0)	(81.0)	(82.0)	(87.0)	(70.0)	(70.0)	(70.0)	(75.7)
PP Set for	92	90	95	185	277	94	95	94	189	283
SARS-CoV-2-specific nAb	(92.0)	(90.0)	(95.0)	(92.5)	(92.3)	(94.0)	(95.0)	(94.0)	(94.5)	(94.3)
from All Lots										
Day 29	90	89	94	183	273	94	90	91	181	275
	(90.0)	(89.0)	(94.0)	(91.5)	(91.0)	(94.0)	(90.0)	(91.0)	(90.5)	(91.7)
Day 57	84	84	86	170	254	91	84	85	169	260
	(84.0)	(84.0)	(86.0)	(85.0)	(84.7)	(91.0)	(84.0)	(85.0)	(84.5)	(86.7)

Notes are listed on last page.

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

bAb = Binding antibody. nAb = Neutralizing antibody.

Percentages are based on the number of randomized subjects.

For the summaries using Safety Set and Solicited Safety Set, if a subject received any study vaccination injection that is at a non-protocol dose, the subject is assigned to a protocol dose (placebo if received placebo, mRNA-1273 vaccine 50 µg if the received dose > 0 µg and ≤ 75 µg, or mRNA-1273 vaccine 100 µg if the received dose > 75 µg) for that injection. Subjects who received a second injection that is different from the first injection are assigned to the higher dose of vaccination group (eg, Placebo < mRNA-1273 50 µg < mRNA-1273 100 µg).

[1] Full Analysis Set for each visit includes all subjects who received any study vaccination, and had immunogenicity data available at both baseline and the corresponding post-injection visit.

[2] The PP Set for each visit includes all subjects in the Full Analysis Set who did not have SARS-CoV-2 infection at baseline, did not have a major protocol deviation that impact immune response, complied with the injection schedule and the timing of immunogenicity blood sampling to have post-injection results available for at least one assay component at the corresponding visit.

Table 14.1.3.1
Baseline Demographics
Safety Set

	Overall				Overall (N=600)
	Placebo (N=200)	mRNA-1273		Total (N=400)	
		50 µg (N=200)	100 µg (N=200)		
Age (Years)					
n	200	200	200	400	600
Mean (SD)	50.8 (15.77)	50.6 (16.30)	51.1 (15.55)	50.8 (15.91)	50.8 (15.85)
Median	54.0	54.5	54.5	54.5	54.5
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	71 (35.5)	63 (31.5)	76 (38.0)	139 (34.8)	210 (35.0)
Female	129 (64.5)	137 (68.5)	124 (62.0)	261 (65.3)	390 (65.0)
Race, n (%)					
White	193 (96.5)	188 (94.0)	188 (94.0)	376 (94.0)	569 (94.8)
Black or African American	3 (1.5)	5 (2.5)	8 (4.0)	13 (3.3)	16 (2.7)
Asian	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
American Indian or Alaska Native	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.5)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.3)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0
Ethnicity, n (%)					
Hispanic or Latino	16 (8.0)	15 (7.5)	16 (8.0)	31 (7.8)	47 (7.8)
Not Hispanic or Latino	184 (92.0)	184 (92.0)	184 (92.0)	368 (92.0)	552 (92.0)
Not Reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0

Percentages are based on the number of safety subjects.

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Table 14.1.3.1
Baseline Demographics
Safety Set

	Overall				
	mRNA-1273				
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
Weight (kg)					
n	200	200	200	400	600
Mean (SD)	73.57 (12.727)	74.21 (11.563)	73.61 (13.548)	73.91 (12.583)	73.80 (12.621)
Median	73.05	73.90	73.00	73.60	73.40
Min, Max	42.8, 103.7	47.9, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	200	200	200	400	600
Mean (SD)	169.93 (10.087)	170.03 (8.776)	171.01 (10.435)	170.52 (9.642)	170.32 (9.788)
Median	168.00	168.90	170.05	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m²)					
n	200	200	200	400	600
Mean (SD)	25.35 (2.855)	25.60 (2.920)	25.02 (2.944)	25.31 (2.943)	25.32 (2.912)
Median	25.73	26.11	25.24	25.64	25.67
Min, Max	18.0, 30.4	17.9, 30.7	18.2, 30.1	17.9, 30.7	17.9, 30.7

Percentages are based on the number of safety subjects.

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Table 14.1.3.1
Baseline Demographics
Safety Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Age (Years)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	37.4 (9.88)	36.6 (9.67)	38.2 (10.44)	37.4 (10.07)	37.4 (9.99)	64.3 (6.08)	64.6 (6.58)	63.9 (6.68)	64.3 (6.63)	64.3 (6.44)
Median	38.0	38.0	38.5	38.0	38.0	64.0	64.5	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	40 (40.0)	36 (36.0)	47 (47.0)	83 (41.5)	123 (41.0)	31 (31.0)	27 (27.0)	29 (29.0)	56 (28.0)	87 (29.0)
Female	60 (60.0)	64 (64.0)	53 (53.0)	117 (58.5)	177 (59.0)	69 (69.0)	73 (73.0)	71 (71.0)	144 (72.0)	213 (71.0)

Percentages are based on the number of safety subjects.

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Table 14.1.3.1
Baseline Demographics
Safety Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Race, n (%)										
White	94 (94.0)	93 (93.0)	90 (90.0)	183 (91.5)	277 (92.3)	99 (99.0)	95 (95.0)	98 (98.0)	193 (96.5)	292 (97.3)
Black or African American	3 (3.0)	3 (3.0)	7 (7.0)	10 (5.0)	13 (4.3)	0	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.0)
Asian	2 (2.0)	0	2 (2.0)	2 (1.0)	4 (1.3)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.0)
American Indian or Alaska Native	0	2 (2.0)	0	2 (1.0)	2 (0.7)	0	0	1 (1.0)	1 (0.5)	1 (0.3)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Multiracial	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Ethnicity, n (%)										
Hispanic or Latino	14 (14.0)	11 (11.0)	8 (8.0)	19 (9.5)	33 (11.0)	2 (2.0)	4 (4.0)	8 (8.0)	12 (6.0)	14 (4.7)
Not Hispanic or Latino	86 (86.0)	89 (89.0)	92 (92.0)	181 (90.5)	267 (89.0)	98 (98.0)	95 (95.0)	92 (92.0)	187 (93.5)	285 (95.0)
Not Reported	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.

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Table 14.1.3.1
Baseline Demographics
Safety Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Weight (kg)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	74.05 (12.094)	75.71 (11.789)	74.41 (13.250)	75.06 (12.526)	74.72 (12.373)	73.09 (13.374)	72.72 (11.192)	72.80 (13.859)	72.76 (12.565)	72.87 (12.819)
Median	74.40	76.80	73.85	74.90	74.55	71.65	71.95	72.90	72.25	72.05
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	47.9, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	170.82 (8.777)	171.69 (8.888)	172.83 (9.690)	172.26 (9.292)	171.78 (9.134)	169.03 (11.219)	168.38 (8.384)	169.20 (10.879)	168.79 (9.696)	168.87 (10.211)
Median	170.00	170.20	171.25	170.20	170.20	167.55	167.60	167.30	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	25.29 (3.033)	25.62 (3.023)	24.79 (3.022)	25.21 (3.043)	25.23 (3.035)	25.41 (2.680)	25.58 (2.829)	25.24 (2.861)	25.41 (2.843)	25.41 (2.785)
Median	25.78	26.48	25.09	25.65	25.71	25.69	25.74	25.36	25.59	25.64
Min, Max	18.0, 30.0	18.5, 30.7	18.2, 29.9	18.2, 30.7	18.0, 30.7	18.9, 30.4	17.9, 30.2	18.3, 30.1	17.9, 30.2	17.9, 30.4

Percentages are based on the number of safety subjects.

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Table 14.1.3.2
Baseline Demographics
Randomized Set

	Overall				
		mRNA-1273			
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
Age (Years)					
n	200	200	200	400	600
Mean (SD)	50.8 (15.80)	50.6 (16.30)	51.1 (15.52)	50.9 (15.90)	50.8 (15.85)
Median	54.0	54.5	54.5	54.5	54.5
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	71 (35.5)	63 (31.5)	76 (38.0)	139 (34.8)	210 (35.0)
Female	129 (64.5)	137 (68.5)	124 (62.0)	261 (65.3)	390 (65.0)
Race, n (%)					
White	193 (96.5)	188 (94.0)	188 (94.0)	376 (94.0)	569 (94.8)
Black or African American	3 (1.5)	5 (2.5)	8 (4.0)	13 (3.3)	16 (2.7)
Asian	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
American Indian or Alaska Native	0	2 (1.0)	1 (0.5)	3 (0.8)	3 (0.5)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.3)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0
Ethnicity, n (%)					
Hispanic or Latino	16 (8.0)	15 (7.5)	16 (8.0)	31 (7.8)	47 (7.8)
Not Hispanic or Latino	184 (92.0)	184 (92.0)	184 (92.0)	368 (92.0)	552 (92.0)
Not Reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0

Percentages are based on the number of randomized subjects.

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Table 14.1.3.2
Baseline Demographics
Randomized Set

	Overall				
	mRNA-1273				
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)	Overall (N=600)
Weight (kg)					
n	200	200	200	400	600
Mean (SD)	73.70 (12.787)	74.21 (11.563)	73.47 (13.490)	73.84 (12.554)	73.80 (12.621)
Median	73.30	73.90	72.90	73.40	73.40
Min, Max	42.8, 103.7	47.9, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	200	200	200	400	600
Mean (SD)	170.04 (10.175)	170.03 (8.776)	170.90 (10.359)	170.47 (9.598)	170.32 (9.788)
Median	168.00	168.90	169.95	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)					
n	200	200	200	400	600
Mean (SD)	25.36 (2.852)	25.60 (2.920)	25.00 (2.945)	25.30 (2.944)	25.32 (2.912)
Median	25.76	26.11	25.19	25.61	25.67
Min, Max	18.0, 30.4	17.9, 30.7	18.2, 30.1	17.9, 30.7	17.9, 30.7

Percentages are based on the number of randomized subjects.

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Table 14.1.3.2
Baseline Demographics
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Age (Years)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	37.3 (9.90)	36.6 (9.67)	38.3 (10.42)	37.5 (10.06)	37.4 (9.99)	64.3 (6.08)	64.6 (6.58)	63.9 (6.68)	64.3 (6.63)	64.3 (6.44)
Median	38.0	38.0	38.5	38.0	38.0	64.0	64.5	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	40 (40.0)	36 (36.0)	47 (47.0)	83 (41.5)	123 (41.0)	31 (31.0)	27 (27.0)	29 (29.0)	56 (28.0)	87 (29.0)
Female	60 (60.0)	64 (64.0)	53 (53.0)	117 (58.5)	177 (59.0)	69 (69.0)	73 (73.0)	71 (71.0)	144 (72.0)	213 (71.0)

Percentages are based on the number of randomized subjects.

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Table 14.1.3.2
Baseline Demographics
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Race, n (%)										
White	94 (94.0)	93 (93.0)	90 (90.0)	183 (91.5)	277 (92.3)	99 (99.0)	95 (95.0)	98 (98.0)	193 (96.5)	292 (97.3)
Black or African American	3 (3.0)	3 (3.0)	7 (7.0)	10 (5.0)	13 (4.3)	0	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.0)
Asian	2 (2.0)	0	2 (2.0)	2 (1.0)	4 (1.3)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.0)
American Indian or Alaska Native	0	2 (2.0)	0	2 (1.0)	2 (0.7)	0	0	1 (1.0)	1 (0.5)	1 (0.3)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Multiracial	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Ethnicity, n (%)										
Hispanic or Latino	14 (14.0)	11 (11.0)	8 (8.0)	19 (9.5)	33 (11.0)	2 (2.0)	4 (4.0)	8 (8.0)	12 (6.0)	14 (4.7)
Not Hispanic or Latino	86 (86.0)	89 (89.0)	92 (92.0)	181 (90.5)	267 (89.0)	98 (98.0)	95 (95.0)	92 (92.0)	187 (93.5)	285 (95.0)
Not Reported	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of randomized subjects.

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Table 14.1.3.2
Baseline Demographics
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)		50 µg (N=100)	100 µg (N=100)	Total (N=200)	Overall (N=300)
Weight (kg)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	74.32 (12.208)	75.71 (11.789)	74.14 (13.147)	74.93 (12.480)	74.72 (12.373)	73.09 (13.374)	72.72 (11.192)	72.80 (13.859)	72.76 (12.565)	72.87 (12.819)
Median	74.50	76.80	72.90	74.70	74.55	71.65	71.95	72.90	72.25	72.05
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	47.9, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	171.04 (8.957)	171.69 (8.888)	172.61 (9.565)	172.15 (9.221)	171.78 (9.134)	169.03 (11.219)	168.38 (8.384)	169.20 (10.879)	168.79 (9.696)	168.87 (10.211)
Median	170.05	170.20	171.00	170.20	170.20	167.55	167.60	167.30	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)										
n	100	100	100	200	300	100	100	100	200	300
Mean (SD)	25.31 (3.028)	25.62 (3.023)	24.77 (3.023)	25.19 (3.045)	25.23 (3.035)	25.41 (2.680)	25.58 (2.829)	25.24 (2.861)	25.41 (2.843)	25.41 (2.785)
Median	25.84	26.48	25.02	25.64	25.71	25.69	25.74	25.36	25.59	25.64
Min, Max	18.0, 30.0	18.5, 30.7	18.2, 29.9	18.2, 30.7	18.0, 30.7	18.9, 30.4	17.9, 30.2	18.3, 30.1	17.9, 30.2	17.9, 30.4

Percentages are based on the number of randomized subjects.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010302.sas 19NOV2020 00:12 Database Lock Date: 05NOV2020

Table 14.1.3.3
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific bAb

	Overall				
	mRNA-1273				
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)	Overall (N=560)
Age (Years)					
n	186	185	189	374	560
Mean (SD)	50.9 (15.87)	51.3 (16.09)	51.2 (15.47)	51.2 (15.76)	51.1 (15.78)
Median	55.0	56.0	54.0	55.0	55.0
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	66 (35.5)	57 (30.8)	70 (37.0)	127 (34.0)	193 (34.5)
Female	120 (64.5)	128 (69.2)	119 (63.0)	247 (66.0)	367 (65.5)
Race, n (%)					
White	179 (96.2)	174 (94.1)	178 (94.2)	352 (94.1)	531 (94.8)
Black or African American	3 (1.6)	5 (2.7)	8 (4.2)	13 (3.5)	16 (2.9)
Asian	3 (1.6)	2 (1.1)	1 (0.5)	3 (0.8)	6 (1.1)
American Indian or Alaska Native	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.4)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.4)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0
Ethnicity, n (%)					
Hispanic or Latino	13 (7.0)	11 (5.9)	15 (7.9)	26 (7.0)	39 (7.0)
Not Hispanic or Latino	173 (93.0)	173 (93.5)	174 (92.1)	347 (92.8)	520 (92.9)
Not Reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010303.sas 19NOV2020 00:13 Database Lock Date: 05NOV2020

Table 14.1.3.3
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific bAb

	Overall				
	mRNA-1273				
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)	Overall (N=560)
Weight (kg)					
n	186	185	189	374	560
Mean (SD)	73.47 (12.746)	74.31 (11.443)	73.39 (13.448)	73.84 (12.488)	73.72 (12.564)
Median	72.90	73.70	72.80	73.15	73.05
Min, Max	42.8, 103.7	47.9, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	186	185	189	374	560
Mean (SD)	169.93 (10.027)	170.07 (8.896)	170.83 (10.351)	170.46 (9.653)	170.28 (9.773)
Median	167.80	168.90	170.00	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)					
n	186	185	189	374	560
Mean (SD)	25.32 (2.895)	25.62 (2.822)	25.00 (2.962)	25.31 (2.907)	25.31 (2.900)
Median	25.76	26.08	25.26	25.65	25.69
Min, Max	18.0, 30.4	17.9, 30.0	18.2, 30.1	17.9, 30.1	17.9, 30.4

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010303.sas 19NOV2020 00:13 Database Lock Date: 05NOV2020

Table 14.1.3.3
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=92)	mRNA-1273				Placebo (N=94)	mRNA-1273			
		50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)		50 µg (N=95)	100 µg (N=94)	Total (N=189)	Overall (N=283)
Age (Years)										
n	92	90	95	185	277	94	95	94	189	283
Mean (SD)	37.3 (9.95)	37.0 (9.45)	38.5 (10.38)	37.8 (9.94)	37.6 (9.93)	64.3 (6.19)	64.8 (6.68)	64.0 (6.74)	64.4 (6.70)	64.3 (6.53)
Median	38.0	38.0	39.0	38.0	38.0	64.0	65.0	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	37 (40.2)	32 (35.6)	43 (45.3)	75 (40.5)	112 (40.4)	29 (30.9)	25 (26.3)	27 (28.7)	52 (27.5)	81 (28.6)
Female	55 (59.8)	58 (64.4)	52 (54.7)	110 (59.5)	165 (59.6)	65 (69.1)	70 (73.7)	67 (71.3)	137 (72.5)	202 (71.4)

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010303.sas 19NOV2020 00:13 Database Lock Date: 05NOV2020

Table 14.1.3.3
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)	Overall (N=283)
Race, n (%)										
White	86 (93.5)	84 (93.3)	86 (90.5)	170 (91.9)	256 (92.4)	93 (98.9)	90 (94.7)	92 (97.9)	182 (96.3)	275 (97.2)
Black or African American	3 (3.3)	3 (3.3)	7 (7.4)	10 (5.4)	13 (4.7)	0	2 (2.1)	1 (1.1)	3 (1.6)	3 (1.1)
Asian	2 (2.2)	0	1 (1.1)	1 (0.5)	3 (1.1)	1 (1.1)	2 (2.1)	0	2 (1.1)	3 (1.1)
American Indian or Alaska Native	0	1 (1.1)	0	1 (0.5)	1 (0.4)	0	0	1 (1.1)	1 (0.5)	1 (0.4)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.1)	0	1 (0.5)	1 (0.4)
Multiracial	1 (1.1)	1 (1.1)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.1)	1 (1.1)	2 (1.1)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Ethnicity, n (%)										
Hispanic or Latino	13 (14.1)	8 (8.9)	8 (8.4)	16 (8.6)	29 (10.5)	0	3 (3.2)	7 (7.4)	10 (5.3)	10 (3.5)
Not Hispanic or Latino	79 (85.9)	82 (91.1)	87 (91.6)	169 (91.4)	248 (89.5)	94 (100)	91 (95.8)	87 (92.6)	178 (94.2)	272 (96.1)
Not Reported	0	0	0	0	0	0	1 (1.1)	0	1 (0.5)	1 (0.4)
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010303.sas 19NOV2020 00:13 Database Lock Date: 05NOV2020

Table 14.1.3.3
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273				Overall (N=277)	mRNA-1273				Overall (N=283)
	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)		Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)	
Weight (kg)										
n	92	90	95	185	277	94	95	94	189	283
Mean (SD)	73.99 (12.223)	76.22 (11.417)	74.20 (13.216)	75.18 (12.382)	74.79 (12.320)	72.97 (13.284)	72.50 (11.229)	72.57 (13.700)	72.53 (12.486)	72.68 (12.735)
Median	74.15	76.80	73.50	74.80	74.50	71.65	71.70	72.80	72.00	71.90
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	47.9, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	92	90	95	185	277	94	95	94	189	283
Mean (SD)	170.87 (8.967)	171.95 (9.040)	172.58 (9.514)	172.27 (9.267)	171.80 (9.176)	169.02 (10.936)	168.30 (8.425)	169.07 (10.900)	168.68 (9.717)	168.79 (10.120)
Median	170.00	170.20	171.00	170.90	170.20	167.55	167.60	167.30	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)										
n	92	90	95	185	277	94	95	94	189	283
Mean (SD)	25.26 (3.070)	25.72 (2.837)	24.80 (3.084)	25.25 (2.994)	25.25 (3.014)	25.38 (2.729)	25.52 (2.821)	25.20 (2.835)	25.36 (2.825)	25.37 (2.789)
Median	25.84	26.48	24.96	26.02	25.88	25.61	25.70	25.36	25.59	25.59
Min, Max	18.0, 29.8	19.3, 30.0	18.2, 29.9	18.2, 30.0	18.0, 30.0	18.9, 30.4	17.9, 29.9	18.3, 30.1	17.9, 30.1	17.9, 30.4

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010303.sas 19NOV2020 00:13 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Overall				Overall (N=546)
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)	
Age (Years)					
n	181	179	186	365	546
Mean (SD)	50.6 (15.90)	50.9 (16.15)	51.0 (15.52)	50.9 (15.81)	50.8 (15.83)
Median	52.0	54.0	54.0	54.0	54.0
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	64 (35.4)	55 (30.7)	69 (37.1)	124 (34.0)	188 (34.4)
Female	117 (64.6)	124 (69.3)	117 (62.9)	241 (66.0)	358 (65.6)
Race, n (%)					
White	174 (96.1)	168 (93.9)	176 (94.6)	344 (94.2)	518 (94.9)
Black or African American	3 (1.7)	5 (2.8)	7 (3.8)	12 (3.3)	15 (2.7)
Asian	3 (1.7)	2 (1.1)	1 (0.5)	3 (0.8)	6 (1.1)
American Indian or Alaska Native	0	1 (0.6)	1 (0.5)	2 (0.5)	2 (0.4)
Native Hawaiian or Other Pacific Islander	0	1 (0.6)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.6)	1 (0.6)	0	1 (0.3)	2 (0.4)
Other	0	1 (0.6)	1 (0.5)	2 (0.5)	2 (0.4)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Overall				Overall (N=546)
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)	
Ethnicity, n (%)					
Hispanic or Latino	13 (7.2)	10 (5.6)	15 (8.1)	25 (6.8)	38 (7.0)
Not Hispanic or Latino	168 (92.8)	168 (93.9)	171 (91.9)	339 (92.9)	507 (92.9)
Not Reported	0	1 (0.6)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0
Weight (kg)					
n	181	179	186	365	546
Mean (SD)	73.52 (12.662)	74.38 (11.319)	73.43 (13.514)	73.90 (12.478)	73.77 (12.529)
Median	72.80	73.70	72.80	73.20	73.05
Min, Max	42.8, 103.7	49.1, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	181	179	186	365	546
Mean (SD)	169.91 (9.886)	170.12 (8.889)	170.96 (10.319)	170.55 (9.640)	170.34 (9.718)
Median	167.60	169.00	170.05	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)					
n	181	179	186	365	546
Mean (SD)	25.35 (2.879)	25.63 (2.787)	24.98 (2.978)	25.30 (2.901)	25.31 (2.891)
Median	25.77	26.08	25.19	25.64	25.69
Min, Max	18.0, 30.4	18.5, 30.0	18.2, 30.1	18.2, 30.1	18.0, 30.4

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=92)	mRNA-1273				Placebo (N=89)	mRNA-1273			
		50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)		50 µg (N=89)	100 µg (N=91)	Total (N=180)	Overall (N=269)
Age (Years)										
n	92	90	95	185	277	89	89	91	180	269
Mean (SD)	37.3 (9.95)	37.0 (9.45)	38.5 (10.38)	37.8 (9.94)	37.6 (9.93)	64.3 (6.26)	64.8 (6.72)	64.0 (6.81)	64.4 (6.76)	64.4 (6.59)
Median	38.0	38.0	39.0	38.0	38.0	64.0	65.0	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	37 (40.2)	32 (35.6)	43 (45.3)	75 (40.5)	112 (40.4)	27 (30.3)	23 (25.8)	26 (28.6)	49 (27.2)	76 (28.3)
Female	55 (59.8)	58 (64.4)	52 (54.7)	110 (59.5)	165 (59.6)	62 (69.7)	66 (74.2)	65 (71.4)	131 (72.8)	193 (71.7)

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=92)	mRNA-1273				Placebo (N=89)	mRNA-1273			
		50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)		50 µg (N=89)	100 µg (N=91)	Total (N=180)	Overall (N=269)
Race, n (%)										
White	86 (93.5)	84 (93.3)	86 (90.5)	170 (91.9)	256 (92.4)	88 (98.9)	84 (94.4)	90 (98.9)	174 (96.7)	262 (97.4)
Black or African American	3 (3.3)	3 (3.3)	7 (7.4)	10 (5.4)	13 (4.7)	0	2 (2.2)	0	2 (1.1)	2 (0.7)
Asian	2 (2.2)	0	1 (1.1)	1 (0.5)	3 (1.1)	1 (1.1)	2 (2.2)	0	2 (1.1)	3 (1.1)
American Indian or Alaska Native	0	1 (1.1)	0	1 (0.5)	1 (0.4)	0	0	1 (1.1)	1 (0.6)	1 (0.4)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.1)	0	1 (0.6)	1 (0.4)
Multiracial	1 (1.1)	1 (1.1)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.1)	1 (1.1)	2 (1.1)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)	Placebo (N=89)	50 µg (N=89)	100 µg (N=91)	Total (N=180)	Overall (N=269)
Ethnicity, n (%)										
Hispanic or Latino	13 (14.1)	8 (8.9)	8 (8.4)	16 (8.6)	29 (10.5)	0	2 (2.2)	7 (7.7)	9 (5.0)	9 (3.3)
Not Hispanic or Latino	79 (85.9)	82 (91.1)	87 (91.6)	169 (91.4)	248 (89.5)	89 (100)	86 (96.6)	84 (92.3)	170 (94.4)	259 (96.3)
Not Reported	0	0	0	0	0	0	1 (1.1)	0	1 (0.6)	1 (0.4)
Unknown	0	0	0	0	0	0	0	0	0	0
Weight (kg)										
n	92	90	95	185	277	89	89	91	180	269
Mean (SD)	73.99 (12.223)	76.22 (11.417)	74.20 (13.216)	75.18 (12.382)	74.79 (12.320)	73.04 (13.153)	72.53 (10.973)	72.63 (13.846)	72.58 (12.473)	72.73 (12.680)
Median	74.15	76.80	73.50	74.80	74.50	71.60	71.70	72.80	71.95	71.70
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	50.4, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	92	90	95	185	277	89	89	91	180	269
Mean (SD)	170.87 (8.967)	171.95 (9.040)	172.58 (9.514)	172.27 (9.267)	171.80 (9.176)	168.92 (10.714)	168.27 (8.386)	169.26 (10.892)	168.77 (9.719)	168.82 (10.040)
Median	170.00	170.20	171.00	170.90	170.20	167.50	167.60	167.00	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.4
Baseline Demographics
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=92)	mRNA-1273				Placebo (N=89)	mRNA-1273			
		50 µg (N=90)	100 µg (N=95)	Total (N=185)	Overall (N=277)		50 µg (N=89)	100 µg (N=91)	Total (N=180)	Overall (N=269)
Body Mass Index (kg/m ²)										
n	92	90	95	185	277	89	89	91	180	269
Mean (SD)	25.26 (3.070)	25.72 (2.837)	24.80 (3.084)	25.25 (2.994)	25.25 (3.014)	25.44 (2.681)	25.54 (2.750)	25.16 (2.869)	25.35 (2.810)	25.38 (2.763)
Median	25.84	26.48	24.96	26.02	25.88	25.68	25.70	25.26	25.55	25.55
Min, Max	18.0, 29.8	19.3, 30.0	18.2, 29.9	18.2, 30.0	18.0, 30.0	18.9, 30.4	18.5, 29.9	18.3, 30.1	18.3, 30.1	18.3, 30.4

Percentages are based on the number of subjects in Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010304.sas 19NOV2020 00:14 Database Lock Date: 05NOV2020

Table 14.1.3.5
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific bAb

	Overall				
		mRNA-1273			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=197)	Total (N=395)	Overall (N=591)
Age (Years)					
n	196	198	197	395	591
Mean (SD)	50.9 (15.92)	50.8 (16.21)	51.1 (15.55)	51.0 (15.87)	51.0 (15.87)
Median	55.0	55.0	54.0	55.0	55.0
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	69 (35.2)	62 (31.3)	75 (38.1)	137 (34.7)	206 (34.9)
Female	127 (64.8)	136 (68.7)	122 (61.9)	258 (65.3)	385 (65.1)
Race, n (%)					
White	189 (96.4)	187 (94.4)	185 (93.9)	372 (94.2)	561 (94.9)
Black or African American	3 (1.5)	5 (2.5)	8 (4.1)	13 (3.3)	16 (2.7)
Asian	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
American Indian or Alaska Native	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.3)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0
Ethnicity, n (%)					
Hispanic or Latino	16 (8.2)	14 (7.1)	15 (7.6)	29 (7.3)	45 (7.6)
Not Hispanic or Latino	180 (91.8)	183 (92.4)	182 (92.4)	365 (92.4)	545 (92.2)
Not Reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010305.sas 19NOV2020 04:40 Database Lock Date: 05NOV2020

Table 14.1.3.5
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific bAb

	Overall				
	mRNA-1273				
	Placebo (N=196)	50 µg (N=198)	100 µg (N=197)	Total (N=395)	Overall (N=591)
Weight (kg)					
n	196	198	197	395	591
Mean (SD)	73.55 (12.847)	74.09 (11.537)	73.45 (13.534)	73.77 (12.561)	73.70 (12.646)
Median	72.90	73.75	72.80	73.20	73.10
Min, Max	42.8, 103.7	47.9, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	196	198	197	395	591
Mean (SD)	169.93 (10.234)	169.99 (8.766)	170.94 (10.359)	170.46 (9.593)	170.29 (9.805)
Median	167.80	168.90	170.00	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)					
n	196	198	197	395	591
Mean (SD)	25.34 (2.866)	25.57 (2.920)	24.98 (2.953)	25.28 (2.947)	25.30 (2.918)
Median	25.76	26.07	25.22	25.60	25.66
Min, Max	18.0, 30.4	17.9, 30.7	18.2, 30.1	17.9, 30.7	17.9, 30.7

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010305.sas 19NOV2020 04:40 Database Lock Date: 05NOV2020

Table 14.1.3.5
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=96)	50 µg (N=98)	100 µg (N=99)	Total (N=197)	Overall (N=293)	Placebo (N=100)	50 µg (N=100)	100 µg (N=98)	Total (N=198)	Overall (N=298)
Age (Years)										
n	96	98	99	197	293	100	100	98	198	298
Mean (SD)	37.0 (9.91)	36.7 (9.62)	38.4 (10.45)	37.6 (10.05)	37.4 (9.99)	64.3 (6.08)	64.6 (6.58)	64.0 (6.73)	64.3 (6.65)	64.3 (6.45)
Median	37.0	38.0	39.0	38.0	38.0	64.0	64.5	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	38 (39.6)	35 (35.7)	46 (46.5)	81 (41.1)	119 (40.6)	31 (31.0)	27 (27.0)	29 (29.6)	56 (28.3)	87 (29.2)
Female	58 (60.4)	63 (64.3)	53 (53.5)	116 (58.9)	174 (59.4)	69 (69.0)	73 (73.0)	69 (70.4)	142 (71.7)	211 (70.8)

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010305.sas 19NOV2020 04:40 Database Lock Date: 05NOV2020

Table 14.1.3.5
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=96)	50 µg (N=98)	100 µg (N=99)	Total (N=197)	Overall (N=293)	Placebo (N=100)	50 µg (N=100)	100 µg (N=98)	Total (N=198)	Overall (N=298)
Race, n (%)										
White	90 (93.8)	92 (93.9)	89 (89.9)	181 (91.9)	271 (92.5)	99 (99.0)	95 (95.0)	96 (98.0)	191 (96.5)	290 (97.3)
Black or African American	3 (3.1)	3 (3.1)	7 (7.1)	10 (5.1)	13 (4.4)	0	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.0)
Asian	2 (2.1)	0	2 (2.0)	2 (1.0)	4 (1.4)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.0)
American Indian or Alaska Native	0	1 (1.0)	0	1 (0.5)	1 (0.3)	0	0	1 (1.0)	1 (0.5)	1 (0.3)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Multiracial	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Ethnicity, n (%)										
Hispanic or Latino	14 (14.6)	10 (10.2)	8 (8.1)	18 (9.1)	32 (10.9)	2 (2.0)	4 (4.0)	7 (7.1)	11 (5.6)	13 (4.4)
Not Hispanic or Latino	82 (85.4)	88 (89.8)	91 (91.9)	179 (90.9)	261 (89.1)	98 (98.0)	95 (95.0)	91 (92.9)	186 (93.9)	284 (95.3)
Not Reported	0	0	0	0	0	0	1 (1.0)	0	1 (0.5)	1 (0.3)
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010305.sas 19NOV2020 04:40 Database Lock Date: 05NOV2020

Table 14.1.3.5
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific bAb

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=96)	50 µg (N=98)	100 µg (N=99)	Total (N=197)	Overall (N=293)	Placebo (N=100)	50 µg (N=100)	100 µg (N=98)	Total (N=198)	Overall (N=298)
Weight (kg)										
n	96	98	99	197	293	100	100	98	198	298
Mean (SD)	74.03 (12.325)	75.50 (11.770)	74.05 (13.181)	74.77 (12.488)	74.53 (12.419)	73.09 (13.374)	72.72 (11.192)	72.85 (13.922)	72.78 (12.585)	72.88 (12.834)
Median	74.15	76.70	72.30	74.50	74.50	71.65	71.95	72.90	72.25	72.05
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	47.9, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	96	98	99	197	293	100	100	98	198	298
Mean (SD)	170.85 (9.061)	171.64 (8.881)	172.52 (9.566)	172.08 (9.218)	171.68 (9.170)	169.03 (11.219)	168.38 (8.384)	169.34 (10.921)	168.86 (9.710)	168.92 (10.223)
Median	169.50	170.20	171.00	170.20	170.20	167.55	167.60	167.60	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)										
n	96	98	99	197	293	100	100	98	198	298
Mean (SD)	25.27 (3.060)	25.56 (3.025)	24.76 (3.038)	25.16 (3.050)	25.20 (3.049)	25.41 (2.680)	25.58 (2.829)	25.21 (2.862)	25.39 (2.844)	25.40 (2.786)
Median	25.84	26.44	24.96	25.63	25.66	25.69	25.74	25.36	25.59	25.64
Min, Max	18.0, 30.0	18.5, 30.7	18.2, 29.9	18.2, 30.7	18.0, 30.7	18.9, 30.4	17.9, 30.2	18.3, 30.1	17.9, 30.2	17.9, 30.4

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific bAb.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010305.sas 19NOV2020 04:40 Database Lock Date: 05NOV2020

Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Overall				Overall (N=578)
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	Total (N=387)	
Age (Years)					
n	191	192	195	387	578
Mean (SD)	50.6 (15.95)	50.4 (16.26)	50.8 (15.61)	50.6 (15.92)	50.6 (15.92)
Median	53.0	54.0	54.0	54.0	54.0
Min, Max	18, 84	18, 87	18, 87	18, 87	18, 87
Gender, n (%)					
Male	67 (35.1)	60 (31.3)	75 (38.5)	135 (34.9)	202 (34.9)
Female	124 (64.9)	132 (68.8)	120 (61.5)	252 (65.1)	376 (65.1)
Race, n (%)					
White	184 (96.3)	181 (94.3)	184 (94.4)	365 (94.3)	549 (95.0)
Black or African American	3 (1.6)	5 (2.6)	7 (3.6)	12 (3.1)	15 (2.6)
Asian	3 (1.6)	2 (1.0)	2 (1.0)	4 (1.0)	7 (1.2)
American Indian or Alaska Native	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Native Hawaiian or Other Pacific Islander	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Multiracial	1 (0.5)	1 (0.5)	0	1 (0.3)	2 (0.3)
Other	0	1 (0.5)	1 (0.5)	2 (0.5)	2 (0.3)
Not Reported	0	0	0	0	0
Unknown	0	0	0	0	0

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010306.sas 19NOV2020 04:41 Database Lock Date: 05NOV2020

Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Overall				Overall (N=578)
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	Total (N=387)	
Ethnicity, n (%)					
Hispanic or Latino	16 (8.4)	13 (6.8)	15 (7.7)	28 (7.2)	44 (7.6)
Not Hispanic or Latino	175 (91.6)	178 (92.7)	180 (92.3)	358 (92.5)	533 (92.2)
Not Reported	0	1 (0.5)	0	1 (0.3)	1 (0.2)
Unknown	0	0	0	0	0
Weight (kg)					
n	191	192	195	387	578
Mean (SD)	73.60 (12.771)	74.15 (11.427)	73.54 (13.581)	73.85 (12.546)	73.76 (12.610)
Median	72.80	73.75	72.80	73.30	73.10
Min, Max	42.8, 103.7	49.1, 105.3	44.0, 110.7	44.0, 110.7	42.8, 110.7
Height (cm)					
n	191	192	195	387	578
Mean (SD)	169.90 (10.109)	170.03 (8.756)	171.11 (10.330)	170.58 (9.584)	170.36 (9.757)
Median	167.60	168.90	170.10	169.00	168.90
Min, Max	144.8, 200.7	151.0, 192.0	144.3, 199.4	144.3, 199.4	144.3, 200.7
Body Mass Index (kg/m ²)					
n	191	192	195	387	578
Mean (SD)	25.37 (2.849)	25.58 (2.892)	24.96 (2.960)	25.27 (2.939)	25.30 (2.908)
Median	25.77	26.07	25.15	25.55	25.65
Min, Max	18.0, 30.4	18.5, 30.7	18.2, 30.1	18.2, 30.7	18.0, 30.7

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010306.sas 19NOV2020 04:41 Database Lock Date: 05NOV2020

Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=96)	mRNA-1273				Placebo (N=95)	mRNA-1273			
		50 µg (N=98)	100 µg (N=100)	Total (N=198)	Overall (N=294)		50 µg (N=94)	100 µg (N=95)	Total (N=189)	Overall (N=284)
Age (Years)										
n	96	98	100	198	294	95	94	95	189	284
Mean (SD)	37.0 (9.91)	36.7 (9.62)	38.3 (10.42)	37.5 (10.04)	37.4 (9.98)	64.3 (6.14)	64.7 (6.62)	64.0 (6.80)	64.3 (6.70)	64.3 (6.51)
Median	37.0	38.0	38.5	38.0	38.0	64.0	64.5	63.0	64.0	64.0
Min, Max	18, 53	18, 54	18, 54	18, 54	18, 54	55, 84	55, 87	55, 87	55, 87	55, 87
Gender, n (%)										
Male	38 (39.6)	35 (35.7)	47 (47.0)	82 (41.4)	120 (40.8)	29 (30.5)	25 (26.6)	28 (29.5)	53 (28.0)	82 (28.9)
Female	58 (60.4)	63 (64.3)	53 (53.0)	116 (58.6)	174 (59.2)	66 (69.5)	69 (73.4)	67 (70.5)	136 (72.0)	202 (71.1)

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010306.sas 19NOV2020 04:41 Database Lock Date: 05NOV2020

Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=96)	50 µg (N=98)	100 µg (N=100)	Total (N=198)	Overall (N=294)	Placebo (N=95)	50 µg (N=94)	100 µg (N=95)	Total (N=189)	Overall (N=284)
Race, n (%)										
White	90 (93.8)	92 (93.9)	90 (90.0)	182 (91.9)	272 (92.5)	94 (98.9)	89 (94.7)	94 (98.9)	183 (96.8)	277 (97.5)
Black or African American	3 (3.1)	3 (3.1)	7 (7.0)	10 (5.1)	13 (4.4)	0	2 (2.1)	0	2 (1.1)	2 (0.7)
Asian	2 (2.1)	0	2 (2.0)	2 (1.0)	4 (1.4)	1 (1.1)	2 (2.1)	0	2 (1.1)	3 (1.1)
American Indian or Alaska Native	0	1 (1.0)	0	1 (0.5)	1 (0.3)	0	0	1 (1.1)	1 (0.5)	1 (0.4)
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	1 (1.1)	0	1 (0.5)	1 (0.4)
Multiracial	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (0.7)	0	0	0	0	0
Other	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (0.7)	0	0	0	0	0
Not Reported	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010306.sas 19NOV2020 04:41 Database Lock Date: 05NOV2020

Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	mRNA-1273					mRNA-1273				
	Placebo (N=96)	50 µg (N=98)	100 µg (N=100)	Total (N=198)	Overall (N=294)	Placebo (N=95)	50 µg (N=94)	100 µg (N=95)	Total (N=189)	Overall (N=284)
Ethnicity, n (%)										
Hispanic or Latino	14 (14.6)	10 (10.2)	8 (8.0)	18 (9.1)	32 (10.9)	2 (2.1)	3 (3.2)	7 (7.4)	10 (5.3)	12 (4.2)
Not Hispanic or Latino	82 (85.4)	88 (89.8)	92 (92.0)	180 (90.9)	262 (89.1)	93 (97.9)	90 (95.7)	88 (92.6)	178 (94.2)	271 (95.4)
Not Reported	0	0	0	0	0	0	1 (1.1)	0	1 (0.5)	1 (0.4)
Unknown	0	0	0	0	0	0	0	0	0	0
Weight (kg)										
n	96	98	100	198	294	95	94	95	189	284
Mean (SD)	74.03 (12.325)	75.50 (11.770)	74.14 (13.147)	74.81 (12.471)	74.56 (12.408)	73.16 (13.257)	72.75 (10.946)	72.91 (14.065)	72.83 (12.577)	72.94 (12.786)
Median	74.15	76.70	72.90	74.55	74.50	71.60	71.95	72.80	72.10	72.00
Min, Max	42.8, 103.7	49.1, 101.0	50.9, 110.7	49.1, 110.7	42.8, 110.7	51.5, 102.4	50.4, 105.3	44.0, 105.4	44.0, 105.4	44.0, 105.4
Height (cm)										
n	96	98	100	198	294	95	94	95	189	284
Mean (SD)	170.85 (9.061)	171.64 (8.881)	172.61 (9.565)	172.13 (9.222)	171.71 (9.174)	168.94 (11.032)	168.36 (8.345)	169.54 (10.909)	168.95 (9.711)	168.95 (10.152)
Median	169.50	170.20	171.00	170.20	170.20	167.50	167.60	167.60	167.60	167.60
Min, Max	154.0, 191.1	152.4, 192.0	153.0, 196.0	152.4, 196.0	152.4, 196.0	144.8, 200.7	151.0, 191.6	144.3, 199.4	144.3, 199.4	144.3, 200.7

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

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Table 14.1.3.6
Baseline Demographics
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=96)	mRNA-1273				Placebo (N=95)	mRNA-1273			
		50 µg (N=98)	100 µg (N=100)	Total (N=198)	Overall (N=294)		50 µg (N=94)	100 µg (N=95)	Total (N=189)	Overall (N=284)
Body Mass Index (kg/m ²)										
n	96	98	100	198	294	95	94	95	189	284
Mean (SD)	25.27 (3.060)	25.56 (3.025)	24.77 (3.023)	25.16 (3.043)	25.20 (3.044)	25.47 (2.631)	25.60 (2.762)	25.17 (2.895)	25.38 (2.831)	25.41 (2.761)
Median	25.84	26.44	25.02	25.57	25.65	25.70	25.74	25.26	25.55	25.64
Min, Max	18.0, 30.0	18.5, 30.7	18.2, 29.9	18.2, 30.7	18.0, 30.7	18.9, 30.4	18.5, 30.2	18.3, 30.1	18.3, 30.2	18.3, 30.4

Percentages are based on the number of subjects in Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot.

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Table 14.1.4.1
Summary of Concomitant Medication
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Any Concomitant Medications or Non-Study Vaccination Within 7 Days Post Injection	34 (17.0)	82 (41.0)	112 (56.0)	194 (48.5)
Any Concomitant Medications or Non-Study Vaccination Within 28 Days Post Injection	56 (28.0)	94 (47.0)	122 (61.0)	216 (54.0)
Prophylactic Antipyretics or Analgesics Medication Within 28 Days Post Injection	0	0	0	0
Antipyretic or Analgesic Medication Within 28 Days Post Injection	31 (15.5)	80 (40.0)	102 (51.0)	182 (45.5)

Percentages are based on the number of safety subjects.

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Table 14.1.4.1
Summary of Concomitant Medication
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Any Concomitant Medications or Non-Study Vaccination Within 7 Days Post Injection	13 (13.0)	46 (46.0)	61 (61.0)	107 (53.5)	21 (21.0)	36 (36.0)	51 (51.0)	87 (43.5)
Any Concomitant Medications or Non-Study Vaccination Within 28 Days Post Injection	23 (23.0)	50 (50.0)	62 (62.0)	112 (56.0)	33 (33.0)	44 (44.0)	60 (60.0)	104 (52.0)
Prophylactic Antipyretics or Analgesics Medication Within 28 Days Post Injection	0	0	0	0	0	0	0	0
Antipyretic or Analgesic Medication Within 28 Days Post Injection	14 (14.0)	46 (46.0)	59 (59.0)	105 (52.5)	17 (17.0)	34 (34.0)	43 (43.0)	77 (38.5)

Percentages are based on the number of safety subjects.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects with At Least One Concomitant Medication	148 (74.0)	165 (82.5)	171 (85.5)	336 (84.0)
IBUPROFEN	22 (11.0)	55 (27.5)	61 (30.5)	116 (29.0)
PARACETAMOL	17 (8.5)	35 (17.5)	55 (27.5)	90 (22.5)
VITAMINS NOS	18 (9.0)	25 (12.5)	22 (11.0)	47 (11.8)
ACETYLSALICYLIC ACID	12 (6.0)	11 (5.5)	11 (5.5)	22 (5.5)
NAPROXEN SODIUM	8 (4.0)	11 (5.5)	11 (5.5)	22 (5.5)
FISH OIL	5 (2.5)	11 (5.5)	10 (5.0)	21 (5.3)
LEVONORGESTREL	5 (2.5)	13 (6.5)	6 (3.0)	19 (4.8)
LORATADINE	10 (5.0)	10 (5.0)	7 (3.5)	17 (4.3)
CETIRIZINE HYDROCHLORIDE	6 (3.0)	10 (5.0)	6 (3.0)	16 (4.0)
VITAMIN D NOS	6 (3.0)	9 (4.5)	7 (3.5)	16 (4.0)
COLECALCIFEROL	3 (1.5)	8 (4.0)	7 (3.5)	15 (3.8)
ASCORBIC ACID	3 (1.5)	7 (3.5)	8 (4.0)	15 (3.8)
ATORVASTATIN	11 (5.5)	5 (2.5)	8 (4.0)	13 (3.3)
ESTRADIOL	9 (4.5)	5 (2.5)	8 (4.0)	13 (3.3)
OMEPRAZOLE	7 (3.5)	6 (3.0)	7 (3.5)	13 (3.3)
NAPROXEN	3 (1.5)	7 (3.5)	5 (2.5)	12 (3.0)
ESCITALOPRAM	3 (1.5)	9 (4.5)	1 (0.5)	10 (2.5)
SUMATRIPTAN	7 (3.5)	8 (4.0)	1 (0.5)	9 (2.3)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
TRAZODONE	4 (2.0)	2 (1.0)	7 (3.5)	9 (2.3)
SIMVASTATIN	3 (1.5)	6 (3.0)	3 (1.5)	9 (2.3)
VITAMIN B12 NOS	2 (1.0)	8 (4.0)	1 (0.5)	9 (2.3)
ETHINYLESTRADIOL;NORGESTIMATE	2 (1.0)	3 (1.5)	6 (3.0)	9 (2.3)
GABAPENTIN	1 (0.5)	5 (2.5)	4 (2.0)	9 (2.3)
CALCIUM	9 (4.5)	4 (2.0)	4 (2.0)	8 (2.0)
FLUTICASONE PROPIONATE	6 (3.0)	5 (2.5)	3 (1.5)	8 (2.0)
DIPHENHYDRAMINE HYDROCHLORIDE	4 (2.0)	5 (2.5)	3 (1.5)	8 (2.0)
VALACICLOVIR	4 (2.0)	3 (1.5)	5 (2.5)	8 (2.0)
MELATONIN	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
LEVOTHYROXINE	2 (1.0)	5 (2.5)	3 (1.5)	8 (2.0)
PROGESTERONE	2 (1.0)	3 (1.5)	5 (2.5)	8 (2.0)
PROBIOTICS NOS	1 (0.5)	3 (1.5)	5 (2.5)	8 (2.0)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	4 (2.0)	5 (2.5)	2 (1.0)	7 (1.8)
ESCITALOPRAM OXALATE	4 (2.0)	2 (1.0)	5 (2.5)	7 (1.8)
MELOXICAM	1 (0.5)	4 (2.0)	3 (1.5)	7 (1.8)
PANTOPRAZOLE	1 (0.5)	2 (1.0)	5 (2.5)	7 (1.8)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	6 (3.0)	2 (1.0)	4 (2.0)	6 (1.5)
SERTRALINE	3 (1.5)	1 (0.5)	5 (2.5)	6 (1.5)
SERTRALINE HYDROCHLORIDE	2 (1.0)	1 (0.5)	5 (2.5)	6 (1.5)
FLUOXETINE HYDROCHLORIDE	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
IRON	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
CETIRIZINE	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
ZOLPIDEM TARTRATE	0	3 (1.5)	3 (1.5)	6 (1.5)
VITAMIN B COMPLEX	0	1 (0.5)	5 (2.5)	6 (1.5)
SPIRONOLACTONE	4 (2.0)	1 (0.5)	4 (2.0)	5 (1.3)
ROSUVASTATIN	3 (1.5)	1 (0.5)	4 (2.0)	5 (1.3)
LATANOPROST	2 (1.0)	3 (1.5)	2 (1.0)	5 (1.3)
BUPROPION	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
LEVOTHYROXINE SODIUM	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
TOPIRAMATE	1 (0.5)	4 (2.0)	1 (0.5)	5 (1.3)
BIOTIN	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
OXYBUTYNIN	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
FIBRE, DIETARY	1 (0.5)	0	5 (2.5)	5 (1.3)
CELECOXIB	4 (2.0)	2 (1.0)	2 (1.0)	4 (1.0)

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Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	4 (2.0)	0	4 (2.0)	4 (1.0)
FEXOFENADINE HYDROCHLORIDE	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
BUPROPION HYDROCHLORIDE	2 (1.0)	4 (2.0)	0	4 (1.0)
TRAMADOL	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
CURCUMA LONGA	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
HYDROCORTISONE	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
CHONDROITIN;GLUCOSAMINE	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	2 (1.0)	0	4 (2.0)	4 (1.0)
DENOSUMAB	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
TAMSULOSIN	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
MINERALS NOS;VITAMINS NOS	0	0	4 (2.0)	4 (1.0)
CLONAZEPAM	4 (2.0)	2 (1.0)	1 (0.5)	3 (0.8)
CALCIUM;VITAMIN D NOS	2 (1.0)	3 (1.5)	0	3 (0.8)
MONTELUKAST SODIUM	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
GLUCOSAMINE	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
CITALOPRAM	2 (1.0)	1 (0.5)	2 (1.0)	3 (0.8)
AMOXICILLIN	1 (0.5)	3 (1.5)	0	3 (0.8)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

WHODrug version: WHODrug-Global-B3 March 2020

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
LOVASTATIN	1 (0.5)	3 (1.5)	0	3 (0.8)
MAGNESIUM	1 (0.5)	3 (1.5)	0	3 (0.8)
VENLAFAXINE HYDROCHLORIDE	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
LISDEXAMFETAMINE MESILATE	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
ROSUVASTATIN CALCIUM	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
DIPHENHYDRAMINE	1 (0.5)	0	3 (1.5)	3 (0.8)
TESTOSTERONE	1 (0.5)	0	3 (1.5)	3 (0.8)
LINUM USITATISSIMUM SEED OIL	0	3 (1.5)	0	3 (0.8)
ZOLPIDEM	0	3 (1.5)	0	3 (0.8)
METHYLPHENIDATE	0	2 (1.0)	1 (0.5)	3 (0.8)
DOXYCYCLINE	0	1 (0.5)	2 (1.0)	3 (0.8)
LISINAPRIL	0	1 (0.5)	2 (1.0)	3 (0.8)
PREDNISONE	0	1 (0.5)	2 (1.0)	3 (0.8)
CICLOSPORIN	0	1 (0.5)	2 (1.0)	3 (0.8)
RALOXIFENE	0	1 (0.5)	2 (1.0)	3 (0.8)
TRIAMCINOLONE ACETONIDE	0	0	3 (1.5)	3 (0.8)
FLUTICASONE	3 (1.5)	1 (0.5)	1 (0.5)	2 (0.5)
BUSPIRONE	3 (1.5)	0	2 (1.0)	2 (0.5)
CEFALEXIN	2 (1.0)	2 (1.0)	0	2 (0.5)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

WHODrug version: WHODrug-Global-B3 March 2020

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
FAMOTIDINE	2 (1.0)	2 (1.0)	0	2 (0.5)
ALPRAZOLAM	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
PRAVASTATIN	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
MEDROXYPROGESTERONE ACETATE	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (1.0)	0	2 (1.0)	2 (0.5)
VENLAFAXINE	1 (0.5)	2 (1.0)	0	2 (0.5)
DULOXETINE HYDROCHLORIDE	1 (0.5)	2 (1.0)	0	2 (0.5)
LEVOCETIRIZINE DIHYDROCHLORIDE	1 (0.5)	2 (1.0)	0	2 (0.5)
LAMOTRIGINE	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
FLUOXETINE	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
METHYLPHENIDATE HYDROCHLORIDE	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
AMFETAMINE;DEXAMFETAMINE	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
METRONIDAZOLE	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
ACICLOVIR	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
TADALAFIL	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
ALLOPURINOL	1 (0.5)	0	2 (1.0)	2 (0.5)
OMEGA-3 NOS	1 (0.5)	0	2 (1.0)	2 (0.5)
LORAZEPAM	1 (0.5)	0	2 (1.0)	2 (0.5)
DOCUSATE SODIUM	1 (0.5)	0	2 (1.0)	2 (0.5)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

WHODrug version: WHODrug-Global-B3 March 2020

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
ETHINYLESTRADIOL;NORETHISTERONE	0	2 (1.0)	0	2 (0.5)
BUTALBITAL;CAFFEINE;PARACETAMOL	0	2 (1.0)	0	2 (0.5)
NITROFURANTOIN	0	2 (1.0)	0	2 (0.5)
OMEGA-3 FATTY ACIDS	0	2 (1.0)	0	2 (0.5)
PROPRANOLOL	0	2 (1.0)	0	2 (0.5)
AMITRIPTYLINE	0	2 (1.0)	0	2 (0.5)
UBIDECARENONE	0	2 (1.0)	0	2 (0.5)
ETHINYLESTRADIOL;ETONOGESTREL	0	1 (0.5)	1 (0.5)	2 (0.5)
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (0.5)	1 (0.5)	2 (0.5)
NORETHISTERONE	0	1 (0.5)	1 (0.5)	2 (0.5)
ESOMEPRAZOLE MAGNESIUM	0	1 (0.5)	1 (0.5)	2 (0.5)
FINASTERIDE	0	1 (0.5)	1 (0.5)	2 (0.5)
GUAIFENESIN	0	1 (0.5)	1 (0.5)	2 (0.5)
METFORMIN	0	1 (0.5)	1 (0.5)	2 (0.5)
PENICILLIN NOS	0	1 (0.5)	1 (0.5)	2 (0.5)
ADEMETHIONINE	0	1 (0.5)	1 (0.5)	2 (0.5)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	1 (0.5)	1 (0.5)	2 (0.5)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
CALCIUM CARBONATE	0	1 (0.5)	1 (0.5)	2 (0.5)
CHONDROITIN	0	1 (0.5)	1 (0.5)	2 (0.5)
FREMANEZUMAB	0	1 (0.5)	1 (0.5)	2 (0.5)
HYALURONIC ACID	0	1 (0.5)	1 (0.5)	2 (0.5)
VARICELLA ZOSTER VACCINE RGE (CHO)	0	1 (0.5)	1 (0.5)	2 (0.5)
VITAMIN E NOS	0	1 (0.5)	1 (0.5)	2 (0.5)
ETHINYLESTRADIOL;NORGESTREL	0	0	2 (1.0)	2 (0.5)
HYDROCODONE;PARACETAMOL	0	0	2 (1.0)	2 (0.5)
CALCIUM CITRATE	0	0	2 (1.0)	2 (0.5)
SILDENAFIL	0	0	2 (1.0)	2 (0.5)
CITALOPRAM HYDROBROMIDE	3 (1.5)	1 (0.5)	0	1 (0.3)
ALENDRONATE SODIUM	3 (1.5)	0	1 (0.5)	1 (0.3)
DESGESTREL;ETHINYLESTRADIOL	2 (1.0)	1 (0.5)	0	1 (0.3)
ETHINYLESTRADIOL;LEVONORGESTREL	2 (1.0)	1 (0.5)	0	1 (0.3)
ETONOGESTREL	2 (1.0)	1 (0.5)	0	1 (0.3)
DIPHENHYDRAMINE	2 (1.0)	1 (0.5)	0	1 (0.3)
HYDROCHLORIDE;PARACETAMOL				
LORATADINE;PSEUDOEPHEDRINE SULFATE	2 (1.0)	1 (0.5)	0	1 (0.3)
PAROXETINE HYDROCHLORIDE	2 (1.0)	1 (0.5)	0	1 (0.3)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	2 (1.0)	0	1 (0.5)	1 (0.3)
VORTIOXETINE HYDROBROMIDE	2 (1.0)	0	1 (0.5)	1 (0.3)
ESOMEPRAZOLE	2 (1.0)	0	1 (0.5)	1 (0.3)
CLINDAMYCIN	1 (0.5)	1 (0.5)	0	1 (0.3)
ATORVASTATIN CALCIUM	1 (0.5)	1 (0.5)	0	1 (0.3)
LINACLOTIDE	1 (0.5)	1 (0.5)	0	1 (0.3)
MEDIUM-CHAIN TRIGLYCERIDES	1 (0.5)	1 (0.5)	0	1 (0.3)
METHYLPREDNISOLONE	1 (0.5)	1 (0.5)	0	1 (0.3)
TRIAMCINOLONE	1 (0.5)	1 (0.5)	0	1 (0.3)
VALACICLOVIR HYDROCHLORIDE	1 (0.5)	1 (0.5)	0	1 (0.3)
LACTOBACILLUS ACIDOPHILUS	1 (0.5)	1 (0.5)	0	1 (0.3)
MIRABEGRON	1 (0.5)	1 (0.5)	0	1 (0.3)
PHENTERMINE	1 (0.5)	1 (0.5)	0	1 (0.3)
RIZATRIPTAN BENZOATE	1 (0.5)	1 (0.5)	0	1 (0.3)
AMITRIPTYLINE HYDROCHLORIDE	1 (0.5)	1 (0.5)	0	1 (0.3)
DICLOFENAC SODIUM	1 (0.5)	1 (0.5)	0	1 (0.3)
DORZOLAMIDE	1 (0.5)	1 (0.5)	0	1 (0.3)
ESTRADIOL;NORETHISTERONE ACETATE	1 (0.5)	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.

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Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
IBANDRONATE SODIUM	1 (0.5)	1 (0.5)	0	1 (0.3)
PRASTERONE	1 (0.5)	1 (0.5)	0	1 (0.3)
ZINC	1 (0.5)	1 (0.5)	0	1 (0.3)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.5)	0	1 (0.5)	1 (0.3)
MACROGOL 3350	1 (0.5)	0	1 (0.5)	1 (0.3)
DEXTROMETHORPHAN	1 (0.5)	0	1 (0.5)	1 (0.3)
HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	1 (0.5)	1 (0.3)
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	1 (0.5)	0	1 (0.5)	1 (0.3)
AZITHROMYCIN	1 (0.5)	0	1 (0.5)	1 (0.3)
DULOXETINE	1 (0.5)	0	1 (0.5)	1 (0.3)
ALLERGENS NOS	1 (0.5)	0	1 (0.5)	1 (0.3)
DESVENLAFAXINE SUCCINATE	1 (0.5)	0	1 (0.5)	1 (0.3)
ESTROGENS CONJUGATED	1 (0.5)	0	1 (0.5)	1 (0.3)
ESZOPICLONE	1 (0.5)	0	1 (0.5)	1 (0.3)
MIRTAZAPINE	1 (0.5)	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)

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Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
ALLIUM SATIVUM	0	1 (0.5)	0	1 (0.3)
AMLODIPINE	0	1 (0.5)	0	1 (0.3)
BORON;CALCIUM;CIMICIFUGA RACEMOSA EXTRACT;FOLIC ACID;GLYCINE MAX EXTRACT;MAGNOLIA OFFICINALIS;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM; THIAMINE;TOCOPHEROL;VITAMIN B12 NOS	0	1 (0.5)	0	1 (0.3)
CALCIUM;MAGNESIUM;ZINC	0	1 (0.5)	0	1 (0.3)
CHLORPHENAMINE	0	1 (0.5)	0	1 (0.3)
MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPH RINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DEXLANSOPRAZOLE	0	1 (0.5)	0	1 (0.3)
DEXTROMETHORPHAN	0	1 (0.5)	0	1 (0.3)

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		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
DEXTROMETHORPHAN	0	1 (0.5)	0	1 (0.3)
HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DICYCLOVERINE	0	1 (0.5)	0	1 (0.3)
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	0	1 (0.5)	0	1 (0.3)
FISH OIL;VITAMIN D NOS	0	1 (0.5)	0	1 (0.3)
GLYCOPYRROLUM	0	1 (0.5)	0	1 (0.3)
HYDROCHLOROTHIAZIDE;TRIAMTERENE	0	1 (0.5)	0	1 (0.3)
HYDROXYZINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
ISOTRETINOIN	0	1 (0.5)	0	1 (0.3)
LACOSAMIDE	0	1 (0.5)	0	1 (0.3)
LEVETIRACETAM	0	1 (0.5)	0	1 (0.3)
LEVOCETIRIZINE	0	1 (0.5)	0	1 (0.3)
LOTEPREDNOL;TOBRAMYCIN	0	1 (0.5)	0	1 (0.3)
MEPYRAMINE	0	1 (0.5)	0	1 (0.3)
MALEATE;PAMABROM;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
MESTRANOL;NORETHISTERONE	0	1 (0.5)	0	1 (0.3)
PAROXETINE	0	1 (0.5)	0	1 (0.3)

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Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
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PHENYLEPHRINE	0	1 (0.5)	0	1 (0.3)
PREGABALIN	0	1 (0.5)	0	1 (0.3)
RANITIDINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
RIZATRIPTAN	0	1 (0.5)	0	1 (0.3)
SUCRALFATE	0	1 (0.5)	0	1 (0.3)
TIZANIDINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
TRAMADOL HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
VILAZODONE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
ACETYLCYSTEINE	0	1 (0.5)	0	1 (0.3)
ADAPALENE	0	1 (0.5)	0	1 (0.3)
ANESTHETICS, LOCAL	0	1 (0.5)	0	1 (0.3)
ARIPIRAZOLE	0	1 (0.5)	0	1 (0.3)
ASCORBIC ACID;BIOTIN;DL-ALPHA TOCOPHERYL ACETATE	0	1 (0.5)	0	1 (0.3)
ASCORBIC ACID;SELENIUM;VITAMIN E NOS;XANTOXYL;ZEAXANTHIN;ZINC	0	1 (0.5)	0	1 (0.3)
BEPOTASTINE	0	1 (0.5)	0	1 (0.3)
BORAGO OFFICINALIS OIL	0	1 (0.5)	0	1 (0.3)

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	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	0	1 (0.5)	0	1 (0.3)
BROLUCIZUMAB DBLL	0	1 (0.5)	0	1 (0.3)
BROMELAINS;QUERCETIN	0	1 (0.5)	0	1 (0.3)
CALCIUM;MAGNESIUM	0	1 (0.5)	0	1 (0.3)
CARMELLOSE SODIUM	0	1 (0.5)	0	1 (0.3)
CLOBETASOL	0	1 (0.5)	0	1 (0.3)
COLECALCIFEROL;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	0	1 (0.5)	0	1 (0.3)
COLLAGEN	0	1 (0.5)	0	1 (0.3)
CYCLOBENZAPRINE	0	1 (0.5)	0	1 (0.3)
DOXYLAMINE SUCCINATE	0	1 (0.5)	0	1 (0.3)
FENOFIBRATE	0	1 (0.5)	0	1 (0.3)
GEMFIBROZIL	0	1 (0.5)	0	1 (0.3)
INFLUENZA VACCINE INACT SPLIT 4V	0	1 (0.5)	0	1 (0.3)
LINUM USITATISSIMUM OIL	0	1 (0.5)	0	1 (0.3)
LOPERAMIDE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
LUBIPROSTONE	0	1 (0.5)	0	1 (0.3)
MINOCYCLINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)

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MONASCUS PURPUREUS	0	1 (0.5)	0	1 (0.3)
MONTELUKAST	0	1 (0.5)	0	1 (0.3)
MORINGA OLEIFERA LEAF	0	1 (0.5)	0	1 (0.3)
NICOTINAMIDE	0	1 (0.5)	0	1 (0.3)
NORTRIPTYLINE	0	1 (0.5)	0	1 (0.3)
OLEA EUROPAEA LEAF	0	1 (0.5)	0	1 (0.3)
OXYCODONE;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
PLANTAGO OVATA	0	1 (0.5)	0	1 (0.3)
PYRIDOXINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
ROPINIROLE	0	1 (0.5)	0	1 (0.3)
SILYBUM MARIANUM	0	1 (0.5)	0	1 (0.3)
TILACTASE	0	1 (0.5)	0	1 (0.3)
TIMOLOL MALEATE	0	1 (0.5)	0	1 (0.3)
UBIQUINOL	0	1 (0.5)	0	1 (0.3)
VACCINIUM MACROCARPON	0	1 (0.5)	0	1 (0.3)
VALSARTAN	0	1 (0.5)	0	1 (0.3)
VITAMIN B NOS	0	1 (0.5)	0	1 (0.3)
VITAMIN K NOS	0	1 (0.5)	0	1 (0.3)
ZOLMITRIPTAN	0	1 (0.5)	0	1 (0.3)

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Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
ASCORBIC ACID;VITAMIN D NOS	0	0	1 (0.5)	1 (0.3)
AZELAIC ACID	0	0	1 (0.5)	1 (0.3)
CARBAMAZEPINE	0	0	1 (0.5)	1 (0.3)
CEFIXIME	0	0	1 (0.5)	1 (0.3)
CHROMIUM PICOLINATE	0	0	1 (0.5)	1 (0.3)
DEXAMETHASONE	0	0	1 (0.5)	1 (0.3)
DEXTROMETHORPHAN	0	0	1 (0.5)	1 (0.3)
HYDROBROMIDE; PARACETAMOL; PHENYLEPH RINE HYDROCHLORIDE				
DROSPIRENONE;ETHINYLESTRADIOL	0	0	1 (0.5)	1 (0.3)
EZETIMIBE	0	0	1 (0.5)	1 (0.3)
FERROUS GLUCONATE	0	0	1 (0.5)	1 (0.3)
GINSENG NOS	0	0	1 (0.5)	1 (0.3)
LEVOMILNACIPRAN HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
NALTREXONE	0	0	1 (0.5)	1 (0.3)
OXYCODONE HYDROCHLORIDE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
PREDNISONE ACETATE	0	0	1 (0.5)	1 (0.3)
PROGESTOGENS AND ESTROGENS IN COMBINATION	0	0	1 (0.5)	1 (0.3)

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	Placebo (N=200) n (%)	mRNA-1273		
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PRUNUS SPP.; SENNA SPP. LEAF	0	0	1 (0.5)	1 (0.3)
QUETIAPINE FUMARATE	0	0	1 (0.5)	1 (0.3)
TEMAZEPAM	0	0	1 (0.5)	1 (0.3)
TERBINAFINE	0	0	1 (0.5)	1 (0.3)
TESTOSTERONE CIPIONATE	0	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID; ASPARTAME; PHENYLALANINE; PHENY LPROPANOLAMINE BITARTRATE	0	0	1 (0.5)	1 (0.3)
ALFUZOSIN	0	0	1 (0.5)	1 (0.3)
ALPHA-AMYLASE SWINE PANCREAS; CELLULASE; LIPASE; PROTEASE NOS	0	0	1 (0.5)	1 (0.3)
ASCORBIC ACID; VACCINIUM MACROCARPON	0	0	1 (0.5)	1 (0.3)
AZELASTINE	0	0	1 (0.5)	1 (0.3)
BRIMONIDINE TARTRATE	0	0	1 (0.5)	1 (0.3)
BUSPIRONE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
CEFUROXIME AXETIL	0	0	1 (0.5)	1 (0.3)
CHONDROITIN SULFATE SODIUM; GLUCOSAMINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)

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COLCHICINE	0	0	1 (0.5)	1 (0.3)
CYCLOBENZAPRINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
DESVENLAFAXINE	0	0	1 (0.5)	1 (0.3)
DICLOFENAC	0	0	1 (0.5)	1 (0.3)
ECHINACEA SPP.; ZINC	0	0	1 (0.5)	1 (0.3)
EFINACONAZOLE	0	0	1 (0.5)	1 (0.3)
ENZYMES NOS; PROBIOTICS NOS	0	0	1 (0.5)	1 (0.3)
ESTROGEN NOS; TESTOSTERONE	0	0	1 (0.5)	1 (0.3)
FEXOFENADINE	0	0	1 (0.5)	1 (0.3)
GLYCEROL	0	0	1 (0.5)	1 (0.3)
HYDROCODONE BITARTRATE; PARACETAMOL	0	0	1 (0.5)	1 (0.3)
HYLAN G-F 20	0	0	1 (0.5)	1 (0.3)
INDOMETACIN	0	0	1 (0.5)	1 (0.3)
LIOthyRONINE	0	0	1 (0.5)	1 (0.3)
MENTHA X PIPERITA OIL	0	0	1 (0.5)	1 (0.3)
MOXIFLOXACIN	0	0	1 (0.5)	1 (0.3)
OSPEMIFENE	0	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
OXYMETAZOLINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)

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		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	0	1 (0.5)	1 (0.3)
PLECANATIDE	0	0	1 (0.5)	1 (0.3)
PREDNISOLONE ACETATE	0	0	1 (0.5)	1 (0.3)
QUETIAPINE	0	0	1 (0.5)	1 (0.3)
TERAZOSIN	0	0	1 (0.5)	1 (0.3)
THYROID	0	0	1 (0.5)	1 (0.3)
CETIRIZINE	3 (1.5)	0	0	0
HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE				
PSEUDOEPHEDRINE	3 (1.5)	0	0	0
BISACODYL	2 (1.0)	0	0	0
FERROUS SULFATE	2 (1.0)	0	0	0
LIFITEGRAST	2 (1.0)	0	0	0
AMOXICILLIN; CLAVULANATE POTASSIUM	1 (0.5)	0	0	0
BIOFLAVONOIDS NOS	1 (0.5)	0	0	0
CALAMINE	1 (0.5)	0	0	0
CIPROFLOXACIN	1 (0.5)	0	0	0
CODEINE PHOSPHATE; PARACETAMOL	1 (0.5)	0	0	0
CRISABOROLE	1 (0.5)	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
DESOXIMETASONE	1 (0.5)	0	0	0
EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE	1 (0.5)	0	0	0
ERENUMAB	1 (0.5)	0	0	0
FACTOR X (STUART PROWER FACTOR)	1 (0.5)	0	0	0
HYDROCORTISONE; NEOMYCIN; POLYMYXIN B	1 (0.5)	0	0	0
LANSOPRAZOLE	1 (0.5)	0	0	0
LIDOCAINE; TRIAMCINOLONE	1 (0.5)	0	0	0
LORATADINE; PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.5)	0	0	0
MAGNESIUM CITRATE	1 (0.5)	0	0	0
MINOCYCLINE	1 (0.5)	0	0	0
SERMORELIN	1 (0.5)	0	0	0
TRAZODONE HYDROCHLORIDE	1 (0.5)	0	0	0
TRIAMTERENE	1 (0.5)	0	0	0
ALGELDRATE; MAGNESIUM HYDROXIDE	1 (0.5)	0	0	0
APIXABAN	1 (0.5)	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
AZELASTINE HYDROCHLORIDE; FLUTICASONE PROPIONATE	1 (0.5)	0	0	0
BACLOFEN	1 (0.5)	0	0	0
BAZEDOXIFENE; ESTROGENS CONJUGATED	1 (0.5)	0	0	0
BIMATOPROST	1 (0.5)	0	0	0
BUPIVACAINE HYDROCHLORIDE	1 (0.5)	0	0	0
CALENDULA OFFICINALIS; GRINDELIA ROBUSTA; PLANTAGO MAJOR	1 (0.5)	0	0	0
CHLORPHENAMINE MALEATE	1 (0.5)	0	0	0
CHLORPHENAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)	0	0	0
DOCUSATE	1 (0.5)	0	0	0
ETHINYLESTRADIOL	1 (0.5)	0	0	0
FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.5)	0	0	0
HYDRALAZINE HYDROCHLORIDE	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
HYDROCODONE	1 (0.5)	0	0	0
KRILL OIL	1 (0.5)	0	0	0
MAGNESIUM CHLORIDE	1 (0.5)	0	0	0
MECLOZINE HYDROCHLORIDE	1 (0.5)	0	0	0
MEDROXYPROGESTERONE	1 (0.5)	0	0	0
MOMETASONE FUROATE	1 (0.5)	0	0	0
NAPROXEN SODIUM; SUMATRIPTAN SUCCINATE	1 (0.5)	0	0	0
NORETHISTERONE ACETATE	1 (0.5)	0	0	0
ONDANSETRON	1 (0.5)	0	0	0
OXYMETAZOLINE	1 (0.5)	0	0	0
PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)	0	0	0
PRAMIPEXOLE	1 (0.5)	0	0	0
ROPINIROLE HYDROCHLORIDE	1 (0.5)	0	0	0
TOLTERODINE L-TARTRATE	1 (0.5)	0	0	0
TRAVOPROST	1 (0.5)	0	0	0
TRETINOIN	1 (0.5)	0	0	0
VARDENAFIL HYDROCHLORIDE	1 (0.5)	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects with At Least One Concomitant Medication	66 (66.0)	77 (77.0)	81 (81.0)	158 (79.0)	82 (82.0)	88 (88.0)	90 (90.0)	178 (89.0)
IBUPROFEN	9 (9.0)	30 (30.0)	36 (36.0)	66 (33.0)	13 (13.0)	25 (25.0)	25 (25.0)	50 (25.0)
PARACETAMOL	4 (4.0)	20 (20.0)	32 (32.0)	52 (26.0)	13 (13.0)	15 (15.0)	23 (23.0)	38 (19.0)
VITAMINS NOS	8 (8.0)	10 (10.0)	7 (7.0)	17 (8.5)	10 (10.0)	15 (15.0)	15 (15.0)	30 (15.0)
ACETYLSALICYLIC ACID	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)	10 (10.0)	8 (8.0)	8 (8.0)	16 (8.0)
NAPROXEN SODIUM	4 (4.0)	3 (3.0)	4 (4.0)	7 (3.5)	4 (4.0)	8 (8.0)	7 (7.0)	15 (7.5)
FISH OIL	1 (1.0)	4 (4.0)	4 (4.0)	8 (4.0)	4 (4.0)	7 (7.0)	6 (6.0)	13 (6.5)
LEVONORGESTREL	5 (5.0)	13 (13.0)	6 (6.0)	19 (9.5)	0	0	0	0
LORATADINE	3 (3.0)	5 (5.0)	3 (3.0)	8 (4.0)	7 (7.0)	5 (5.0)	4 (4.0)	9 (4.5)
CETIRIZINE HYDROCHLORIDE	3 (3.0)	4 (4.0)	4 (4.0)	8 (4.0)	3 (3.0)	6 (6.0)	2 (2.0)	8 (4.0)
VITAMIN D NOS	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	5 (5.0)	8 (8.0)	5 (5.0)	13 (6.5)
COLECALCIFEROL	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	2 (2.0)	7 (7.0)	5 (5.0)	12 (6.0)
ASCORBIC ACID	0	0	3 (3.0)	3 (1.5)	3 (3.0)	7 (7.0)	5 (5.0)	12 (6.0)
ATORVASTATIN	2 (2.0)	0	3 (3.0)	3 (1.5)	9 (9.0)	5 (5.0)	5 (5.0)	10 (5.0)
ESTRADIOL	3 (3.0)	0	2 (2.0)	2 (1.0)	6 (6.0)	5 (5.0)	6 (6.0)	11 (5.5)
OMEPRAZOLE	2 (2.0)	1 (1.0)	4 (4.0)	5 (2.5)	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)
NAPROXEN	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	6 (6.0)	3 (3.0)	9 (4.5)
ESCITALOPRAM	3 (3.0)	2 (2.0)	0	2 (1.0)	0	7 (7.0)	1 (1.0)	8 (4.0)
SUMATRIPTAN	2 (2.0)	3 (3.0)	0	3 (1.5)	5 (5.0)	5 (5.0)	1 (1.0)	6 (3.0)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
TRAZODONE	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	1 (1.0)	6 (6.0)	7 (3.5)
SIMVASTATIN	1 (1.0)	0	0	0	2 (2.0)	6 (6.0)	3 (3.0)	9 (4.5)
VITAMIN B12 NOS	0	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	6 (6.0)	0	6 (3.0)
ETHINYLESTRADIOL;NORGESTIMATE	2 (2.0)	3 (3.0)	6 (6.0)	9 (4.5)	0	0	0	0
GABAPENTIN	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	4 (4.0)	2 (2.0)	6 (3.0)
CALCIUM	1 (1.0)	0	1 (1.0)	1 (0.5)	8 (8.0)	4 (4.0)	3 (3.0)	7 (3.5)
FLUTICASONE PROPIONATE	6 (6.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	3 (3.0)	2 (2.0)	5 (2.5)
DIPHENHYDRAMINE HYDROCHLORIDE	1 (1.0)	1 (1.0)	0	1 (0.5)	3 (3.0)	4 (4.0)	3 (3.0)	7 (3.5)
VALACICLOVIR	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	3 (3.0)	2 (2.0)	4 (4.0)	6 (3.0)
MELATONIN	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	5 (5.0)	1 (1.0)	6 (3.0)
LEVOTHYROXINE	0	1 (1.0)	0	1 (0.5)	2 (2.0)	4 (4.0)	3 (3.0)	7 (3.5)
PROGESTERONE	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	3 (3.0)	4 (4.0)	7 (3.5)
PROBIOTICS NOS	0	0	2 (2.0)	2 (1.0)	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE	1 (1.0)	5 (5.0)	1 (1.0)	6 (3.0)	3 (3.0)	0	1 (1.0)	1 (0.5)
ESCITALOPRAM OXALATE	3 (3.0)	2 (2.0)	5 (5.0)	7 (3.5)	1 (1.0)	0	0	0
MELOXICAM	0	1 (1.0)	0	1 (0.5)	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
PANTOPRAZOLE	0	0	2 (2.0)	2 (1.0)	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	4 (4.0)	2 (2.0)	0	2 (1.0)	2 (2.0)	0	4 (4.0)	4 (2.0)
SERTRALINE	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	3 (3.0)	3 (1.5)
SERTRALINE HYDROCHLORIDE	0	1 (1.0)	2 (2.0)	3 (1.5)	2 (2.0)	0	3 (3.0)	3 (1.5)
FLUOXETINE HYDROCHLORIDE	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
IRON	0	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
CETIRIZINE	0	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)
ZOLPIDEM TARTRATE	0	0	0	0	0	3 (3.0)	3 (3.0)	6 (3.0)
VITAMIN B COMPLEX	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	3 (3.0)	4 (2.0)
SPIRONOLACTONE	3 (3.0)	1 (1.0)	3 (3.0)	4 (2.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
ROSUVASTATIN	1 (1.0)	0	0	0	2 (2.0)	1 (1.0)	4 (4.0)	5 (2.5)
LATANOPROST	0	0	0	0	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)
BUPROPION	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	2 (2.0)	2 (1.0)
LEVOTHYROXINE SODIUM	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)
TOPIRAMATE	0	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
BIOTIN	0	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)
OXYBUTYNIN	0	0	0	0	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
FIBRE, DIETARY	1 (1.0)	0	2 (2.0)	2 (1.0)	0	0	3 (3.0)	3 (1.5)
CELECOXIB	2 (2.0)	0	0	0	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE	4 (4.0)	0	4 (4.0)	4 (2.0)	0	0	0	0
FEXOFENADINE HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	3 (3.0)	3 (3.0)	0	3 (1.5)
BUPROPION HYDROCHLORIDE	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
TRAMADOL	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
CURCUMA LONGA	0	0	0	0	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
HYDROCORTISONE	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)
CHONDROITIN;GLUCOSAMINE	0	0	1 (1.0)	1 (0.5)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
ETHINYLESTRADIOL;NORETHISTERONE ACETATE	2 (2.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
DENOSUMAB	0	0	0	0	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
TAMSULOSIN	0	0	0	0	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
MINERALS NOS;VITAMINS NOS	0	0	4 (4.0)	4 (2.0)	0	0	0	0
CLONAZEPAM	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
CALCIUM;VITAMIN D NOS	0	0	0	0	2 (2.0)	3 (3.0)	0	3 (1.5)
MONTELUKAST SODIUM	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
GLUCOSAMINE	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
CITALOPRAM	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
AMOXICILLIN	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
LOVASTATIN	0	0	0	0	1 (1.0)	3 (3.0)	0	3 (1.5)
MAGNESIUM	0	0	0	0	1 (1.0)	3 (3.0)	0	3 (1.5)
VENLAFAXINE HYDROCHLORIDE	1 (1.0)	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
LISDEXAMFETAMINE MESILATE	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
ROSUVASTATIN CALCIUM	0	0	0	0	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
DIPHENHYDRAMINE	0	0	0	0	1 (1.0)	0	3 (3.0)	3 (1.5)
TESTOSTERONE	0	0	0	0	1 (1.0)	0	3 (3.0)	3 (1.5)
LINUM USITATISSIMUM SEED OIL	0	0	0	0	0	3 (3.0)	0	3 (1.5)
ZOLPIDEM	0	0	0	0	0	3 (3.0)	0	3 (1.5)
METHYLPHENIDATE	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
DOXYCYCLINE	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
LISINOPRIL	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
PREDNISONE	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
CICLOSPORIN	0	0	0	0	0	1 (1.0)	2 (2.0)	3 (1.5)
RALOXIFENE	0	0	0	0	0	1 (1.0)	2 (2.0)	3 (1.5)
TRIAMCINOLONE ACETONIDE	0	0	3 (3.0)	3 (1.5)	0	0	0	0
FLUTICASONE	1 (1.0)	0	0	0	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
BUSPIRONE	2 (2.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
CEFALEXIN	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
FAMOTIDINE	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	0	0	0
ALPRAZOLAM	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
PRAVASTATIN	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
MEDROXYPROGESTERONE ACETATE	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.0)	0	0	0	0	0	2 (2.0)	2 (1.0)
VENLAFAXINE	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	0	0
DULOXETINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
LEVOCETIRIZINE DIHYDROCHLORIDE	0	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)
LAMOTRIGINE	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
FLUOXETINE	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
METHYLPHENIDATE HYDROCHLORIDE	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
AMFETAMINE;DEXAMFETAMINE	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
METRONIDAZOLE	1 (1.0)	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
ACICLOVIR	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
TADALAFIL	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
ALLOPURINOL	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
OMEGA-3 NOS	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
LORAZEPAM	1 (1.0)	0	0	0	0	0	2 (2.0)	2 (1.0)
DOCUSATE SODIUM	0	0	0	0	1 (1.0)	0	2 (2.0)	2 (1.0)

Percentages are based on the number of safety subjects.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
ETHINYLESTRADIOL;NORETHISTERONE	0	2 (2.0)	0	2 (1.0)	0	0	0	0
BUTALBITAL;CAFFEINE;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
NITROFURANTOIN	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
OMEGA-3 FATTY ACIDS	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
PROPRANOLOL	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
AMITRIPTYLINE	0	0	0	0	0	2 (2.0)	0	2 (1.0)
UBIDECARENONE	0	0	0	0	0	2 (2.0)	0	2 (1.0)
ETHINYLESTRADIOL;ETONOGESTREL	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
INTRAUTERINE CONTRACEPTIVE DEVICE	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
NORETHISTERONE	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
ESOMEPRAZOLE MAGNESIUM	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
FINASTERIDE	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
GUAIFENESIN	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
METFORMIN	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
PENICILLIN NOS	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
ADEMETHIONINE	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
ASCORBIC ACID;BETACAROTENE;CUPRIC OXIDE;TOCOPHERYL ACETATE;ZINC OXIDE	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
CALCIUM CARBONATE	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
CHONDROITIN	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
FREMANEZUMAB	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
HYALURONIC ACID	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
VARICELLA ZOSTER VACCINE RGE (CHO)	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
VITAMIN E NOS	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
ETHINYLESTRADIOL;NORGESTREL	0	0	2 (2.0)	2 (1.0)	0	0	0	0
HYDROCODONE;PARACETAMOL	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
CALCIUM CITRATE	0	0	0	0	0	0	2 (2.0)	2 (1.0)
SILDENAFIL	0	0	0	0	0	0	2 (2.0)	2 (1.0)
CITALOPRAM HYDROBROMIDE	1 (1.0)	0	0	0	2 (2.0)	1 (1.0)	0	1 (0.5)
ALENDRONATE SODIUM	1 (1.0)	0	0	0	2 (2.0)	0	1 (1.0)	1 (0.5)
DESGESTREL;ETHINYLESTRADIOL	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
ETHINYLESTRADIOL;LEVONORGESTREL	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
ETONOGESTREL	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
DIPHENHYDRAMINE	2 (2.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
HYDROCHLORIDE;PARACETAMOL								
LORATADINE;PSEUDOEPHEDRINE SULFATE	1 (1.0)	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
PAROXETINE HYDROCHLORIDE	0	0	0	0	2 (2.0)	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
GUAIFENESIN;PSEUDOEPHEDRINE HYDROCHLORIDE	2 (2.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
VORTIOXETINE HYDROBROMIDE	2 (2.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
ESOMEPRAZOLE	0	0	0	0	2 (2.0)	0	1 (1.0)	1 (0.5)
CLINDAMYCIN	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
ATORVASTATIN CALCIUM	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
LINACLOTIDE	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
MEDIUM-CHAIN TRIGLYCERIDES	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
METHYLPREDNISOLONE	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
TRIAMCINOLONE	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
VALACICLOVIR HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
LACTOBACILLUS ACIDOPHILUS	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
MIRABEGRON	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
PHENTERMINE	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
RIZATRIPTAN BENZOATE	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
DICLOFENAC SODIUM	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
DORZOLAMIDE	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
ESTRADIOL;NORETHISTERONE ACETATE	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
IBANDRONATE SODIUM	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
PRASTERONE	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
ZINC	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
MACROGOL 3350	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
AZITHROMYCIN	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
DULOXETINE	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
ALLERGENS NOS	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
DESVENLAFAXINE SUCCINATE	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
ESTROGENS CONJUGATED	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
ESZOPICLONE	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
MIRTAZAPINE	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
ALLIUM SATIVUM	0	1 (1.0)	0	1 (0.5)	0	0	0	0
AMLODIPINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
BORON;CALCIUM;CIMICIFUGA RACEMOSA EXTRACT;FOLIC ACID;GLYCINE MAX EXTRACT;MAGNOLIA OFFICINALIS;NICOTINIC ACID;PYRIDOXINE HYDROCHLORIDE;RIBOFLAVIN;SELENIUM; THIAMINE;TOCOPHEROL;VITAMIN B12 NOS	0	1 (1.0)	0	1 (0.5)	0	0	0	0
CALCIUM;MAGNESIUM;ZINC	0	1 (1.0)	0	1 (0.5)	0	0	0	0
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPH RINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DEXLANSOPRAZOLE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
DEXTROMETHORPHAN	0	1 (1.0)	0	1 (0.5)	0	0	0	0
HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICYCLOVERINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
FISH OIL;VITAMIN D NOS	0	1 (1.0)	0	1 (0.5)	0	0	0	0
GLYCOPYRRONIUM	0	1 (1.0)	0	1 (0.5)	0	0	0	0
HYDROCHLOROTHIAZIDE;TRIAMTERENE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
HYDROXYZINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
ISOTRETINOIN	0	1 (1.0)	0	1 (0.5)	0	0	0	0
LACOSAMIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
LEVETIRACETAM	0	1 (1.0)	0	1 (0.5)	0	0	0	0
LEVOCETIRIZINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
LOTEPREDNOL;TOBRAMYCIN	0	1 (1.0)	0	1 (0.5)	0	0	0	0
MEPYRAMINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
MALEATE;PAMABROM;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
MESTRANOL;NORETHISTERONE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
PAROXETINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
PHENYLEPHRINE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
PREGABALIN	0	1 (1.0)	0	1 (0.5)	0	0	0	0
RANITIDINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
RIZATRIPTAN	0	1 (1.0)	0	1 (0.5)	0	0	0	0
SUCRALFATE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
TIZANIDINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
TRAMADOL HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
VILAZODONE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
ACETYLCYSTEINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ADAPALENE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ANESTHETICS, LOCAL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ARIPIRAZOLE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ASCORBIC ACID;BIOTIN;DL-ALPHA TOCOPHERYL ACETATE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ASCORBIC ACID;SELENIUM;VITAMIN E NOS;XANTOXYL;ZEAXANTHIN;ZINC	0	0	0	0	0	1 (1.0)	0	1 (0.5)
BEPOTASTINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
BORAGO OFFICINALIS OIL	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg	100 µg	Total		50 µg	100 µg	Total
		(N=100)	(N=100)	(N=200)		(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
BRIMONIDINE TARTRATE;TIMOLOL MALEATE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
BROLUCIZUMAB DBLL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
BROMELAINS;QUERCETIN	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CALCIUM;MAGNESIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CARMELLOSE SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CLOBETASOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
COLECALCIFEROL;DOCOSAHEXAENOIC ACID;EICOSAPENTAENOIC ACID	0	0	0	0	0	1 (1.0)	0	1 (0.5)
COLLAGEN	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CYCLOBENZAPRINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
DOXYLAMINE SUCCINATE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
FENOFIBRATE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
GEMFIBROZIL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
INFLUENZA VACCINE INACT SPLIT 4V	0	0	0	0	0	1 (1.0)	0	1 (0.5)
LINUM USITATISSIMUM OIL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
LOPERAMIDE HYDROCHLORIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
LUBIPROSTONE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
MINOCYCLINE HYDROCHLORIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg	100 µg	Total		50 µg	100 µg	Total
		(N=100)	(N=100)	(N=200)		(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
MONASCUS PURPUREUS	0	0	0	0	0	1 (1.0)	0	1 (0.5)
MONTELUKAST	0	0	0	0	0	1 (1.0)	0	1 (0.5)
MORINGA OLEIFERA LEAF	0	0	0	0	0	1 (1.0)	0	1 (0.5)
NICOTINAMIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
NORTRIPTYLINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
OLEA EUROPAEA LEAF	0	0	0	0	0	1 (1.0)	0	1 (0.5)
OXYCODONE;PARACETAMOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
PLANTAGO OVATA	0	0	0	0	0	1 (1.0)	0	1 (0.5)
PYRIDOXINE HYDROCHLORIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ROPINIROLE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
SILYBUM MARIANUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
TILACTASE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
TIMOLOL MALEATE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
UBIQUINOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
VACCINIUM MACROCARPON	0	0	0	0	0	1 (1.0)	0	1 (0.5)
VALSARTAN	0	0	0	0	0	1 (1.0)	0	1 (0.5)
VITAMIN B NOS	0	0	0	0	0	1 (1.0)	0	1 (0.5)
VITAMIN K NOS	0	0	0	0	0	1 (1.0)	0	1 (0.5)
ZOLMITRIPTAN	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
ASCORBIC ACID;VITAMIN D NOS	0	0	1 (1.0)	1 (0.5)	0	0	0	0
AZELAIC ACID	0	0	1 (1.0)	1 (0.5)	0	0	0	0
CARBAMAZEPINE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
CEFIXIME	0	0	1 (1.0)	1 (0.5)	0	0	0	0
CHROMIUM PICOLINATE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DEXAMETHASONE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN	0	0	1 (1.0)	1 (0.5)	0	0	0	0
HYDROBROMIDE; PARACETAMOL; PHENYLEPH RINE HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DROSPIRENONE; ETHINYLESTRADIOL	0	0	1 (1.0)	1 (0.5)	0	0	0	0
EZETIMIBE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
FERROUS GLUCONATE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
GINSENG NOS	0	0	1 (1.0)	1 (0.5)	0	0	0	0
LEVOMILNACIPRAN HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
NALTREXONE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
OXYCODONE HYDROCHLORIDE; PARACETAMOL	0	0	1 (1.0)	1 (0.5)	0	0	0	0
PREDNISONE ACETATE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
PROGESTOGENS AND ESTROGENS IN COMBINATION	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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WHODrug version: WHODrug-Global-B3 March 2020

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
PRUNUS SPP.; SENNA SPP. LEAF	0	0	1 (1.0)	1 (0.5)	0	0	0	0
QUETIAPINE FUMARATE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
TEMAZEPAM	0	0	1 (1.0)	1 (0.5)	0	0	0	0
TERBINAFINE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
TESTOSTERONE CIPIONATE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
ACETYLSALICYLIC ACID; ASPARTAME; PHENYLALANINE; PHENY LPROPANOLAMINE BITARTRATE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ALFUZOSIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ALPHA-AMYLASE SWINE PANCREAS; CELLULASE; LIPASE; PROTEASE NOS	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ASCORBIC ACID; VACCINIUM MACROCARPON	0	0	0	0	0	0	1 (1.0)	1 (0.5)
AZELASTINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
BRIMONIDINE TARTRATE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
BUSPIRONE HYDROCHLORIDE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
CEFUROXIME AXETIL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
CHONDROITIN SULFATE SODIUM; GLUCOSAMINE HYDROCHLORIDE	0	0	0	0	0	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.

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WHODrug version: WHODrug-Global-B3 March 2020

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg	100 µg	Total		50 µg	100 µg	Total
		(N=100)	(N=100)	(N=200)		(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COLCHICINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
CYCLOBENZAPRINE HYDROCHLORIDE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
DESVENLAFAXINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
DICLOFENAC	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ECHINACEA SPP.; ZINC	0	0	0	0	0	0	1 (1.0)	1 (0.5)
EFINACONAZOLE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ENZYMES NOS; PROBIOTICS NOS	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ESTROGEN NOS; TESTOSTERONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
FEXOFENADINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
GLYCEROL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
HYDROCODONE BITARTRATE; PARACETAMOL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
HYLAN G-F 20	0	0	0	0	0	0	1 (1.0)	1 (0.5)
INDOMETACIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
LIOETHYRONINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
MENTHA X PIPERITA OIL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
MOXIFLOXACIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OSPEMIFENE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYMETAZOLINE HYDROCHLORIDE	0	0	0	0	0	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.

Concomitant medication is defined as medication continued or newly received at or after the first vaccination through 28 days after the last vaccination.

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
PANTOPRAZOLE SODIUM SESQUIHYDRATE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
PLECANATIDE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
PREDNISOLONE ACETATE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
QUETIAPINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
TERAZOSIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
THYROID	0	0	0	0	0	0	1 (1.0)	1 (0.5)
CETIRIZINE	2 (2.0)	0	0	0	1 (1.0)	0	0	0
HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE								
PSEUDOEPHEDRINE	1 (1.0)	0	0	0	2 (2.0)	0	0	0
BISACODYL	0	0	0	0	2 (2.0)	0	0	0
FERROUS SULFATE	0	0	0	0	2 (2.0)	0	0	0
LIFITEGRAST	0	0	0	0	2 (2.0)	0	0	0
AMOXICILLIN; CLAVULANATE POTASSIUM	1 (1.0)	0	0	0	0	0	0	0
BIOFLAVONOIDS NOS	1 (1.0)	0	0	0	0	0	0	0
CALAMINE	1 (1.0)	0	0	0	0	0	0	0
CIPROFLOXACIN	1 (1.0)	0	0	0	0	0	0	0
CODEINE PHOSPHATE; PARACETAMOL	1 (1.0)	0	0	0	0	0	0	0
CRISABOROLE	1 (1.0)	0	0	0	0	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
DESOXIMETASONE	1 (1.0)	0	0	0	0	0	0	0
EMTRICITABINE; TENOFOVIR ALAFENAMIDE FUMARATE	1 (1.0)	0	0	0	0	0	0	0
ERENUMAB	1 (1.0)	0	0	0	0	0	0	0
FACTOR X (STUART PROWER FACTOR)	1 (1.0)	0	0	0	0	0	0	0
HYDROCORTISONE; NEOMYCIN; POLYMYXIN B	1 (1.0)	0	0	0	0	0	0	0
LANSOPRAZOLE	1 (1.0)	0	0	0	0	0	0	0
LIDOCAINE; TRIAMCINOLONE	1 (1.0)	0	0	0	0	0	0	0
LORATADINE; PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0)	0	0	0	0	0	0	0
MAGNESIUM CITRATE	1 (1.0)	0	0	0	0	0	0	0
MINOCYCLINE	1 (1.0)	0	0	0	0	0	0	0
SERMORELIN	1 (1.0)	0	0	0	0	0	0	0
TRAZODONE HYDROCHLORIDE	1 (1.0)	0	0	0	0	0	0	0
TRIAMTERENE	1 (1.0)	0	0	0	0	0	0	0
ALGELDRATE; MAGNESIUM HYDROXIDE	0	0	0	0	1 (1.0)	0	0	0
APIXABAN	0	0	0	0	1 (1.0)	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
AZELASTINE	0	0	0	0	1 (1.0)	0	0	0
HYDROCHLORIDE; FLUTICASONE PROPIONATE								
BACLOFEN	0	0	0	0	1 (1.0)	0	0	0
BAZEDOXIFENE; ESTROGENS CONJUGATED	0	0	0	0	1 (1.0)	0	0	0
BIMATOPROST	0	0	0	0	1 (1.0)	0	0	0
BUPIVACAINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
CALENDULA OFFICINALIS; GRINDELIA ROBUSTA; PLANTAGO MAJOR	0	0	0	0	1 (1.0)	0	0	0
CHLORPHENAMINE MALEATE	0	0	0	0	1 (1.0)	0	0	0
CHLORPHENAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
DOCUSATE	0	0	0	0	1 (1.0)	0	0	0
ETHINYLESTRADIOL	0	0	0	0	1 (1.0)	0	0	0
FEXOFENADINE	0	0	0	0	1 (1.0)	0	0	0
HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE								
HYDRALAZINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0

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Table 14.1.4.2
Summary of Concomitant Medication by Preferred Term
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg	100 µg	Total		50 µg	100 µg	Total
		(N=100)	(N=100)	(N=200)		(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
HYDROCODONE	0	0	0	0	1 (1.0)	0	0	0
KRILL OIL	0	0	0	0	1 (1.0)	0	0	0
MAGNESIUM CHLORIDE	0	0	0	0	1 (1.0)	0	0	0
MECLOZINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
MEDROXYPROGESTERONE	0	0	0	0	1 (1.0)	0	0	0
MOMETASONE FUROATE	0	0	0	0	1 (1.0)	0	0	0
NAPROXEN SODIUM;SUMATRIPTAN SUCCINATE	0	0	0	0	1 (1.0)	0	0	0
NORETHISTERONE ACETATE	0	0	0	0	1 (1.0)	0	0	0
ONDANSETRON	0	0	0	0	1 (1.0)	0	0	0
OXYMETAZOLINE	0	0	0	0	1 (1.0)	0	0	0
PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
PRAMIPEXOLE	0	0	0	0	1 (1.0)	0	0	0
ROPINIROLE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
TOLTERODINE L-TARTRATE	0	0	0	0	1 (1.0)	0	0	0
TRAVOPROST	0	0	0	0	1 (1.0)	0	0	0
TRETINOIN	0	0	0	0	1 (1.0)	0	0	0
VARDENAFIL HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0

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Ad-hoc Table 14.1.4.3.1.1
Summary of Analgesics/Antipyretics Use on Day 1 or afterwards after First Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50ug (N=200) n (%)	100ug (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	25 (12.5)	44 (22.0)	36 (18.0)	80 (20.0)
IBUPROFEN	9 (4.5)	26 (13.0)	17 (8.5)	43 (10.8)
PARACETAMOL	9 (4.5)	8 (4.0)	12 (6.0)	20 (5.0)
NAPROXEN SODIUM	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
ACETYLSALICYLIC ACID	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
NAPROXEN	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
AMITRIPTYLINE	0	1 (0.5)	0	1 (0.3)
AMITRIPTYLINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
BUTALBITAL;CAFFEINE;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDOEPHEDRINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DICLOFENAC	0	0	1 (0.5)	1 (0.3)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	1 (0.5)	0	1 (0.3)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (0.5)	0	1 (0.5)	1 (0.3)
INDOMETACIN	0	0	1 (0.5)	1 (0.3)
MELOXICAM	0	1 (0.5)	0	1 (0.3)
OXYCODONE;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
TRAMADOL HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)	0	0	0
HYDROCODONE	1 (0.5)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 1 or afterwards after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.1.1
Summary of Analgesics/Antipyretics Use on Day 1 or afterwards after First Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=100) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	11 (11.0)	23 (23.0)	18 (18.0)	41 (20.5)	14 (14.0)	21 (21.0)	18 (18.0)	39 (19.5)
IBUPROFEN	5 (5.0)	14 (14.0)	8 (8.0)	22 (11.0)	4 (4.0)	12 (12.0)	9 (9.0)	21 (10.5)
PARACETAMOL	1 (1.0)	5 (5.0)	9 (9.0)	14 (7.0)	8 (8.0)	3 (3.0)	3 (3.0)	6 (3.0)
NAPROXEN SODIUM	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
NAPROXEN	1 (1.0)	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
AMITRIPTYLINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
BUTALBITAL;CAFFEINE;PARACETAMOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN;PARACETAMOL;PSEUDO EPHEDRINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC	0	0	0	0	0	0	1 (1.0)	1 (0.5)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
IBUPROFEN;PSEUDOEPHEDRINE HYDROCHLORIDE	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
INDOMETACIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
MELOXICAM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
OXYCODONE;PARACETAMOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
TRAMADOL HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
HYDROCODONE	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 1 or afterwards after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.1.2
Summary of Analgesics/Antipyretics Use on Day 1 or afterwards after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	19 (9.8)	72 (36.9)	101 (51.0)	173 (44.0)
IBUPROFEN	4 (2.1)	42 (21.5)	49 (24.7)	91 (23.2)
PARACETAMOL	6 (3.1)	27 (13.8)	46 (23.2)	73 (18.6)
NAPROXEN SODIUM	2 (1.0)	3 (1.5)	6 (3.0)	9 (2.3)
ACETYLSALICYLIC ACID	2 (1.0)	1 (0.5)	7 (3.5)	8 (2.0)
NAPROXEN	1 (0.5)	3 (1.5)	4 (2.0)	7 (1.8)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	1 (0.5)	1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
DICLOFENAC SODIUM	0	1 (0.5)	0	1 (0.3)
HYDROCODONE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
KETOROLAC TROMETHAMINE	0	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
TRAMADOL	0	1 (0.5)	0	1 (0.3)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	0	0	0
MELOXICAM	1 (0.5)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 1 or afterwards after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.1.2
Summary of Analgesics/Antipyretics Use on Day 1 or afterwards after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	8 (8.5)	41 (42.3)	57 (57.6)	98 (50.0)	11 (11.0)	31 (31.6)	44 (44.4)	75 (38.1)
IBUPROFEN	2 (2.1)	24 (24.7)	32 (32.3)	56 (28.6)	2 (2.0)	18 (18.4)	17 (17.2)	35 (17.8)
PARACETAMOL	2 (2.1)	17 (17.5)	26 (26.3)	43 (21.9)	4 (4.0)	10 (10.2)	20 (20.2)	30 (15.2)
NAPROXEN SODIUM	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	2 (2.0)	4 (4.0)	6 (3.0)
ACETYLSALICYLIC ACID	2 (2.1)	0	3 (3.0)	3 (1.5)	0	1 (1.0)	4 (4.0)	5 (2.5)
NAPROXEN	0	0	2 (2.0)	2 (1.0)	1 (1.0)	3 (3.1)	2 (2.0)	5 (2.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (2.1)	2 (2.1)	0	2 (1.0)	1 (1.0)	0	2 (2.0)	2 (1.0)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DICLOFENAC SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
HYDROCODONE;PARACETAMOL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
KETOROLAC TROMETHAMINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
TRAMADOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0
MELOXICAM	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 1 or afterwards after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.2.1
Summary of Analgesics/Antipyretics Use within 1-week after First Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50ug (N=200) n (%)	100ug (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	20 (10.0)	34 (17.0)	32 (16.0)	66 (16.5)
IBUPROFEN	8 (4.0)	22 (11.0)	16 (8.0)	38 (9.5)
PARACETAMOL	7 (3.5)	6 (3.0)	10 (5.0)	16 (4.0)
NAPROXEN SODIUM	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
ACETYLSALICYLIC ACID	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.5)	0	1 (0.5)	1 (0.3)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DICLOFENAC	0	0	1 (0.5)	1 (0.3)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
NAPROXEN	0	1 (0.5)	0	1 (0.3)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 1-week after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.2.1
Summary of Analgesics/Antipyretics Use within 1-week after First Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=100) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	8 (8.0)	19 (19.0)	16 (16.0)	35 (17.5)	12 (12.0)	15 (15.0)	16 (16.0)	31 (15.5)
IBUPROFEN	5 (5.0)	13 (13.0)	7 (7.0)	20 (10.0)	3 (3.0)	9 (9.0)	9 (9.0)	18 (9.0)
PARACETAMOL	1 (1.0)	4 (4.0)	8 (8.0)	12 (6.0)	6 (6.0)	2 (2.0)	2 (2.0)	4 (2.0)
NAPROXEN SODIUM	2 (2.0)	0	2 (2.0)	2 (1.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC	0	0	0	0	0	0	1 (1.0)	1 (0.5)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
NAPROXEN	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 1-week after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.2.2
Summary of Analgesics/Antipyretics Use within 1-week after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	10 (5.2)	69 (35.4)	99 (50.0)	168 (42.7)
IBUPROFEN	3 (1.5)	41 (21.0)	48 (24.2)	89 (22.6)
PARACETAMOL	4 (2.1)	27 (13.8)	45 (22.7)	72 (18.3)
ACETYLSALICYLIC ACID	0	1 (0.5)	7 (3.5)	8 (2.0)
NAPROXEN SODIUM	1 (0.5)	2 (1.0)	5 (2.5)	7 (1.8)
NAPROXEN	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
HYDROCODONE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
TRAMADOL	0	1 (0.5)	0	1 (0.3)

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 1-week after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.2.2
Summary of Analgesics/Antipyretics Use within 1-week after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	4 (4.3)	40 (41.2)	57 (57.6)	97 (49.5)	6 (6.0)	29 (29.6)	42 (42.4)	71 (36.0)
IBUPROFEN	2 (2.1)	23 (23.7)	32 (32.3)	55 (28.1)	1 (1.0)	18 (18.4)	16 (16.2)	34 (17.3)
PARACETAMOL	1 (1.1)	17 (17.5)	26 (26.3)	43 (21.9)	3 (3.0)	10 (10.2)	19 (19.2)	29 (14.7)
ACETYLSALICYLIC ACID	0	0	3 (3.0)	3 (1.5)	0	1 (1.0)	4 (4.0)	5 (2.5)
NAPROXEN SODIUM	1 (1.1)	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	4 (4.0)	5 (2.5)
NAPROXEN	0	0	2 (2.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	2 (2.1)	0	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
HYDROCODONE;PARACETAMOL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
TRAMADOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 1-week after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.3.1
Summary of Analgesics/Antipyretics Use within 2-week after First Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50ug (N=200) n (%)	100ug (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	21 (10.5)	39 (19.5)	33 (16.5)	72 (18.0)
IBUPROFEN	8 (4.0)	24 (12.0)	16 (8.0)	40 (10.0)
PARACETAMOL	8 (4.0)	7 (3.5)	11 (5.5)	18 (4.5)
NAPROXEN SODIUM	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
ACETYLSALICYLIC ACID	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
NAPROXEN	0	2 (1.0)	0	2 (0.5)
AMITRIPTYLINE	0	1 (0.5)	0	1 (0.3)
AMITRIPTYLINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (0.5)	0	1 (0.3)
DICLOFENAC	0	0	1 (0.5)	1 (0.3)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
INDOMETACIN	0	0	1 (0.5)	1 (0.3)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	1 (0.5)	0	0	0
HYDROCODONE	1 (0.5)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 2-week after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.3.1
Summary of Analgesics/Antipyretics Use within 2-week after First Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=100) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)		50ug (N=100) n(%)	100ug (N=100) n(%)	Total (N=200) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	8 (8.0)	21 (21.0)	16 (16.0)	37 (18.5)	13 (13.0)	18 (18.0)	17 (17.0)	35 (17.5)
IBUPROFEN	5 (5.0)	14 (14.0)	7 (7.0)	21 (10.5)	3 (3.0)	10 (10.0)	9 (9.0)	19 (9.5)
PARACETAMOL	1 (1.0)	5 (5.0)	8 (8.0)	13 (6.5)	7 (7.0)	2 (2.0)	3 (3.0)	5 (2.5)
NAPROXEN SODIUM	2 (2.0)	0	2 (2.0)	2 (1.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
NAPROXEN	0	0	0	0	0	2 (2.0)	0	2 (1.0)
AMITRIPTYLINE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
AMITRIPTYLINE HYDROCHLORIDE	0	0	0	0	0	1 (1.0)	0	1 (0.5)
CHLORPHENAMINE MALEATE;DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC	0	0	0	0	0	0	1 (1.0)	1 (0.5)
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	0	0	0	0	0	1 (1.0)	0	1 (0.5)
INDOMETACIN	0	0	0	0	0	0	1 (1.0)	1 (0.5)
CHLORPHENAMINE MALEATE;IBUPROFEN;PHENYLEPHRINE HYDROCHLORIDE	0	0	0	0	1 (1.0)	0	0	0
HYDROCODONE	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the first vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 2-week after the first vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.3.2
Summary of Analgesics/Antipyretics Use within 2-week after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	13 (6.7)	69 (35.4)	100 (50.5)	169 (43.0)
IBUPROFEN	4 (2.1)	41 (21.0)	48 (24.2)	89 (22.6)
PARACETAMOL	5 (2.6)	27 (13.8)	46 (23.2)	73 (18.6)
ACETYLSALICYLIC ACID	1 (0.5)	1 (0.5)	7 (3.5)	8 (2.0)
NAPROXEN SODIUM	1 (0.5)	3 (1.5)	5 (2.5)	8 (2.0)
NAPROXEN	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (0.5)	1 (0.3)
HYDROCODONE;PARACETAMOL	0	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
TRAMADOL	0	1 (0.5)	0	1 (0.3)

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 2-week after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.3.2
Summary of Analgesics/Antipyretics Use within 2-week after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	5 (5.3)	40 (41.2)	57 (57.6)	97 (49.5)	8 (8.0)	29 (29.6)	43 (43.4)	72 (36.5)
IBUPROFEN	2 (2.1)	23 (23.7)	32 (32.3)	55 (28.1)	2 (2.0)	18 (18.4)	16 (16.2)	34 (17.3)
PARACETAMOL	1 (1.1)	17 (17.5)	26 (26.3)	43 (21.9)	4 (4.0)	10 (10.2)	20 (20.2)	30 (15.2)
ACETYLSALICYLIC ACID	1 (1.1)	0	3 (3.0)	3 (1.5)	0	1 (1.0)	4 (4.0)	5 (2.5)
NAPROXEN SODIUM	1 (1.1)	1 (1.0)	1 (1.0)	2 (1.0)	0	2 (2.0)	4 (4.0)	6 (3.0)
NAPROXEN	0	0	2 (2.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	0	2 (2.1)	0	2 (1.0)	1 (1.0)	0	2 (2.0)	2 (1.0)
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	1 (1.0)	1 (0.5)	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;PARACETAMOL;PHENYLEPHRINE HYDROCHLORIDE	0	0	1 (1.0)	1 (0.5)	0	0	0	0
HYDROCODONE;PARACETAMOL	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
TRAMADOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics within 2-week after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.4.1
Summary of Analgesics/Antipyretics Use Starting on Day 8 or later after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	10 (5.2)	5 (2.6)	9 (4.5)	14 (3.6)
IBUPROFEN	2 (1.0)	1 (0.5)	4 (2.0)	5 (1.3)
PARACETAMOL	2 (1.0)	0	3 (1.5)	3 (0.8)
NAPROXEN	0	1 (0.5)	1 (0.5)	2 (0.5)
NAPROXEN SODIUM	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1.0)	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
DICLOFENAC SODIUM	0	1 (0.5)	0	1 (0.3)
KETOROLAC TROMETHAMINE	0	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID	2 (1.0)	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	0	0	0
MELOXICAM	1 (0.5)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 8 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.4.1
Summary of Analgesics/Antipyretics Use Starting on Day 8 or later after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	5 (5.3)	2 (2.1)	3 (3.0)	5 (2.6)	5 (5.0)	3 (3.1)	6 (6.1)	9 (4.6)
IBUPROFEN	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
PARACETAMOL	1 (1.1)	0	0	0	1 (1.0)	0	3 (3.0)	3 (1.5)
NAPROXEN	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
NAPROXEN SODIUM	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (2.1)	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
KETOROLAC TROMETHAMINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID	2 (2.1)	0	0	0	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	0	0	1 (1.0)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0
MELOXICAM	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 8 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.4.2
Summary of Analgesics/Antipyretics Use on Day 8 or afterwards after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	11 (5.7)	8 (4.1)	11 (5.6)	19 (4.8)
IBUPROFEN	3 (1.5)	3 (1.5)	5 (2.5)	8 (2.0)
PARACETAMOL	2 (1.0)	1 (0.5)	4 (2.0)	5 (1.3)
NAPROXEN	0	1 (0.5)	1 (0.5)	2 (0.5)
NAPROXEN SODIUM	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1.0)	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
DICLOFENAC SODIUM	0	1 (0.5)	0	1 (0.3)
KETOROLAC TROMETHAMINE	0	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID	2 (1.0)	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	0	0	0
MELOXICAM	1 (0.5)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 8 or afterwards after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.4.2
Summary of Analgesics/Antipyretics Use on Day 8 or afterwards after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	5 (5.3)	5 (5.2)	5 (5.1)	10 (5.1)	6 (6.0)	3 (3.1)	6 (6.1)	9 (4.6)
IBUPROFEN	1 (1.1)	3 (3.1)	3 (3.0)	6 (3.1)	2 (2.0)	0	2 (2.0)	2 (1.0)
PARACETAMOL	1 (1.1)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	3 (3.0)	3 (1.5)
NAPROXEN	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
NAPROXEN SODIUM	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (2.1)	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
KETOROLAC TROMETHAMINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID	2 (2.1)	0	0	0	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	0	0	1 (1.0)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0
MELOXICAM	0	0	0	0	1 (1.0)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on day 8 or afterwards after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.5.1
Summary of Analgesics/Antipyretics Use Starting on Day 15 or later after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	7 (3.6)	4 (2.1)	5 (2.5)	9 (2.3)
IBUPROFEN	1 (0.5)	1 (0.5)	4 (2.0)	5 (1.3)
NAPROXEN	0	1 (0.5)	1 (0.5)	2 (0.5)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
DICLOFENAC SODIUM	0	1 (0.5)	0	1 (0.3)
KETOROLAC TROMETHAMINE	0	0	1 (0.5)	1 (0.3)
NAPROXEN SODIUM	1 (0.5)	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID	1 (0.5)	0	0	0
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1.0)	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	0	0	0
MELOXICAM	1 (0.5)	0	0	0
PARACETAMOL	1 (0.5)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 15 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.5.1
Summary of Analgesics/Antipyretics Use Starting on Day 15 or later after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	4 (4.3)	2 (2.1)	3 (3.0)	5 (2.6)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
IBUPROFEN	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	0	0	2 (2.0)	2 (1.0)
NAPROXEN	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
KETOROLAC TROMETHAMINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
NAPROXEN SODIUM	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
ACETYLSALICYLIC ACID	1 (1.1)	0	0	0	0	0	0	0
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (2.1)	0	0	0	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	0	0	1 (1.0)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0
MELOXICAM	0	0	0	0	1 (1.0)	0	0	0
PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 15 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.5.2
Summary of Analgesics/Antipyretics Use on Day 15 or afterwards after Second Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50ug (N=195) n (%)	100ug (N=198) n (%)	Total (N=393) n (%)
Number of Subjects Who Used Analgesic/Antipyretic	8 (4.1)	5 (2.6)	7 (3.5)	12 (3.1)
IBUPROFEN	1 (0.5)	2 (1.0)	5 (2.5)	7 (1.8)
NAPROXEN	0	1 (0.5)	1 (0.5)	2 (0.5)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (1.0)	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (0.5)	0	1 (0.3)
DICLOFENAC SODIUM	0	1 (0.5)	0	1 (0.3)
KETOROLAC TROMETHAMINE	0	0	1 (0.5)	1 (0.3)
NAPROXEN SODIUM	1 (0.5)	0	1 (0.5)	1 (0.3)
OXYCODONE	0	0	1 (0.5)	1 (0.3)
ACETYLSALICYLIC ACID	2 (1.0)	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	1 (0.5)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (0.5)	0	0	0
MELOXICAM	1 (0.5)	0	0	0
PARACETAMOL	1 (0.5)	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 15 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.3.5.2
Summary of Analgesics/Antipyretics Use on Day 15 or afterwards after Second Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placbo (N=94) n(%)	mRNA-1273			Placbo (N=100) n(%)	mRNA-1273		
		50ug (N=97) n(%)	100ug (N=99) n(%)	Total (N=196) n(%)		50ug (N=98) n(%)	100ug (N=99) n(%)	Total (N=197) n(%)
Number of Subjects Who Used Analgesic/Antipyretic	5 (5.3)	3 (3.1)	4 (4.0)	7 (3.6)	3 (3.0)	2 (2.0)	3 (3.0)	5 (2.5)
IBUPROFEN	1 (1.1)	2 (2.1)	3 (3.0)	5 (2.6)	0	0	2 (2.0)	2 (1.0)
NAPROXEN	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL	2 (2.1)	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID;PARACETAMOL	0	1 (1.0)	0	1 (0.5)	0	0	0	0
DICLOFENAC SODIUM	0	0	0	0	0	1 (1.0)	0	1 (0.5)
KETOROLAC TROMETHAMINE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
NAPROXEN SODIUM	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
OXYCODONE	0	0	0	0	0	0	1 (1.0)	1 (0.5)
ACETYLSALICYLIC ACID	2 (2.1)	0	0	0	0	0	0	0
DEXTROMETHORPHAN HYDROBROMIDE;DOXYLAMINE SUCCINATE;PARACETAMOL	0	0	0	0	1 (1.0)	0	0	0
DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0
MELOXICAM	0	0	0	0	1 (1.0)	0	0	0
PARACETAMOL	1 (1.1)	0	0	0	0	0	0	0

N: Number of participants who had the second vaccination in Safety Set

n: Number of participants who used Analgesics/Antipyretics on Day 15 or later after the second vaccination

Preferred Product Name is sorted by descending frequency in overall total column

Ad-hoc Table 14.1.4.4.1.1
Summary of Medications for Solicited Adverse Reactions within 7 Days of First Vaccination
First Injection Solicited Safety Set

	Overall			
	Placebo (N=199) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	21 (10.6)	30 (15.0)	30 (15.0)	60 (15.0)
Prevent Pain or Fever	3 (1.5)	5 (2.5)	4 (2.0)	9 (2.3)
Treat Pain or Fever	20 (10.1)	28 (14.0)	29 (14.5)	57 (14.3)

Ad-hoc Table 14.1.4.4.1.1
Summary of Medications for Solicited Adverse Reactions within 7 Days of First Vaccination
First Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	9 (9.0)	16 (16.0)	17 (17.0)	33 (16.5)	12 (12.1)	14 (14.0)	13 (13.0)	27 (13.5)
Prevent Pain or Fever	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Treat Pain or Fever	9 (9.0)	15 (15.0)	16 (16.0)	31 (15.5)	11 (11.1)	13 (13.0)	13 (13.0)	26 (13.0)

Ad-hoc Table 14.1.4.4.1.2
Summary of Medications for Solicited Adverse Reactions within 7 Days of Second Vaccination
Second Injection Solicited Safety Set

	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	mRNA-1273 100 µg (N=198) n (%)	Total (N=393) n (%)
Medication Taken Today for Pain or Fever	13 (6.7)	69 (35.4)	97 (49.0)	166 (42.2)
Prevent Pain or Fever	0	9 (4.6)	14 (7.1)	23 (5.9)
Treat Pain or Fever	13 (6.7)	67 (34.4)	96 (48.5)	163 (41.5)

Ad-hoc Table 14.1.4.4.1.2
Summary of Medications for Solicited Adverse Reactions within 7 Days of Second Vaccination
Second Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	50 µg (N=97)	mRNA-1273		Placebo (N=100)	50 µg (N=98)	mRNA-1273	
			100 µg (N=99)	Total (N=196)			100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Medication Taken Today for Pain or Fever	5 (5.3)	41 (42.3)	52 (52.5)	93 (47.4)	8 (8.0)	28 (28.6)	45 (45.5)	73 (37.1)
Prevent Pain or Fever	0	5 (5.2)	12 (12.1)	17 (8.7)	0	4 (4.1)	2 (2.0)	6 (3.0)
Treat Pain or Fever	5 (5.3)	39 (40.2)	51 (51.5)	90 (45.9)	8 (8.0)	28 (28.6)	45 (45.5)	73 (37.1)

Ad-hoc Table 14.1.4.4.1.3
Summary of Medications for Solicited Adverse Reactions within 7 Days of Any Vaccination
Solicited Safety Set

	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	29 (14.5)	79 (39.5)	103 (51.5)	182 (45.5)
Prevent Pain or Fever	3 (1.5)	14 (7.0)	16 (8.0)	30 (7.5)
Treat Pain or Fever	29 (14.5)	76 (38.0)	102 (51.0)	178 (44.5)

Ad-hoc Table 14.1.4.4.1.3
Summary of Medications for Solicited Adverse Reactions within 7 Days of Any Vaccination
Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
			mRNA-1273				mRNA-1273	
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	12 (12.0)	45 (45.0)	55 (55.0)	100 (50.0)	17 (17.0)	34 (34.0)	48 (48.0)	82 (41.0)
Prevent Pain or Fever	1 (1.0)	7 (7.0)	13 (13.0)	20 (10.0)	2 (2.0)	7 (7.0)	3 (3.0)	10 (5.0)
Treat Pain or Fever	12 (12.0)	43 (43.0)	54 (54.0)	97 (48.5)	17 (17.0)	33 (33.0)	48 (48.0)	81 (40.5)

Ad-hoc Table 14.1.4.4.2.1
Summary of Medications for Solicited Adverse Reactions after First Vaccination
First Injection Solicited Safety Set

	Overall			
	Placebo (N=199) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	21 (10.6)	30 (15.0)	30 (15.0)	60 (15.0)
Prevent Pain or Fever	3 (1.5)	5 (2.5)	4 (2.0)	9 (2.3)
Treat Pain or Fever	20 (10.1)	28 (14.0)	29 (14.5)	57 (14.3)

Ad-hoc Table 14.1.4.4.2.1
Summary of Medications for Solicited Adverse Reactions after First Vaccination
First Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	9 (9.0)	16 (16.0)	17 (17.0)	33 (16.5)	12 (12.1)	14 (14.0)	13 (13.0)	27 (13.5)
Prevent Pain or Fever	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Treat Pain or Fever	9 (9.0)	15 (15.0)	16 (16.0)	31 (15.5)	11 (11.1)	13 (13.0)	13 (13.0)	26 (13.0)

Ad-hoc Table 14.1.4.4.2.2
Summary of Medications for Solicited Adverse Reactions after Second Vaccination
Second Injection Solicited Safety Set

	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	mRNA-1273 100 µg (N=198) n (%)	Total (N=393) n (%)
Medication Taken Today for Pain or Fever	13 (6.7)	69 (35.4)	97 (49.0)	166 (42.2)
Prevent Pain or Fever	0	9 (4.6)	14 (7.1)	23 (5.9)
Treat Pain or Fever	13 (6.7)	67 (34.4)	96 (48.5)	163 (41.5)

Ad-hoc Table 14.1.4.4.2.2
Summary of Medications for Solicited Adverse Reactions after Second Vaccination
Second Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	50 µg (N=97)	mRNA-1273		Placebo (N=100)	50 µg (N=98)	mRNA-1273	
			100 µg (N=99)	Total (N=196)			100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Medication Taken Today for Pain or Fever	5 (5.3)	41 (42.3)	52 (52.5)	93 (47.4)	8 (8.0)	28 (28.6)	45 (45.5)	73 (37.1)
Prevent Pain or Fever	0	5 (5.2)	12 (12.1)	17 (8.7)	0	4 (4.1)	2 (2.0)	6 (3.0)
Treat Pain or Fever	5 (5.3)	39 (40.2)	51 (51.5)	90 (45.9)	8 (8.0)	28 (28.6)	45 (45.5)	73 (37.1)

Ad-hoc Table 14.1.4.4.2.3
Summary of Medications for Solicited Adverse Reactions after Any Vaccination
Solicited Safety Set

	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	29 (14.5)	79 (39.5)	103 (51.5)	182 (45.5)
Prevent Pain or Fever	3 (1.5)	14 (7.0)	16 (8.0)	30 (7.5)
Treat Pain or Fever	29 (14.5)	76 (38.0)	102 (51.0)	178 (44.5)

Ad-hoc Table 14.1.4.4.2.3
Summary of Medications for Solicited Adverse Reactions after Any Vaccination
Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
			mRNA-1273				mRNA-1273	
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	12 (12.0)	45 (45.0)	55 (55.0)	100 (50.0)	17 (17.0)	34 (34.0)	48 (48.0)	82 (41.0)
Prevent Pain or Fever	1 (1.0)	7 (7.0)	13 (13.0)	20 (10.0)	2 (2.0)	7 (7.0)	3 (3.0)	10 (5.0)
Treat Pain or Fever	12 (12.0)	43 (43.0)	54 (54.0)	97 (48.5)	17 (17.0)	33 (33.0)	48 (48.0)	81 (40.5)

Ad-hoc Table 14.1.4.4.3.1
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of First Vaccination
First Injection Solicited Safety Set

	Overall			
	Placebo (N=199) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	1 (0.5)	0	4 (2.0)	4 (1.0)
Prevent Pain or Fever	1 (0.5)	0	3 (1.5)	3 (0.8)
Treat Pain or Fever	1 (0.5)	0	2 (1.0)	2 (0.5)

Ad-hoc Table 14.1.4.4.3.1
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of First Vaccination
First Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	0	0	2 (2.0)	2 (1.0)	1 (1.0)	0	2 (2.0)	2 (1.0)
Prevent Pain or Fever	0	0	2 (2.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Treat Pain or Fever	0	0	0	0	1 (1.0)	0	2 (2.0)	2 (1.0)

Ad-hoc Table 14.1.4.4.3.2
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of Second Vaccination
Second Injection Solicited Safety Set

	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	mRNA-1273 100 µg (N=198) n (%)	Total (N=393) n (%)
Medication Taken Today for Pain or Fever	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Prevent Pain or Fever	0	0	0	0
Treat Pain or Fever	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

Ad-hoc Table 14.1.4.4.3.2
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of Second Vaccination
Second Injection Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	50 µg (N=97)	mRNA-1273		Placebo (N=100)	50 µg (N=98)	mRNA-1273	
			100 µg (N=99)	Total (N=196)			100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Medication Taken Today for Pain or Fever	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Prevent Pain or Fever	0	0	0	0	0	0	0	0
Treat Pain or Fever	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0

Ad-hoc Table 14.1.4.4.3.3
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of Any Vaccination
Solicited Safety Set

	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Medication Taken Today for Pain or Fever	2 (1.0)	1 (0.5)	5 (2.5)	6 (1.5)
Prevent Pain or Fever	1 (0.5)	0	3 (1.5)	3 (0.8)
Treat Pain or Fever	2 (1.0)	1 (0.5)	3 (1.5)	4 (1.0)

Ad-hoc Table 14.1.4.4.3.3
Summary of Medications for Solicited Adverse Reactions beyond 7 Days of Any Vaccination
Solicited Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	mRNA-1273 100 µg (N=100) n (%)	Total (N=200) n (%)
Medication Taken Today for Pain or Fever	0	1 (1.0)	3 (3.0)	4 (2.0)	2 (2.0)	0	2 (2.0)	2 (1.0)
Prevent Pain or Fever	0	0	2 (2.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Treat Pain or Fever	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	0	2 (2.0)	2 (1.0)

Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects with At Least One Medical History	179 (89.5)	181 (90.5)	169 (84.5)	350 (87.5)
Infections and infestations	21 (10.5)	19 (9.5)	25 (12.5)	44 (11.0)
Appendicitis	9 (4.5)	7 (3.5)	6 (3.0)	13 (3.3)
Tonsillitis	1 (0.5)	2 (1.0)	7 (3.5)	9 (2.3)
Herpes simplex	3 (1.5)	5 (2.5)	1 (0.5)	6 (1.5)
Bronchitis	0	1 (0.5)	3 (1.5)	4 (1.0)
Oral herpes	2 (1.0)	0	3 (1.5)	3 (0.8)
Diverticulitis	2 (1.0)	0	2 (1.0)	2 (0.5)
Genital herpes	0	1 (0.5)	1 (0.5)	2 (0.5)
Herpes zoster	0	2 (1.0)	0	2 (0.5)
Onychomycosis	1 (0.5)	0	2 (1.0)	2 (0.5)
Vulvovaginal mycotic infection	0	1 (0.5)	1 (0.5)	2 (0.5)
Adenoiditis	0	1 (0.5)	0	1 (0.3)
Appendicitis perforated	0	0	1 (0.5)	1 (0.3)
Atypical pneumonia	0	0	1 (0.5)	1 (0.3)
Chronic sinusitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Chronic tonsillitis	0	1 (0.5)	0	1 (0.3)
Genital herpes simplex	0	0	1 (0.5)	1 (0.3)
Nail infection	0	0	1 (0.5)	1 (0.3)
Otitis media chronic	0	1 (0.5)	0	1 (0.3)
Papilloma viral infection	0	1 (0.5)	0	1 (0.3)
Pharyngitis streptococcal	1 (0.5)	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Infections and infestations (cont.)				
Pilonidal cyst	0	0	1 (0.5)	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Tinea pedis	0	1 (0.5)	0	1 (0.3)
Urinary tract infection	0	0	1 (0.5)	1 (0.3)
Meningitis bacterial	1 (0.5)	0	0	0
Sialoadenitis	1 (0.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	21 (10.5)	17 (8.5)	20 (10.0)	37 (9.3)
Uterine leiomyoma	8 (4.0)	5 (2.5)	10 (5.0)	15 (3.8)
Basal cell carcinoma	6 (3.0)	2 (1.0)	4 (2.0)	6 (1.5)
Benign neoplasm of thyroid gland	0	2 (1.0)	0	2 (0.5)
Breast cancer	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Lipoma	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Malignant melanoma	0	1 (0.5)	1 (0.5)	2 (0.5)
Benign breast neoplasm	0	0	1 (0.5)	1 (0.3)
Benign hepatic neoplasm	0	1 (0.5)	0	1 (0.3)
Brain neoplasm benign	0	0	1 (0.5)	1 (0.3)
Cholesteatoma	0	1 (0.5)	0	1 (0.3)
Colorectal cancer stage III	0	0	1 (0.5)	1 (0.3)
Fibroadenoma of breast	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)				
Large intestine benign neoplasm	0	1 (0.5)	0	1 (0.3)
Lip squamous cell carcinoma	0	0	1 (0.5)	1 (0.3)
Melanocytic naevus	1 (0.5)	0	1 (0.5)	1 (0.3)
Oesophageal carcinoma	0	1 (0.5)	0	1 (0.3)
Prolactin-producing pituitary tumour	0	0	1 (0.5)	1 (0.3)
Prostate cancer	0	1 (0.5)	0	1 (0.3)
Squamous cell carcinoma of skin	0	0	1 (0.5)	1 (0.3)
Benign neoplasm of spinal cord	1 (0.5)	0	0	0
Benign uterine neoplasm	1 (0.5)	0	0	0
Invasive ductal breast carcinoma	1 (0.5)	0	0	0
Ovarian cancer	1 (0.5)	0	0	0
Blood and lymphatic system disorders	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
Anaemia	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Iron deficiency anaemia	0	0	1 (0.5)	1 (0.3)
Neutropenia	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Immune system disorders	74 (37.0)	92 (46.0)	76 (38.0)	168 (42.0)
Seasonal allergy	54 (27.0)	64 (32.0)	49 (24.5)	113 (28.3)
Drug hypersensitivity	24 (12.0)	32 (16.0)	37 (18.5)	69 (17.3)
Food allergy	1 (0.5)	6 (3.0)	1 (0.5)	7 (1.8)
Allergy to animal	2 (1.0)	2 (1.0)	4 (2.0)	6 (1.5)
Rubber sensitivity	0	3 (1.5)	1 (0.5)	4 (1.0)
Allergy to arthropod sting	0	2 (1.0)	0	2 (0.5)
Allergy to metals	0	2 (1.0)	0	2 (0.5)
Allergy to plants	1 (0.5)	0	1 (0.5)	1 (0.3)
Cockroach allergy	0	0	1 (0.5)	1 (0.3)
Contrast media allergy	0	0	1 (0.5)	1 (0.3)
Dust allergy	0	1 (0.5)	0	1 (0.3)
Iodine allergy	2 (1.0)	0	1 (0.5)	1 (0.3)
Mite allergy	0	1 (0.5)	0	1 (0.3)
Allergy to arthropod bite	1 (0.5)	0	0	0
Allergy to chemicals	1 (0.5)	0	0	0
Endocrine disorders	6 (3.0)	7 (3.5)	9 (4.5)	16 (4.0)
Hypothyroidism	4 (2.0)	6 (3.0)	8 (4.0)	14 (3.5)
Hyperthyroidism	0	1 (0.5)	0	1 (0.3)
Hypogonadism	0	0	1 (0.5)	1 (0.3)
Oestrogen deficiency	2 (1.0)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Metabolism and nutrition disorders	32 (16.0)	35 (17.5)	27 (13.5)	62 (15.5)
Hypercholesterolaemia	11 (5.5)	19 (9.5)	13 (6.5)	32 (8.0)
Hyperlipidaemia	10 (5.0)	3 (1.5)	3 (1.5)	6 (1.5)
Dyslipidaemia	6 (3.0)	1 (0.5)	4 (2.0)	5 (1.3)
Obesity	0	3 (1.5)	2 (1.0)	5 (1.3)
Gout	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
Dairy intolerance	0	1 (0.5)	2 (1.0)	3 (0.8)
Lactose intolerance	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Vitamin D deficiency	3 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)
Gluten sensitivity	1 (0.5)	2 (1.0)	0	2 (0.5)
Iron deficiency	0	1 (0.5)	1 (0.5)	2 (0.5)
Glucose tolerance impaired	0	1 (0.5)	0	1 (0.3)
Vitamin B12 deficiency	1 (0.5)	0	0	0
Psychiatric disorders	61 (30.5)	59 (29.5)	47 (23.5)	106 (26.5)
Anxiety	28 (14.0)	27 (13.5)	22 (11.0)	49 (12.3)
Depression	20 (10.0)	23 (11.5)	19 (9.5)	42 (10.5)
Insomnia	19 (9.5)	16 (8.0)	18 (9.0)	34 (8.5)
Attention deficit hyperactivity disorder	7 (3.5)	11 (5.5)	10 (5.0)	21 (5.3)
Adjustment disorder with depressed mood	0	1 (0.5)	1 (0.5)	2 (0.5)
Post-traumatic stress disorder	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Psychiatric disorders (cont.)				
Affective disorder	0	1 (0.5)	0	1 (0.3)
Bulimia nervosa	0	0	1 (0.5)	1 (0.3)
Generalised anxiety disorder	1 (0.5)	1 (0.5)	0	1 (0.3)
Major depression	1 (0.5)	0	1 (0.5)	1 (0.3)
Persistent depressive disorder	0	1 (0.5)	0	1 (0.3)
Alcoholism	1 (0.5)	0	0	0
Bipolar disorder	1 (0.5)	0	0	0
Enuresis	1 (0.5)	0	0	0
Panic attack	1 (0.5)	0	0	0
Perinatal depression	1 (0.5)	0	0	0
Nervous system disorders	31 (15.5)	40 (20.0)	24 (12.0)	64 (16.0)
Migraine	15 (7.5)	18 (9.0)	10 (5.0)	28 (7.0)
Headache	7 (3.5)	13 (6.5)	7 (3.5)	20 (5.0)
Carpal tunnel syndrome	3 (1.5)	4 (2.0)	1 (0.5)	5 (1.3)
Restless legs syndrome	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Sciatica	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Tension headache	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Guillain-Barre syndrome	0	0	1 (0.5)	1 (0.3)
Hypoaesthesia	0	0	1 (0.5)	1 (0.3)
Migraine with aura	0	1 (0.5)	0	1 (0.3)
Neuropathy peripheral	0	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nervous system disorders (cont.)				
Peripheral sensory neuropathy	0	1 (0.5)	0	1 (0.3)
Polyneuropathy	0	1 (0.5)	0	1 (0.3)
Radiculopathy	0	1 (0.5)	0	1 (0.3)
Seizure	0	1 (0.5)	0	1 (0.3)
Sinus headache	0	0	1 (0.5)	1 (0.3)
Syncope	0	1 (0.5)	0	1 (0.3)
Transient ischaemic attack	0	0	1 (0.5)	1 (0.3)
Memory impairment	1 (0.5)	0	0	0
Piriformis syndrome	1 (0.5)	0	0	0
Eye disorders	13 (6.5)	40 (20.0)	27 (13.5)	67 (16.8)
Myopia	5 (2.5)	19 (9.5)	9 (4.5)	28 (7.0)
Hypermetropia	4 (2.0)	7 (3.5)	7 (3.5)	14 (3.5)
Presbyopia	0	6 (3.0)	5 (2.5)	11 (2.8)
Dry eye	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Glaucoma	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Cataract	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Astigmatism	0	0	3 (1.5)	3 (0.8)
Retinal detachment	1 (0.5)	2 (1.0)	0	2 (0.5)
Episcleritis	0	0	1 (0.5)	1 (0.3)
Eye pain	0	0	1 (0.5)	1 (0.3)
Macular degeneration	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Eye disorders (cont.)				
Pupils unequal	0	0	1 (0.5)	1 (0.3)
Retinal drusen	0	1 (0.5)	0	1 (0.3)
Vision blurred	0	1 (0.5)	0	1 (0.3)
Vitreous floaters	0	1 (0.5)	0	1 (0.3)
Blindness unilateral	1 (0.5)	0	0	0
Eye haemorrhage	1 (0.5)	0	0	0
Open angle glaucoma	1 (0.5)	0	0	0
Optic neuropathy	1 (0.5)	0	0	0
Ear and labyrinth disorders	9 (4.5)	4 (2.0)	4 (2.0)	8 (2.0)
Meniere's disease	0	0	2 (1.0)	2 (0.5)
Vertigo	2 (1.0)	2 (1.0)	0	2 (0.5)
Deafness bilateral	1 (0.5)	1 (0.5)	0	1 (0.3)
Deafness unilateral	1 (0.5)	0	1 (0.5)	1 (0.3)
Otosclerosis	0	0	1 (0.5)	1 (0.3)
Tympanic membrane perforation	0	1 (0.5)	0	1 (0.3)
Hypoacusis	2 (1.0)	0	0	0
Tinnitus	2 (1.0)	0	0	0
Vertigo positional	1 (0.5)	0	0	0
Cardiac disorders	3 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)
Bradycardia	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Cardiac disorders (cont.)				
Supraventricular tachycardia	0	1 (0.5)	0	1 (0.3)
Vascular disorders	6 (3.0)	10 (5.0)	7 (3.5)	17 (4.3)
Hot flush	5 (2.5)	5 (2.5)	3 (1.5)	8 (2.0)
Raynaud's phenomenon	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Varicose vein	0	1 (0.5)	2 (1.0)	3 (0.8)
Hypertension	0	1 (0.5)	1 (0.5)	2 (0.5)
Aortic dilatation	0	0	1 (0.5)	1 (0.3)
Haematoma	0	1 (0.5)	0	1 (0.3)
Respiratory, thoracic and mediastinal disorders	7 (3.5)	6 (3.0)	8 (4.0)	14 (3.5)
Rhinitis allergic	2 (1.0)	4 (2.0)	4 (2.0)	8 (2.0)
Sleep apnoea syndrome	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Allergic sinusitis	0	0	1 (0.5)	1 (0.3)
Epistaxis	0	1 (0.5)	0	1 (0.3)
Nasal septum deviation	1 (0.5)	0	1 (0.5)	1 (0.3)
Pulmonary embolism	1 (0.5)	1 (0.5)	0	1 (0.3)
Tonsillar hypertrophy	2 (1.0)	0	0	0
Gastrointestinal disorders	29 (14.5)	35 (17.5)	30 (15.0)	65 (16.3)
Gastroesophageal reflux disease	13 (6.5)	17 (8.5)	13 (6.5)	30 (7.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Inguinal hernia	3 (1.5)	5 (2.5)	4 (2.0)	9 (2.3)
Irritable bowel syndrome	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Constipation	2 (1.0)	2 (1.0)	4 (2.0)	6 (1.5)
Dyspepsia	3 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)
Diverticulum	0	2 (1.0)	1 (0.5)	3 (0.8)
Abdominal hernia	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Hiatus hernia	0	1 (0.5)	1 (0.5)	2 (0.5)
Large intestine polyp	1 (0.5)	2 (1.0)	0	2 (0.5)
Toothache	2 (1.0)	2 (1.0)	0	2 (0.5)
Abdominal fat apron	0	1 (0.5)	0	1 (0.3)
Anal fistula	0	1 (0.5)	0	1 (0.3)
Diarrhoea	0	0	1 (0.5)	1 (0.3)
Impaired gastric emptying	0	0	1 (0.5)	1 (0.3)
Intestinal obstruction	0	0	1 (0.5)	1 (0.3)
Tooth impacted	0	1 (0.5)	0	1 (0.3)
Duodenal ulcer	1 (0.5)	0	0	0
Haemorrhoids	1 (0.5)	0	0	0
Nausea	1 (0.5)	0	0	0
Umbilical hernia	3 (1.5)	0	0	0
Hepatobiliary disorders	12 (6.0)	10 (5.0)	9 (4.5)	19 (4.8)
Cholecystitis	8 (4.0)	8 (4.0)	3 (1.5)	11 (2.8)
Cholelithiasis	4 (2.0)	2 (1.0)	4 (2.0)	6 (1.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Hepatobiliary disorders (cont.)				
Gallbladder disorder	0	0	1 (0.5)	1 (0.3)
Hepatic lesion	0	0	1 (0.5)	1 (0.3)
Skin and subcutaneous tissue disorders	13 (6.5)	20 (10.0)	9 (4.5)	29 (7.3)
Acne	8 (4.0)	3 (1.5)	4 (2.0)	7 (1.8)
Rosacea	1 (0.5)	4 (2.0)	1 (0.5)	5 (1.3)
Eczema	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Dermatitis contact	0	2 (1.0)	1 (0.5)	3 (0.8)
Acne cystic	0	1 (0.5)	0	1 (0.3)
Actinic keratosis	1 (0.5)	1 (0.5)	0	1 (0.3)
Alopecia	0	1 (0.5)	0	1 (0.3)
Angiokeratoma	0	0	1 (0.5)	1 (0.3)
Dermatitis atopic	0	1 (0.5)	0	1 (0.3)
Drug eruption	0	1 (0.5)	0	1 (0.3)
Hyperhidrosis	0	1 (0.5)	0	1 (0.3)
Lichen planus	0	1 (0.5)	0	1 (0.3)
Night sweats	0	1 (0.5)	0	1 (0.3)
Rash	0	0	1 (0.5)	1 (0.3)
Ingrowing nail	1 (0.5)	0	0	0
Photodermatosis	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	41 (20.5)	51 (25.5)	43 (21.5)	94 (23.5)
Osteoarthritis	11 (5.5)	15 (7.5)	14 (7.0)	29 (7.3)
Back pain	6 (3.0)	12 (6.0)	4 (2.0)	16 (4.0)
Arthralgia	3 (1.5)	5 (2.5)	4 (2.0)	9 (2.3)
Osteopenia	6 (3.0)	6 (3.0)	3 (1.5)	9 (2.3)
Musculoskeletal pain	3 (1.5)	6 (3.0)	1 (0.5)	7 (1.8)
Osteoporosis	6 (3.0)	4 (2.0)	3 (1.5)	7 (1.8)
Foot deformity	1 (0.5)	1 (0.5)	5 (2.5)	6 (1.5)
Intervertebral disc protrusion	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Neck pain	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Rotator cuff syndrome	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Spinal osteoarthritis	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Intervertebral disc degeneration	1 (0.5)	5 (2.5)	0	5 (1.3)
Myalgia	2 (1.0)	3 (1.5)	0	3 (0.8)
Pain in extremity	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Scoliosis	0	2 (1.0)	1 (0.5)	3 (0.8)
Fibromyalgia	0	1 (0.5)	1 (0.5)	2 (0.5)
Spinal stenosis	0	1 (0.5)	1 (0.5)	2 (0.5)
Arthritis	1 (0.5)	1 (0.5)	0	1 (0.3)
Bursitis	0	0	1 (0.5)	1 (0.3)
Cervical spinal stenosis	0	0	1 (0.5)	1 (0.3)
Chondropathy	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Dupuytren's contracture	0	1 (0.5)	0	1 (0.3)
Exostosis	0	0	1 (0.5)	1 (0.3)
Jaw cyst	0	0	1 (0.5)	1 (0.3)
Ligament laxity	0	1 (0.5)	0	1 (0.3)
Muscle spasms	0	1 (0.5)	0	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Periarthritis	0	1 (0.5)	0	1 (0.3)
Spinal deformity	0	0	1 (0.5)	1 (0.3)
Synovial cyst	0	0	1 (0.5)	1 (0.3)
Tendonitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Trigger finger	0	0	1 (0.5)	1 (0.3)
Diastasis recti abdominis	1 (0.5)	0	0	0
Kyphosis	1 (0.5)	0	0	0
Muscle atrophy	1 (0.5)	0	0	0
Muscle tightness	1 (0.5)	0	0	0
Nose deformity	1 (0.5)	0	0	0
Plantar fasciitis	1 (0.5)	0	0	0
Renal and urinary disorders	9 (4.5)	7 (3.5)	7 (3.5)	14 (3.5)
Hypertonic bladder	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Haematuria	0	1 (0.5)	0	1 (0.3)
Incontinence	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Renal and urinary disorders (cont.)				
Micturition urgency	0	0	1 (0.5)	1 (0.3)
Nephrolithiasis	3 (1.5)	0	1 (0.5)	1 (0.3)
Nocturia	0	0	1 (0.5)	1 (0.3)
Pollakiuria	0	0	1 (0.5)	1 (0.3)
Renal impairment	0	1 (0.5)	0	1 (0.3)
Urinary incontinence	0	1 (0.5)	0	1 (0.3)
Urinary retention	0	0	1 (0.5)	1 (0.3)
Bladder prolapse	1 (0.5)	0	0	0
Cystitis interstitial	1 (0.5)	0	0	0
Neurogenic bladder	1 (0.5)	0	0	0
Urethral dilatation	1 (0.5)	0	0	0
Pregnancy, puerperium and perinatal conditions	3 (1.5)	1 (0.5)	2 (1.0)	3 (0.8)
Abortion spontaneous	2 (1.0)	0	1 (0.5)	1 (0.3)
Postpartum haemorrhage	0	1 (0.5)	0	1 (0.3)
Pregnancy	1 (0.5)	0	1 (0.5)	1 (0.3)
Reproductive system and breast disorders	31 (15.5)	26 (13.0)	32 (16.0)	58 (14.5)
Menorrhagia	8 (4.0)	8 (4.0)	6 (3.0)	14 (3.5)
Endometriosis	6 (3.0)	2 (1.0)	6 (3.0)	8 (2.0)
Erectile dysfunction	3 (1.5)	3 (1.5)	3 (1.5)	6 (1.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Reproductive system and breast disorders (cont.)				
Dysmenorrhoea	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
Polycystic ovaries	0	3 (1.5)	2 (1.0)	5 (1.3)
Benign prostatic hyperplasia	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Uterine prolapse	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)
Amenorrhoea	0	1 (0.5)	1 (0.5)	2 (0.5)
Premenstrual dysphoric disorder	0	1 (0.5)	1 (0.5)	2 (0.5)
Uterine haemorrhage	0	0	2 (1.0)	2 (0.5)
Breast cyst	1 (0.5)	0	1 (0.5)	1 (0.3)
Cystocele	0	1 (0.5)	0	1 (0.3)
Dyspareunia	0	0	1 (0.5)	1 (0.3)
Endometrial hyperplasia	0	0	1 (0.5)	1 (0.3)
Infertility	0	0	1 (0.5)	1 (0.3)
Menometrorrhagia	0	1 (0.5)	0	1 (0.3)
Menopausal symptoms	0	1 (0.5)	0	1 (0.3)
Premenstrual syndrome	0	1 (0.5)	0	1 (0.3)
Prostatomegaly	0	1 (0.5)	0	1 (0.3)
Uterine polyp	0	1 (0.5)	0	1 (0.3)
Vulvovaginal dryness	0	0	1 (0.5)	1 (0.3)
Nipple swelling	1 (0.5)	0	0	0
Ovarian cyst	4 (2.0)	0	0	0
Ovarian cyst ruptured	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Reproductive system and breast disorders (cont.)				
Pelvic pain	1 (0.5)	0	0	0
Testicular torsion	1 (0.5)	0	0	0
Congenital, familial and genetic disorders	3 (1.5)	3 (1.5)	5 (2.5)	8 (2.0)
Congenital scoliosis	0	0	2 (1.0)	2 (0.5)
Arnold-Chiari malformation	0	1 (0.5)	0	1 (0.3)
Factor V Leiden carrier	0	1 (0.5)	0	1 (0.3)
Factor V Leiden mutation	0	1 (0.5)	0	1 (0.3)
Gilbert's syndrome	0	0	1 (0.5)	1 (0.3)
Type IIa hyperlipidaemia	1 (0.5)	0	1 (0.5)	1 (0.3)
Type V hyperlipidaemia	0	0	1 (0.5)	1 (0.3)
Ehlers-Danlos syndrome	1 (0.5)	0	0	0
Renal aplasia	1 (0.5)	0	0	0
General disorders and administration site conditions	7 (3.5)	4 (2.0)	2 (1.0)	6 (1.5)
Pain	4 (2.0)	3 (1.5)	1 (0.5)	4 (1.0)
Oedema peripheral	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Cyst	1 (0.5)	0	0	0
Hernia	1 (0.5)	0	0	0
Oedema	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Investigations	8 (4.0)	8 (4.0)	12 (6.0)	20 (5.0)
Arthroscopy	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Biopsy breast normal	0	0	3 (1.5)	3 (0.8)
Blood cholesterol increased	0	0	2 (1.0)	2 (0.5)
Blood pressure increased	0	0	2 (1.0)	2 (0.5)
Blood testosterone decreased	1 (0.5)	0	2 (1.0)	2 (0.5)
Cardiac murmur	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Liver function test increased	0	1 (0.5)	0	1 (0.3)
Mammogram abnormal	0	0	1 (0.5)	1 (0.3)
Endoscopy upper gastrointestinal tract	1 (0.5)	0	0	0
Precancerous cells present	1 (0.5)	0	0	0
Injury, poisoning and procedural complications	11 (5.5)	24 (12.0)	16 (8.0)	40 (10.0)
Meniscus injury	1 (0.5)	4 (2.0)	3 (1.5)	7 (1.8)
Cartilage injury	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Wrist fracture	0	2 (1.0)	2 (1.0)	4 (1.0)
Ligament rupture	0	3 (1.5)	0	3 (0.8)
Foot fracture	1 (0.5)	2 (1.0)	0	2 (0.5)
Hip fracture	0	1 (0.5)	1 (0.5)	2 (0.5)
Joint dislocation	0	2 (1.0)	0	2 (0.5)
Limb injury	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Radius fracture	0	1 (0.5)	1 (0.5)	2 (0.5)
Tendon injury	0	0	2 (1.0)	2 (0.5)
Tendon rupture	0	1 (0.5)	1 (0.5)	2 (0.5)
Ulna fracture	0	0	2 (1.0)	2 (0.5)
Accident	0	1 (0.5)	0	1 (0.3)
Animal bite	0	0	1 (0.5)	1 (0.3)
Ankle fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Arthropod bite	0	1 (0.5)	0	1 (0.3)
Epicondylitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Facial bones fracture	0	1 (0.5)	0	1 (0.3)
Fall	0	0	1 (0.5)	1 (0.3)
Joint injury	1 (0.5)	1 (0.5)	0	1 (0.3)
Ligament injury	0	1 (0.5)	0	1 (0.3)
Ligament sprain	0	1 (0.5)	0	1 (0.3)
Lower limb fracture	0	0	1 (0.5)	1 (0.3)
Nerve injury	0	1 (0.5)	0	1 (0.3)
Patella fracture	0	1 (0.5)	0	1 (0.3)
Sciatic nerve injury	0	1 (0.5)	0	1 (0.3)
Skin laceration	0	1 (0.5)	0	1 (0.3)
Splenic rupture	0	1 (0.5)	0	1 (0.3)
Hand fracture	1 (0.5)	0	0	0
Skin abrasion	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Upper limb fracture	2 (1.0)	0	0	0
Surgical and medical procedures	104 (52.0)	96 (48.0)	91 (45.5)	187 (46.8)
Hysterectomy	26 (13.0)	20 (10.0)	26 (13.0)	46 (11.5)
Female sterilisation	20 (10.0)	13 (6.5)	13 (6.5)	26 (6.5)
Vasectomy	16 (8.0)	12 (6.0)	10 (5.0)	22 (5.5)
Cholecystectomy	12 (6.0)	12 (6.0)	7 (3.5)	19 (4.8)
Appendicectomy	10 (5.0)	9 (4.5)	8 (4.0)	17 (4.3)
Tonsillectomy	3 (1.5)	3 (1.5)	11 (5.5)	14 (3.5)
Caesarean section	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Knee arthroplasty	2 (1.0)	2 (1.0)	5 (2.5)	7 (1.8)
Ligament operation	0	7 (3.5)	0	7 (1.8)
Hip arthroplasty	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Inguinal hernia repair	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Keratomileusis	0	4 (2.0)	2 (1.0)	6 (1.5)
Skin neoplasm excision	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Bunion operation	1 (0.5)	1 (0.5)	4 (2.0)	5 (1.3)
Carpal tunnel decompression	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Endometrial ablation	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
Fracture treatment	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Surgical and medical procedures (cont.)				
Intervertebral disc operation	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
Rotator cuff repair	2 (1.0)	1 (0.5)	3 (1.5)	4 (1.0)
Spinal fusion surgery	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
Ankle operation	0	2 (1.0)	1 (0.5)	3 (0.8)
Meniscus operation	0	2 (1.0)	1 (0.5)	3 (0.8)
Shoulder operation	0	2 (1.0)	1 (0.5)	3 (0.8)
Tenoplasty	0	1 (0.5)	2 (1.0)	3 (0.8)
Abdominal hernia repair	0	1 (0.5)	1 (0.5)	2 (0.5)
Abdominoplasty	0	1 (0.5)	1 (0.5)	2 (0.5)
Cataract operation	1 (0.5)	2 (1.0)	0	2 (0.5)
Hip surgery	0	1 (0.5)	1 (0.5)	2 (0.5)
Intraocular lens implant	0	1 (0.5)	1 (0.5)	2 (0.5)
Mammoplasty	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Open reduction of fracture	3 (1.5)	0	2 (1.0)	2 (0.5)
Retinal operation	0	1 (0.5)	1 (0.5)	2 (0.5)
Spinal laminectomy	0	1 (0.5)	1 (0.5)	2 (0.5)
Vision correction operation	0	1 (0.5)	1 (0.5)	2 (0.5)
Adenoidectomy	1 (0.5)	1 (0.5)	0	1 (0.3)
Anal fistula repair	0	1 (0.5)	0	1 (0.3)
Axillary lymphadenectomy	0	1 (0.5)	0	1 (0.3)
Benign breast lump removal	0	1 (0.5)	0	1 (0.3)
Bone cyst excision	0	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Surgical and medical procedures (cont.)				
Brain operation	0	1 (0.5)	0	1 (0.3)
Breast cyst excision	1 (0.5)	0	1 (0.5)	1 (0.3)
CSF shunt operation	0	1 (0.5)	0	1 (0.3)
Cautery to nose	0	1 (0.5)	0	1 (0.3)
Colostomy	0	0	1 (0.5)	1 (0.3)
Dupuytren's contracture operation	0	1 (0.5)	0	1 (0.3)
Ear operation	0	1 (0.5)	0	1 (0.3)
Ear tube insertion	0	1 (0.5)	0	1 (0.3)
Ear tube removal	0	1 (0.5)	0	1 (0.3)
Endovenous ablation	0	1 (0.5)	0	1 (0.3)
Eye excision	0	1 (0.5)	0	1 (0.3)
Eye laser surgery	0	0	1 (0.5)	1 (0.3)
Eye operation	0	0	1 (0.5)	1 (0.3)
Finger repair operation	0	1 (0.5)	0	1 (0.3)
Foot operation	1 (0.5)	1 (0.5)	0	1 (0.3)
In vitro fertilisation	0	0	1 (0.5)	1 (0.3)
Joint debridement	0	1 (0.5)	0	1 (0.3)
Joint dislocation reduction	0	1 (0.5)	0	1 (0.3)
Lipoma excision	1 (0.5)	0	1 (0.5)	1 (0.3)
Loop electrosurgical excision procedure	0	1 (0.5)	0	1 (0.3)
Mastectomy	1 (0.5)	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Surgical and medical procedures (cont.)				
Medical device removal	0	1 (0.5)	0	1 (0.3)
Myomectomy	1 (0.5)	0	1 (0.5)	1 (0.3)
Nasal septal operation	0	0	1 (0.5)	1 (0.3)
Nephrectomy	1 (0.5)	1 (0.5)	0	1 (0.3)
Oesophagectomy	0	1 (0.5)	0	1 (0.3)
Oesophagogastric fundoplasty	0	1 (0.5)	0	1 (0.3)
Oophorectomy bilateral	1 (0.5)	0	1 (0.5)	1 (0.3)
Osteotomy	0	1 (0.5)	0	1 (0.3)
Ovarian cystectomy	0	1 (0.5)	0	1 (0.3)
Ovarian operation	0	0	1 (0.5)	1 (0.3)
Prostatectomy	0	1 (0.5)	0	1 (0.3)
Rhinoplasty	1 (0.5)	1 (0.5)	0	1 (0.3)
Scleral buckling surgery	0	1 (0.5)	0	1 (0.3)
Shoulder arthroplasty	0	1 (0.5)	0	1 (0.3)
Sinus operation	0	1 (0.5)	0	1 (0.3)
Splenectomy	0	1 (0.5)	0	1 (0.3)
Tendon sheath incision	0	0	1 (0.5)	1 (0.3)
Toe operation	0	0	1 (0.5)	1 (0.3)
Turbinoplasty	0	1 (0.5)	0	1 (0.3)
Tympanoplasty	0	1 (0.5)	0	1 (0.3)
Urethral dilation procedure	0	1 (0.5)	0	1 (0.3)
Vaginal operation	0	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Surgical and medical procedures (cont.)				
Wisdom teeth removal	2 (1.0)	1 (0.5)	0	1 (0.3)
Wrist surgery	0	1 (0.5)	0	1 (0.3)
Breast conserving surgery	1 (0.5)	0	0	0
Chondroplasty	1 (0.5)	0	0	0
Colectomy	2 (1.0)	0	0	0
Contraception	1 (0.5)	0	0	0
Extracorporeal shock wave therapy	1 (0.5)	0	0	0
Gastrectomy	1 (0.5)	0	0	0
Hernia repair	1 (0.5)	0	0	0
Knee operation	1 (0.5)	0	0	0
Large intestinal polypectomy	1 (0.5)	0	0	0
Micrographic skin surgery	1 (0.5)	0	0	0
Mole excision	1 (0.5)	0	0	0
Muscle operation	1 (0.5)	0	0	0
Nail operation	1 (0.5)	0	0	0
Oophorectomy	3 (1.5)	0	0	0
Orchidectomy	1 (0.5)	0	0	0
Salivary gland resection	1 (0.5)	0	0	0
Salpingectomy	1 (0.5)	0	0	0
Spinal operation	2 (1.0)	0	0	0
Thyroid nodule removal	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Surgical and medical procedures (cont.)				
Trabeculectomy	1 (0.5)	0	0	0
Umbilical hernia repair	1 (0.5)	0	0	0
Urinary bladder suspension	1 (0.5)	0	0	0
Uterine dilation and curettage	3 (1.5)	0	0	0
Uterine operation	1 (0.5)	0	0	0
Social circumstances	64 (32.0)	63 (31.5)	62 (31.0)	125 (31.3)
Postmenopause	52 (26.0)	58 (29.0)	47 (23.5)	105 (26.3)
Menopause	12 (6.0)	4 (2.0)	15 (7.5)	19 (4.8)
Corrective lens user	0	0	1 (0.5)	1 (0.3)
Hearing aid user	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects with At Least One Medical History	84 (84.0)	82 (82.0)	75 (75.0)	157 (78.5)	95 (95.0)	99 (99.0)	94 (94.0)	193 (96.5)
Infections and infestations	12 (12.0)	9 (9.0)	12 (12.0)	21 (10.5)	9 (9.0)	10 (10.0)	13 (13.0)	23 (11.5)
Appendicitis	6 (6.0)	4 (4.0)	2 (2.0)	6 (3.0)	3 (3.0)	3 (3.0)	4 (4.0)	7 (3.5)
Tonsillitis	1 (1.0)	1 (1.0)	4 (4.0)	5 (2.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
Herpes simplex	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	3 (3.0)	0	3 (1.5)
Bronchitis	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Oral herpes	0	0	2 (2.0)	2 (1.0)	2 (2.0)	0	1 (1.0)	1 (0.5)
Diverticulitis	1 (1.0)	0	0	0	1 (1.0)	0	2 (2.0)	2 (1.0)
Genital herpes	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Herpes zoster	0	0	0	0	0	2 (2.0)	0	2 (1.0)
Onychomycosis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Vulvovaginal mycotic infection	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Adenoiditis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Appendicitis perforated	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Atypical pneumonia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Chronic sinusitis	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Chronic tonsillitis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Genital herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nail infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Otitis media chronic	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Papilloma viral infection	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pharyngitis streptococcal	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Infections and infestations (cont.)								
Pilonidal cyst	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tinea pedis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Urinary tract infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Meningitis bacterial	1 (1.0)	0	0	0	0	0	0	0
Sialoadenitis	0	0	0	0	1 (1.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)	18 (18.0)	14 (14.0)	17 (17.0)	31 (15.5)
Uterine leiomyoma	2 (2.0)	1 (1.0)	0	1 (0.5)	6 (6.0)	4 (4.0)	10 (10.0)	14 (7.0)
Basal cell carcinoma	0	0	1 (1.0)	1 (0.5)	6 (6.0)	2 (2.0)	3 (3.0)	5 (2.5)
Benign neoplasm of thyroid gland	0	0	0	0	0	2 (2.0)	0	2 (1.0)
Breast cancer	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Lipoma	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Malignant melanoma	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Benign breast neoplasm	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Benign hepatic neoplasm	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Brain neoplasm benign	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Cholesteatoma	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Colorectal cancer stage III	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Fibroadenoma of breast	0	1 (1.0)	0	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)								
Large intestine benign neoplasm	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Lip squamous cell carcinoma	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Melanocytic naevus	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Oesophageal carcinoma	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Prolactin-producing pituitary tumour	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Prostate cancer	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Squamous cell carcinoma of skin	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Benign neoplasm of spinal cord	0	0	0	0	1 (1.0)	0	0	0
Benign uterine neoplasm	0	0	0	0	1 (1.0)	0	0	0
Invasive ductal breast carcinoma	0	0	0	0	1 (1.0)	0	0	0
Ovarian cancer	0	0	0	0	1 (1.0)	0	0	0
Blood and lymphatic system disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
Anaemia	0	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Iron deficiency anaemia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Neutropenia	0	0	0	0	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Immune system disorders	38 (38.0)	43 (43.0)	36 (36.0)	79 (39.5)	36 (36.0)	49 (49.0)	40 (40.0)	89 (44.5)
Seasonal allergy	28 (28.0)	29 (29.0)	23 (23.0)	52 (26.0)	26 (26.0)	35 (35.0)	26 (26.0)	61 (30.5)
Drug hypersensitivity	12 (12.0)	12 (12.0)	21 (21.0)	33 (16.5)	12 (12.0)	20 (20.0)	16 (16.0)	36 (18.0)
Food allergy	1 (1.0)	4 (4.0)	0	4 (2.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
Allergy to animal	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)
Rubber sensitivity	0	0	0	0	0	3 (3.0)	1 (1.0)	4 (2.0)
Allergy to arthropod sting	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Allergy to metals	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Allergy to plants	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Cockroach allergy	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Contrast media allergy	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dust allergy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Iodine allergy	1 (1.0)	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mite allergy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Allergy to arthropod bite	1 (1.0)	0	0	0	0	0	0	0
Allergy to chemicals	1 (1.0)	0	0	0	0	0	0	0
Endocrine disorders	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	5 (5.0)	5 (5.0)	7 (7.0)	12 (6.0)
Hypothyroidism	0	2 (2.0)	1 (1.0)	3 (1.5)	4 (4.0)	4 (4.0)	7 (7.0)	11 (5.5)
Hyperthyroidism	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Hypogonadism	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oestrogen deficiency	1 (1.0)	0	0	0	1 (1.0)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Metabolism and nutrition disorders	9 (9.0)	7 (7.0)	5 (5.0)	12 (6.0)	23 (23.0)	28 (28.0)	22 (22.0)	50 (25.0)
Hypercholesterolaemia	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	10 (10.0)	18 (18.0)	12 (12.0)	30 (15.0)
Hyperlipidaemia	4 (4.0)	1 (1.0)	0	1 (0.5)	6 (6.0)	2 (2.0)	3 (3.0)	5 (2.5)
Dyslipidaemia	2 (2.0)	0	2 (2.0)	2 (1.0)	4 (4.0)	1 (1.0)	2 (2.0)	3 (1.5)
Obesity	0	1 (1.0)	0	1 (0.5)	0	2 (2.0)	2 (2.0)	4 (2.0)
Gout	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Dairy intolerance	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Lactose intolerance	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Vitamin D deficiency	0	0	0	0	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Gluten sensitivity	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	0	0
Iron deficiency	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Glucose tolerance impaired	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vitamin B12 deficiency	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	34 (34.0)	28 (28.0)	20 (20.0)	48 (24.0)	27 (27.0)	31 (31.0)	27 (27.0)	58 (29.0)
Anxiety	18 (18.0)	15 (15.0)	12 (12.0)	27 (13.5)	10 (10.0)	12 (12.0)	10 (10.0)	22 (11.0)
Depression	11 (11.0)	13 (13.0)	6 (6.0)	19 (9.5)	9 (9.0)	10 (10.0)	13 (13.0)	23 (11.5)
Insomnia	7 (7.0)	1 (1.0)	5 (5.0)	6 (3.0)	12 (12.0)	15 (15.0)	13 (13.0)	28 (14.0)
Attention deficit hyperactivity disorder	3 (3.0)	10 (10.0)	5 (5.0)	15 (7.5)	4 (4.0)	1 (1.0)	5 (5.0)	6 (3.0)
Adjustment disorder with depressed mood	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Post-traumatic stress disorder	1 (1.0)	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Psychiatric disorders (cont.)								
Affective disorder	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Bulimia nervosa	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Generalised anxiety disorder	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Major depression	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Persistent depressive disorder	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Alcoholism	1 (1.0)	0	0	0	0	0	0	0
Bipolar disorder	1 (1.0)	0	0	0	0	0	0	0
Enuresis	1 (1.0)	0	0	0	0	0	0	0
Panic attack	1 (1.0)	0	0	0	0	0	0	0
Perinatal depression	1 (1.0)	0	0	0	0	0	0	0
Nervous system disorders	13 (13.0)	18 (18.0)	9 (9.0)	27 (13.5)	18 (18.0)	22 (22.0)	15 (15.0)	37 (18.5)
Migraine	6 (6.0)	7 (7.0)	3 (3.0)	10 (5.0)	9 (9.0)	11 (11.0)	7 (7.0)	18 (9.0)
Headache	2 (2.0)	9 (9.0)	3 (3.0)	12 (6.0)	5 (5.0)	4 (4.0)	4 (4.0)	8 (4.0)
Carpal tunnel syndrome	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	3 (3.0)	0	3 (1.5)
Restless legs syndrome	0	1 (1.0)	1 (1.0)	2 (1.0)	3 (3.0)	2 (2.0)	0	2 (1.0)
Sciatica	1 (1.0)	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
Tension headache	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Guillain-Barre syndrome	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hypoaesthesia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Migraine with aura	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Neuropathy peripheral	0	0	0	0	0	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Nervous system disorders (cont.)								
Peripheral sensory neuropathy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Polyneuropathy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Radiculopathy	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Seizure	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Sinus headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Syncope	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Transient ischaemic attack	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Memory impairment	0	0	0	0	1 (1.0)	0	0	0
Piriformis syndrome	1 (1.0)	0	0	0	0	0	0	0
Eye disorders	0	10 (10.0)	10 (10.0)	20 (10.0)	13 (13.0)	30 (30.0)	17 (17.0)	47 (23.5)
Myopia	0	6 (6.0)	4 (4.0)	10 (5.0)	5 (5.0)	13 (13.0)	5 (5.0)	18 (9.0)
Hypermetropia	0	2 (2.0)	2 (2.0)	4 (2.0)	4 (4.0)	5 (5.0)	5 (5.0)	10 (5.0)
Presbyopia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	5 (5.0)	4 (4.0)	9 (4.5)
Dry eye	0	0	0	0	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)
Glaucoma	0	0	0	0	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)
Cataract	0	0	0	0	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
Astigmatism	0	0	2 (2.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Retinal detachment	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Episcleritis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Eye pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Macular degeneration	0	0	0	0	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Eye disorders (cont.)								
Pupils unequal	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Retinal drusen	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vision blurred	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Vitreous floaters	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Blindness unilateral	0	0	0	0	1 (1.0)	0	0	0
Eye haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Open angle glaucoma	0	0	0	0	1 (1.0)	0	0	0
Optic neuropathy	0	0	0	0	1 (1.0)	0	0	0
Ear and labyrinth disorders	1 (1.0)	0	1 (1.0)	1 (0.5)	8 (8.0)	4 (4.0)	3 (3.0)	7 (3.5)
Meniere's disease	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Vertigo	0	0	0	0	2 (2.0)	2 (2.0)	0	2 (1.0)
Deafness bilateral	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Deafness unilateral	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Otosclerosis	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tympanic membrane perforation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Hypoacusis	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Tinnitus	0	0	0	0	2 (2.0)	0	0	0
Vertigo positional	0	0	0	0	1 (1.0)	0	0	0
Cardiac disorders	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Bradycardia	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Cardiac disorders (cont.)								
Supraventricular tachycardia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vascular disorders	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	5 (5.0)	7 (7.0)	6 (6.0)	13 (6.5)
Hot flush	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	4 (4.0)	4 (4.0)	2 (2.0)	6 (3.0)
Raynaud's phenomenon	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Varicose vein	0	0	0	0	0	1 (1.0)	2 (2.0)	3 (1.5)
Hypertension	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Aortic dilatation	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haematoma	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	3 (3.0)	2 (2.0)	5 (5.0)	7 (3.5)	4 (4.0)	4 (4.0)	3 (3.0)	7 (3.5)
Rhinitis allergic	0	1 (1.0)	2 (2.0)	3 (1.5)	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)
Sleep apnoea syndrome	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Allergic sinusitis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Epistaxis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Nasal septum deviation	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Pulmonary embolism	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Tonsillar hypertrophy	2 (2.0)	0	0	0	0	0	0	0
Gastrointestinal disorders	13 (13.0)	13 (13.0)	14 (14.0)	27 (13.5)	16 (16.0)	22 (22.0)	16 (16.0)	38 (19.0)
Gastroesophageal reflux disease	3 (3.0)	5 (5.0)	5 (5.0)	10 (5.0)	10 (10.0)	12 (12.0)	8 (8.0)	20 (10.0)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Inguinal hernia	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Irritable bowel syndrome	3 (3.0)	1 (1.0)	2 (2.0)	3 (1.5)	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)
Constipation	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
Dyspepsia	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	0	2 (2.0)	2 (1.0)
Diverticulum	0	0	1 (1.0)	1 (0.5)	0	2 (2.0)	0	2 (1.0)
Abdominal hernia	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Hiatus hernia	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Large intestine polyp	0	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)
Toothache	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Abdominal fat apron	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Anal fistula	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diarrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Impaired gastric emptying	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Intestinal obstruction	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth impacted	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Duodenal ulcer	1 (1.0)	0	0	0	0	0	0	0
Haemorrhoids	0	0	0	0	1 (1.0)	0	0	0
Nausea	0	0	0	0	1 (1.0)	0	0	0
Umbilical hernia	0	0	0	0	3 (3.0)	0	0	0
Hepatobiliary disorders	8 (8.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	5 (5.0)	7 (7.0)	12 (6.0)
Cholecystitis	5 (5.0)	5 (5.0)	1 (1.0)	6 (3.0)	3 (3.0)	3 (3.0)	2 (2.0)	5 (2.5)
Cholelithiasis	3 (3.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Hepatobiliary disorders (cont.)								
Gallbladder disorder	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hepatic lesion	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Skin and subcutaneous tissue disorders	9 (9.0)	10 (10.0)	7 (7.0)	17 (8.5)	4 (4.0)	10 (10.0)	2 (2.0)	12 (6.0)
Acne	7 (7.0)	2 (2.0)	3 (3.0)	5 (2.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Rosacea	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	3 (3.0)	0	3 (1.5)
Eczema	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Dermatitis contact	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Acne cystic	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Actinic keratosis	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Alopecia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Angiokeratoma	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dermatitis atopic	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Drug eruption	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Hyperhidrosis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lichen planus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Night sweats	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Rash	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ingrowing nail	1 (1.0)	0	0	0	0	0	0	0
Photodermatosis	0	0	0	0	1 (1.0)	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders	9 (9.0)	16 (16.0)	10 (10.0)	26 (13.0)	32 (32.0)	35 (35.0)	33 (33.0)	68 (34.0)
Osteoarthritis	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	9 (9.0)	14 (14.0)	13 (13.0)	27 (13.5)
Back pain	2 (2.0)	7 (7.0)	3 (3.0)	10 (5.0)	4 (4.0)	5 (5.0)	1 (1.0)	6 (3.0)
Arthralgia	0	1 (1.0)	1 (1.0)	2 (1.0)	3 (3.0)	4 (4.0)	3 (3.0)	7 (3.5)
Osteopenia	0	0	0	0	6 (6.0)	6 (6.0)	3 (3.0)	9 (4.5)
Musculoskeletal pain	1 (1.0)	2 (2.0)	0	2 (1.0)	2 (2.0)	4 (4.0)	1 (1.0)	5 (2.5)
Osteoporosis	1 (1.0)	0	0	0	5 (5.0)	4 (4.0)	3 (3.0)	7 (3.5)
Foot deformity	0	0	2 (2.0)	2 (1.0)	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)
Intervertebral disc protrusion	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	2 (2.0)	2 (2.0)	4 (2.0)
Neck pain	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)
Rotator cuff syndrome	0	0	0	0	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
Spinal osteoarthritis	1 (1.0)	0	0	0	0	3 (3.0)	3 (3.0)	6 (3.0)
Intervertebral disc degeneration	1 (1.0)	1 (1.0)	0	1 (0.5)	0	4 (4.0)	0	4 (2.0)
Myalgia	0	2 (2.0)	0	2 (1.0)	2 (2.0)	1 (1.0)	0	1 (0.5)
Pain in extremity	0	0	0	0	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
Scoliosis	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Fibromyalgia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Spinal stenosis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Arthritis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Bursitis	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Cervical spinal stenosis	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Chondropathy	0	1 (1.0)	0	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Dupuytren's contracture	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Exostosis	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Jaw cyst	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Ligament laxity	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Muscle spasms	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Periarthritis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Spinal deformity	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Synovial cyst	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Tendonitis	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Trigger finger	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Diastasis recti abdominis	1 (1.0)	0	0	0	0	0	0	0
Kyphosis	0	0	0	0	1 (1.0)	0	0	0
Muscle atrophy	0	0	0	0	1 (1.0)	0	0	0
Muscle tightness	0	0	0	0	1 (1.0)	0	0	0
Nose deformity	1 (1.0)	0	0	0	0	0	0	0
Plantar fasciitis	1 (1.0)	0	0	0	0	0	0	0
Renal and urinary disorders	3 (3.0)	0	0	0	6 (6.0)	7 (7.0)	7 (7.0)	14 (7.0)
Hypertonic bladder	0	0	0	0	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)
Haematuria	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Incontinence	0	0	0	0	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Renal and urinary disorders (cont.)								
Micturition urgency	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nephrolithiasis	1 (1.0)	0	0	0	2 (2.0)	0	1 (1.0)	1 (0.5)
Nocturia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Pollakiuria	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Renal impairment	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Urinary incontinence	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Urinary retention	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Bladder prolapse	0	0	0	0	1 (1.0)	0	0	0
Cystitis interstitial	1 (1.0)	0	0	0	0	0	0	0
Neurogenic bladder	0	0	0	0	1 (1.0)	0	0	0
Urethral dilatation	1 (1.0)	0	0	0	0	0	0	0
Pregnancy, puerperium and perinatal conditions	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Abortion spontaneous	2 (2.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Postpartum haemorrhage	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pregnancy	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Reproductive system and breast disorders	13 (13.0)	11 (11.0)	15 (15.0)	26 (13.0)	18 (18.0)	15 (15.0)	17 (17.0)	32 (16.0)
Menorrhagia	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)
Endometriosis	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	0	4 (4.0)	4 (2.0)
Erectile dysfunction	0	0	0	0	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Reproductive system and breast disorders (cont.)								
Dysmenorrhoea	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Polycystic ovaries	0	3 (3.0)	2 (2.0)	5 (2.5)	0	0	0	0
Benign prostatic hyperplasia	0	0	0	0	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Uterine prolapse	0	1 (1.0)	1 (1.0)	2 (1.0)	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)
Amenorrhoea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Premenstrual dysphoric disorder	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Uterine haemorrhage	0	0	0	0	0	0	2 (2.0)	2 (1.0)
Breast cyst	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Cystocele	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Dyspareunia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Endometrial hyperplasia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Infertility	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Menometrorrhagia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Menopausal symptoms	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Premenstrual syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Prostatomegaly	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Uterine polyp	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vulvovaginal dryness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nipple swelling	1 (1.0)	0	0	0	0	0	0	0
Ovarian cyst	2 (2.0)	0	0	0	2 (2.0)	0	0	0
Ovarian cyst ruptured	1 (1.0)	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Reproductive system and breast disorders (cont.)								
Pelvic pain	1 (1.0)	0	0	0	0	0	0	0
Testicular torsion	1 (1.0)	0	0	0	0	0	0	0
Congenital, familial and genetic disorders	3 (3.0)	0	1 (1.0)	1 (0.5)	0	3 (3.0)	4 (4.0)	7 (3.5)
Congenital scoliosis	0	0	0	0	0	0	2 (2.0)	2 (1.0)
Arnold-Chiari malformation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Factor V Leiden carrier	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Factor V Leiden mutation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Gilbert's syndrome	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Type IIa hyperlipidaemia	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Type V hyperlipidaemia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ehlers-Danlos syndrome	1 (1.0)	0	0	0	0	0	0	0
Renal aplasia	1 (1.0)	0	0	0	0	0	0	0
General disorders and administration site conditions	2 (2.0)	1 (1.0)	0	1 (0.5)	5 (5.0)	3 (3.0)	2 (2.0)	5 (2.5)
Pain	1 (1.0)	0	0	0	3 (3.0)	3 (3.0)	1 (1.0)	4 (2.0)
Oedema peripheral	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Cyst	0	0	0	0	1 (1.0)	0	0	0
Hernia	0	0	0	0	1 (1.0)	0	0	0
Oedema	1 (1.0)	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Investigations	2 (2.0)	6 (6.0)	4 (4.0)	10 (5.0)	6 (6.0)	2 (2.0)	8 (8.0)	10 (5.0)
Arthroscopy	1 (1.0)	5 (5.0)	1 (1.0)	6 (3.0)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
Biopsy breast normal	0	0	1 (1.0)	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Blood cholesterol increased	0	0	0	0	0	0	2 (2.0)	2 (1.0)
Blood pressure increased	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Blood testosterone decreased	0	0	0	0	1 (1.0)	0	2 (2.0)	2 (1.0)
Cardiac murmur	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Liver function test increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mammogram abnormal	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Endoscopy upper gastrointestinal tract	0	0	0	0	1 (1.0)	0	0	0
Precancerous cells present	0	0	0	0	1 (1.0)	0	0	0
Injury, poisoning and procedural complications	4 (4.0)	13 (13.0)	6 (6.0)	19 (9.5)	7 (7.0)	11 (11.0)	10 (10.0)	21 (10.5)
Meniscus injury	0	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
Cartilage injury	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Wrist fracture	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Ligament rupture	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Foot fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Hip fracture	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Joint dislocation	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Limb injury	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Radius fracture	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Tendon injury	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Tendon rupture	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Ulna fracture	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Accident	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Animal bite	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ankle fracture	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Arthropod bite	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Epicondylitis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Facial bones fracture	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Fall	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Joint injury	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Ligament injury	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Ligament sprain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lower limb fracture	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nerve injury	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Patella fracture	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sciatic nerve injury	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Skin laceration	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Splenic rupture	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Hand fracture	1 (1.0)	0	0	0	0	0	0	0
Skin abrasion	0	0	0	0	1 (1.0)	0	0	0

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Upper limb fracture	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Surgical and medical procedures	53 (53.0)	38 (38.0)	40 (40.0)	78 (39.0)	51 (51.0)	58 (58.0)	51 (51.0)	109 (54.5)
Hysterectomy	6 (6.0)	4 (4.0)	6 (6.0)	10 (5.0)	20 (20.0)	16 (16.0)	20 (20.0)	36 (18.0)
Female sterilisation	14 (14.0)	4 (4.0)	8 (8.0)	12 (6.0)	6 (6.0)	9 (9.0)	5 (5.0)	14 (7.0)
Vasectomy	8 (8.0)	5 (5.0)	6 (6.0)	11 (5.5)	8 (8.0)	7 (7.0)	4 (4.0)	11 (5.5)
Cholecystectomy	8 (8.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	7 (7.0)	5 (5.0)	12 (6.0)
Appendicectomy	7 (7.0)	5 (5.0)	2 (2.0)	7 (3.5)	3 (3.0)	4 (4.0)	6 (6.0)	10 (5.0)
Tonsillectomy	3 (3.0)	2 (2.0)	8 (8.0)	10 (5.0)	0	1 (1.0)	3 (3.0)	4 (2.0)
Caesarean section	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	1 (1.0)	2 (2.0)	3 (1.5)
Knee arthroplasty	0	0	0	0	2 (2.0)	2 (2.0)	5 (5.0)	7 (3.5)
Ligament operation	0	7 (7.0)	0	7 (3.5)	0	0	0	0
Hip arthroplasty	0	0	1 (1.0)	1 (0.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Inguinal hernia repair	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Keratomileusis	0	1 (1.0)	0	1 (0.5)	0	3 (3.0)	2 (2.0)	5 (2.5)
Skin neoplasm excision	0	0	1 (1.0)	1 (0.5)	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)
Bunion operation	0	0	2 (2.0)	2 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
Carpal tunnel decompression	3 (3.0)	0	1 (1.0)	1 (0.5)	0	3 (3.0)	0	3 (1.5)
Endometrial ablation	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	0	0	0	0
Fracture treatment	1 (1.0)	0	2 (2.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)

Percentages are based on the number of safety subjects.
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Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Surgical and medical procedures (cont.)								
Intervertebral disc operation	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Rotator cuff repair	0	0	0	0	2 (2.0)	1 (1.0)	3 (3.0)	4 (2.0)
Spinal fusion surgery	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	2 (2.0)	2 (1.0)
Ankle operation	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Meniscus operation	0	2 (2.0)	0	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Shoulder operation	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Tenoplasty	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Abdominal hernia repair	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Abdominoplasty	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Cataract operation	0	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)
Hip surgery	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Intraocular lens implant	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mammoplasty	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Open reduction of fracture	1 (1.0)	0	0	0	2 (2.0)	0	2 (2.0)	2 (1.0)
Retinal operation	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Spinal laminectomy	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Vision correction operation	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Adenoidectomy	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Anal fistula repair	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Axillary lymphadenectomy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Benign breast lump removal	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Bone cyst excision	0	0	1 (1.0)	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010501.sas 19NOV2020 01:58 Database Lock Date: 05NOV2020

Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Surgical and medical procedures (cont.)								
Brain operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Breast cyst excision	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
CSF shunt operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Cautery to nose	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Colostomy	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dupuytren's contracture operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ear operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ear tube insertion	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Ear tube removal	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Endovenous ablation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Eye excision	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Eye laser surgery	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Eye operation	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Finger repair operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Foot operation	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
In vitro fertilisation	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Joint debridement	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Joint dislocation reduction	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lipoma excision	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Loop electrosurgical excision procedure	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mastectomy	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010501.sas 19NOV2020 01:58 Database Lock Date: 05NOV2020

Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Surgical and medical procedures (cont.)								
Medical device removal	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Myomectomy	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Nasal septal operation	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nephrectomy	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Oesophagectomy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Oesophagogastric fundoplasty	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Oophorectomy bilateral	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Osteotomy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ovarian cystectomy	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Ovarian operation	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Prostatectomy	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Rhinoplasty	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Scleral buckling surgery	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Shoulder arthroplasty	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinus operation	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Splenectomy	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tendon sheath incision	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Toe operation	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Turbinoplasty	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tympanoplasty	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Urethral dilation procedure	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vaginal operation	0	0	1 (1.0)	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010501.sas 19NOV2020 01:58 Database Lock Date: 05NOV2020

Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Surgical and medical procedures (cont.)								
Wisdom teeth removal	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Wrist surgery	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Breast conserving surgery	0	0	0	0	1 (1.0)	0	0	0
Chondroplasty	1 (1.0)	0	0	0	0	0	0	0
Colectomy	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Contraception	1 (1.0)	0	0	0	0	0	0	0
Extracorporeal shock wave therapy	0	0	0	0	1 (1.0)	0	0	0
Gastrectomy	1 (1.0)	0	0	0	0	0	0	0
Hernia repair	0	0	0	0	1 (1.0)	0	0	0
Knee operation	1 (1.0)	0	0	0	0	0	0	0
Large intestinal polypectomy	0	0	0	0	1 (1.0)	0	0	0
Micrographic skin surgery	0	0	0	0	1 (1.0)	0	0	0
Mole excision	0	0	0	0	1 (1.0)	0	0	0
Muscle operation	1 (1.0)	0	0	0	0	0	0	0
Nail operation	1 (1.0)	0	0	0	0	0	0	0
Oophorectomy	1 (1.0)	0	0	0	2 (2.0)	0	0	0
Orchidectomy	1 (1.0)	0	0	0	0	0	0	0
Salivary gland resection	0	0	0	0	1 (1.0)	0	0	0
Salpingectomy	1 (1.0)	0	0	0	0	0	0	0
Spinal operation	0	0	0	0	2 (2.0)	0	0	0
Thyroid nodule removal	0	0	0	0	1 (1.0)	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14010501.sas 19NOV2020 01:58 Database Lock Date: 05NOV2020

Table 14.1.5.1
Summary of Medical History by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Surgical and medical procedures (cont.)								
Trabeculectomy	0	0	0	0	1 (1.0)	0	0	0
Umbilical hernia repair	0	0	0	0	1 (1.0)	0	0	0
Urinary bladder suspension	0	0	0	0	1 (1.0)	0	0	0
Uterine dilation and curettage	2 (2.0)	0	0	0	1 (1.0)	0	0	0
Uterine operation	0	0	0	0	1 (1.0)	0	0	0
Social circumstances	7 (7.0)	3 (3.0)	3 (3.0)	6 (3.0)	57 (57.0)	60 (60.0)	59 (59.0)	119 (59.5)
Postmenopause	5 (5.0)	3 (3.0)	2 (2.0)	5 (2.5)	47 (47.0)	55 (55.0)	45 (45.0)	100 (50.0)
Menopause	2 (2.0)	0	1 (1.0)	1 (0.5)	10 (10.0)	4 (4.0)	14 (14.0)	18 (9.0)
Corrective lens user	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hearing aid user	0	0	0	0	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.2.3.1
Summary of SARS-CoV-2 Test by RT-PCR
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Overall [1]				
n [2]	200 (100)	200 (100)	200 (100)	400 (100)
Detected	4 (2.0)	1 (0.5)	0	1 (0.3)
Not Detected	196 (98.0)	199 (99.5)	200 (100)	399 (99.8)
Baseline				
n [2]	199 (99.5)	200 (100)	200 (100)	400 (100)
Detected	0	0	0	0
Not Detected	199 (99.5)	200 (100)	200 (100)	400 (100)
Day 29				
n [2]	196 (98.0)	193 (96.5)	199 (99.5)	392 (98.0)
Detected	2 (1.0)	0	0	0
Not Detected	194 (97.0)	193 (96.5)	199 (99.5)	392 (98.0)
Day 57				
n [2]	195 (97.5)	193 (96.5)	199 (99.5)	392 (98.0)
Detected	2 (1.0)	1 (0.5)	0	1 (0.3)
Not Detected	193 (96.5)	192 (96.0)	199 (99.5)	391 (97.8)

This table is based on SARS-CoV-2 test performed by Viracor lab. Percentages are based on the number of safety subjects.
[1] Subjects are counted under Detected if the subjects have at least one result reported as Detected at any visit.
[2] Number of subjects provided RT-PCR sample.

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Table 14.2.3.1
Summary of SARS-CoV-2 Test by RT-PCR
Safety Set

	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
					mRNA-1273								mRNA-1273			
	Placebo		50 µg		100 µg		Total		Placebo		50 µg		100 µg		Total	
	(N=100)		(N=100)		(N=100)		(N=200)		(N=100)		(N=100)		(N=100)		(N=200)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Overall [1]																
n [2]	100	(100)	100	(100)	100	(100)	200	(100)	100	(100)	100	(100)	100	(100)	200	(100)
Detected	3	(3.0)	1	(1.0)	0		1	(0.5)	1	(1.0)	0		0		0	
Not Detected	97	(97.0)	99	(99.0)	100	(100)	199	(99.5)	99	(99.0)	100	(100)	100	(100)	200	(100)
Baseline																
n [2]	100	(100)	100	(100)	100	(100)	200	(100)	99	(99.0)	100	(100)	100	(100)	200	(100)
Detected	0		0		0		0		0		0		0		0	
Not Detected	100	(100)	100	(100)	100	(100)	200	(100)	99	(99.0)	100	(100)	100	(100)	200	(100)
Day 29																
n [2]	96	(96.0)	95	(95.0)	100	(100)	195	(97.5)	100	(100)	98	(98.0)	99	(99.0)	197	(98.5)
Detected	2	(2.0)	0		0		0		0		0		0		0	
Not Detected	94	(94.0)	95	(95.0)	100	(100)	195	(97.5)	100	(100)	98	(98.0)	99	(99.0)	197	(98.5)
Day 57																
n [2]	95	(95.0)	94	(94.0)	100	(100)	194	(97.0)	100	(100)	99	(99.0)	99	(99.0)	198	(99.0)
Detected	1	(1.0)	1	(1.0)	0		1	(0.5)	1	(1.0)	0		0		0	
Not Detected	94	(94.0)	93	(93.0)	100	(100)	193	(96.5)	99	(99.0)	99	(99.0)	99	(99.0)	198	(99.0)

This table is based on SARS-CoV-2 test performed by Viracor lab. Percentages are based on the number of safety subjects.
[1] Subjects are counted under Detected if the subjects have at least one result reported as Detected at any visit.
[2] Number of subjects provided RT-PCR sample.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Day 1				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	200 (100)	200 (100)	199 (99.5)	399 (99.8)
Yes	0	0	0	0
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	0	0	0
Reason for Exposure [1], n(%)				
Social Setting	0	0	0	0
Family Member	0	0	0	0
Health Care Facility	0	0	0	0
Work	0	0	0	0
Travel	0	0	0	0
Other	0	0	0	0
Length of Exposure (Days)				
n	0	0	0	0
Mean (SD)				
Median				
Min, Max				

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	200 (100)	200 (100)	199 (99.5)	399 (99.8)
Yes	0	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	0	0	0	0
Cough	0	0	0	0
Shortness of Breath	0	0	0	0
Fever	0	0	0	0
Sore Throat	0	0	0	0
Chest Tightness/Pressure	0	0	0	0
Headache	0	0	0	0
Lethargy	0	0	0	0
Myalgia	0	0	0	0
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	0	0	0
Other	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Day 8				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	199 (99.5)	199 (99.5)	200 (100)	399 (99.8)
Yes	0	1 (0.5)	0	1 (0.3)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	1 (0.5)	0	1 (0.3)
Reason for Exposure [1], n(%)				
Social Setting	0	0	0	0
Family Member	0	1 (0.5)	0	1 (0.3)
Health Care Facility	0	0	0	0
Work	0	0	0	0
Travel	0	0	0	0
Other	0	0	0	0
Length of Exposure (Days)				
n	0	1	0	1
Mean (SD)		2.0 (NA)		2.0 (NA)
Median		2.0		2.0
Min, Max		2, 2		2, 2

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	199 (99.5)	199 (99.5)	200 (100)	399 (99.8)
Yes	0	1 (0.5)	0	1 (0.3)
Symptoms of Potential COVID-19 [1], n(%)	0	1 (0.5)	0	1 (0.3)
Cough	0	1 (0.5)	0	1 (0.3)
Shortness of Breath	0	0	0	0
Fever	0	0	0	0
Sore Throat	0	0	0	0
Chest Tightness/Pressure	0	0	0	0
Headache	0	0	0	0
Lethargy	0	1 (0.5)	0	1 (0.3)
Myalgia	0	0	0	0
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	1 (0.5)	0	1 (0.3)
Other	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Day 15				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	197 (98.5)	198 (99.0)	200 (100)	398 (99.5)
Yes	1 (0.5)	1 (0.5)	0	1 (0.3)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	1 (0.5)	1 (0.5)	0	1 (0.3)
Reason for Exposure [1], n(%)				
Social Setting	0	0	0	0
Family Member	1 (0.5)	0	0	0
Health Care Facility	0	0	0	0
Work	0	1 (0.5)	0	1 (0.3)
Travel	0	0	0	0
Other	0	0	0	0
Length of Exposure (Days)				
n	1	1	0	1
Mean (SD)	4.0 (NA)	4.0 (NA)		4.0 (NA)
Median	4.0	4.0		4.0
Min, Max	4, 4	4, 4		4, 4

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	195 (97.5)	199 (99.5)	200 (100)	399 (99.8)
Yes	3 (1.5)	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	3 (1.5)	0	0	0
Cough	2 (1.0)	0	0	0
Shortness of Breath	0	0	0	0
Fever	1 (0.5)	0	0	0
Sore Throat	1 (0.5)	0	0	0
Chest Tightness/Pressure	0	0	0	0
Headache	1 (0.5)	0	0	0
Lethargy	0	0	0	0
Myalgia	0	0	0	0
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	0	0	0
Other	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Day 29				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	196 (98.0)	196 (98.0)	198 (99.0)	394 (98.5)
Yes	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Reason for Exposure [1], n(%)				
Social Setting	1 (0.5)	0	0	0
Family Member	0	0	1 (0.5)	1 (0.3)
Health Care Facility	0	0	0	0
Work	1 (0.5)	1 (0.5)	0	1 (0.3)
Travel	0	0	0	0
Other	0	1 (0.5)	0	1 (0.3)
Length of Exposure (Days)				
n	2	2	1	3
Mean (SD)	1.0 (0.00)	3.0 (1.41)	5.0 (NA)	3.7 (1.53)
Median	1.0	3.0	5.0	4.0
Min, Max	1, 1	2, 4	5, 5	2, 5

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	196 (98.0)	195 (97.5)	198 (99.0)	393 (98.3)
Yes	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
Symptoms of Potential COVID-19 [1], n(%)	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Cough	0	1 (0.5)	0	1 (0.3)
Shortness of Breath	0	0	0	0
Fever	0	1 (0.5)	0	1 (0.3)
Sore Throat	0	2 (1.0)	0	2 (0.5)
Chest Tightness/Pressure	0	0	0	0
Headache	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Lethargy	1 (0.5)	1 (0.5)	0	1 (0.3)
Myalgia	1 (0.5)	2 (1.0)	0	2 (0.5)
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	1 (0.5)	0	1 (0.3)
Other	1 (0.5)	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	mRNA-1273 100 µg (N=200) n (%)	Total (N=400) n (%)
Day 36				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	195 (97.5)	195 (97.5)	196 (98.0)	391 (97.8)
Yes	2 (1.0)	1 (0.5)	2 (1.0)	3 (0.8)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	2 (1.0)	1 (0.5)	2 (1.0)	3 (0.8)
Reason for Exposure [1], n(%)				
Social Setting	0	1 (0.5)	0	1 (0.3)
Family Member	0	0	1 (0.5)	1 (0.3)
Health Care Facility	0	0	0	0
Work	1 (0.5)	0	1 (0.5)	1 (0.3)
Travel	0	0	0	0
Other	1 (0.5)	0	0	0
Length of Exposure (Days)				
n	2	1	2	3
Mean (SD)	4.5 (3.54)	3.0 (NA)	3.0 (2.83)	3.0 (2.00)
Median	4.5	3.0	3.0	3.0
Min, Max	2, 7	3, 3	1, 5	1, 5

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	196 (98.0)	196 (98.0)	197 (98.5)	393 (98.3)
Yes	1 (0.5)	0	1 (0.5)	1 (0.3)
Symptoms of Potential COVID-19 [1], n(%)	1 (0.5)	0	1 (0.5)	1 (0.3)
Cough	1 (0.5)	0	0	0
Shortness of Breath	0	0	0	0
Fever	1 (0.5)	0	0	0
Sore Throat	1 (0.5)	0	1 (0.5)	1 (0.3)
Chest Tightness/Pressure	0	0	0	0
Headache	1 (0.5)	0	0	0
Lethargy	0	0	0	0
Myalgia	0	0	0	0
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	1 (0.5)	0	0	0
Other	1 (0.5)	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Day 43				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	197 (98.5)	194 (97.0)	196 (98.0)	390 (97.5)
Yes	0	1 (0.5)	2 (1.0)	3 (0.8)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	1 (0.5)	2 (1.0)	3 (0.8)
Reason for Exposure [1], n(%)				
Social Setting	0	0	1 (0.5)	1 (0.3)
Family Member	0	0	1 (0.5)	1 (0.3)
Health Care Facility	0	0	0	0
Work	0	1 (0.5)	0	1 (0.3)
Travel	0	0	0	0
Other	0	0	0	0
Length of Exposure (Days)				
n	0	1	1	2
Mean (SD)		1.0 (NA)	3.0 (NA)	2.0 (1.41)
Median		1.0	3.0	2.0
Min, Max		1, 1	3, 3	1, 3

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	197 (98.5)	194 (97.0)	197 (98.5)	391 (97.8)
Yes	0	1 (0.5)	1 (0.5)	2 (0.5)
Symptoms of Potential COVID-19 [1], n(%)	0	1 (0.5)	1 (0.5)	2 (0.5)
Cough	0	1 (0.5)	0	1 (0.3)
Shortness of Breath	0	0	0	0
Fever	0	0	0	0
Sore Throat	0	0	0	0
Chest Tightness/Pressure	0	1 (0.5)	0	1 (0.3)
Headache	0	1 (0.5)	1 (0.5)	2 (0.5)
Lethargy	0	1 (0.5)	0	1 (0.3)
Myalgia	0	1 (0.5)	0	1 (0.3)
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	0	0	0
Other	0	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Day 57				
Exposed or Potentially Exposed to COVID-19, n(%)				
No	192 (96.0)	194 (97.0)	196 (98.0)	390 (97.5)
Yes	5 (2.5)	1 (0.5)	3 (1.5)	4 (1.0)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	5 (2.5)	1 (0.5)	3 (1.5)	4 (1.0)
Reason for Exposure [1], n(%)				
Social Setting	1 (0.5)	0	1 (0.5)	1 (0.3)
Family Member	2 (1.0)	0	0	0
Health Care Facility	0	0	0	0
Work	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Travel	0	0	0	0
Other	0	0	2 (1.0)	2 (0.5)
Length of Exposure (Days)				
n	5	1	3	4
Mean (SD)	7.0 (5.52)	1.0 (NA)	1.7 (1.15)	1.5 (1.00)
Median	10.0	1.0	1.0	1.0
Min, Max	1, 12	1, 1	1, 3	1, 3

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
COVID-19 Symptomatic, n(%)				
No	195 (97.5)	194 (97.0)	198 (99.0)	392 (98.0)
Yes	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Symptoms of Potential COVID-19 [1], n(%)	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Cough	1 (0.5)	1 (0.5)	0	1 (0.3)
Shortness of Breath	0	0	0	0
Fever	1 (0.5)	0	0	0
Sore Throat	2 (1.0)	0	0	0
Chest Tightness/Pressure	0	0	0	0
Headache	0	0	1 (0.5)	1 (0.3)
Lethargy	0	0	0	0
Myalgia	1 (0.5)	0	0	0
Anosmia	0	0	0	0
Dysgeusia	0	0	0	0
Repeated Shaking with Chills	0	0	0	0
Chills	0	0	0	0
Other	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	100 (100)	100 (100)	99 (99.0)	199 (99.5)	100 (100)	100 (100)	100 (100)	200 (100)
Yes	0	0	0	0	0	0	0	0
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	0	0	0	0	0	0	0
Reason for Exposure [1], n(%)								
Social Setting	0	0	0	0	0	0	0	0
Family Member	0	0	0	0	0	0	0	0
Health Care Facility	0	0	0	0	0	0	0	0
Work	0	0	0	0	0	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Length of Exposure (Days)								
n	0	0	0	0	0	0	0	0
Mean (SD)								
Median								
Min, Max								

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	100 (100)	100 (100)	99 (99.0)	199 (99.5)	100 (100)	100 (100)	100 (100)	200 (100)
Yes	0	0	0	0	0	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	0	0	0	0	0	0	0	0
Cough	0	0	0	0	0	0	0	0
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	0	0	0	0
Sore Throat	0	0	0	0	0	0	0	0
Chest Tightness/Pressure	0	0	0	0	0	0	0	0
Headache	0	0	0	0	0	0	0	0
Lethargy	0	0	0	0	0	0	0	0
Myalgia	0	0	0	0	0	0	0	0
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 8								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	100 (100)	100 (100)	100 (100)	200 (100)	99 (99.0)	99 (99.0)	100 (100)	199 (99.5)
Yes	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Reason for Exposure [1], n(%)								
Social Setting	0	0	0	0	0	0	0	0
Family Member	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Health Care Facility	0	0	0	0	0	0	0	0
Work	0	0	0	0	0	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Length of Exposure (Days)								
n	0	0	0	0	0	1	0	1
Mean (SD)						2.0 (NA)		2.0 (NA)
Median						2.0		2.0
Min, Max						2, 2		2, 2

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	100 (100)	99 (99.0)	100 (100)	199 (99.5)	99 (99.0)	100 (100)	100 (100)	200 (100)
Yes	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Cough	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	0	0	0	0
Sore Throat	0	0	0	0	0	0	0	0
Chest Tightness/Pressure	0	0	0	0	0	0	0	0
Headache	0	0	0	0	0	0	0	0
Lethargy	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Myalgia	0	0	0	0	0	0	0	0
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Other	0	1 (1.0)	0	1 (0.5)	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 15								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	99 (99.0)	98 (98.0)	100 (100)	198 (99.0)	98 (98.0)	100 (100)	100 (100)	200 (100)
Yes	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Reason for Exposure [1], n(%)								
Social Setting	0	0	0	0	0	0	0	0
Family Member	0	0	0	0	1 (1.0)	0	0	0
Health Care Facility	0	0	0	0	0	0	0	0
Work	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Length of Exposure (Days)								
n	0	1	0	1	1	0	0	0
Mean (SD)		4.0 (NA)		4.0 (NA)	4.0 (NA)			
Median		4.0		4.0	4.0			
Min, Max		4, 4		4, 4	4, 4			

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	97 (97.0)	99 (99.0)	100 (100)	199 (99.5)	98 (98.0)	100 (100)	100 (100)	200 (100)
Yes	2 (2.0)	0	0	0	1 (1.0)	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	2 (2.0)	0	0	0	1 (1.0)	0	0	0
Cough	2 (2.0)	0	0	0	0	0	0	0
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	1 (1.0)	0	0	0
Sore Throat	1 (1.0)	0	0	0	0	0	0	0
Chest Tightness/Pressure	0	0	0	0	0	0	0	0
Headache	0	0	0	0	1 (1.0)	0	0	0
Lethargy	0	0	0	0	0	0	0	0
Myalgia	0	0	0	0	0	0	0	0
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 29								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	96 (96.0)	96 (96.0)	99 (99.0)	195 (97.5)	100 (100)	100 (100)	99 (99.0)	199 (99.5)
Yes	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Reason for Exposure [1], n(%)								
Social Setting	1 (1.0)	0	0	0	0	0	0	0
Family Member	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Health Care Facility	0	0	0	0	0	0	0	0
Work	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Length of Exposure (Days)								
n	2	2	1	3	0	0	0	0
Mean (SD)	1.0 (0.00)	3.0 (1.41)	5.0 (NA)	3.7 (1.53)				
Median	1.0	3.0	5.0	4.0				
Min, Max	1, 1	2, 4	5, 5	2, 5				

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	96 (96.0)	98 (98.0)	99 (99.0)	197 (98.5)	100 (100)	97 (97.0)	99 (99.0)	196 (98.0)
Yes	2 (2.0)	0	1 (1.0)	1 (0.5)	0	3 (3.0)	0	3 (1.5)
Symptoms of Potential COVID-19 [1], n(%)	1 (1.0)	0	1 (1.0)	1 (0.5)	0	3 (3.0)	0	3 (1.5)
Cough	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sore Throat	0	0	0	0	0	2 (2.0)	0	2 (1.0)
Chest Tightness/Pressure	0	0	0	0	0	0	0	0
Headache	1 (1.0)	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Lethargy	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Myalgia	1 (1.0)	0	0	0	0	2 (2.0)	0	2 (1.0)
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Other	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 36								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	96 (96.0)	96 (96.0)	98 (98.0)	194 (97.0)	99 (99.0)	99 (99.0)	98 (98.0)	197 (98.5)
Yes	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	0	0
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	0	0
Reason for Exposure [1], n(%)								
Social Setting	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Family Member	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Health Care Facility	0	0	0	0	0	0	0	0
Work	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	1 (1.0)	0	0	0	0	0	0	0
Length of Exposure (Days)								
n	1	1	2	3	1	0	0	0
Mean (SD)	7.0 (NA)	3.0 (NA)	3.0 (2.83)	3.0 (2.00)	2.0 (NA)			
Median	7.0	3.0	3.0	3.0	2.0			
Min, Max	7, 7	3, 3	1, 5	1, 5	2, 2			

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
	mRNA-1273								mRNA-1273							
	Placebo	50 µg		100 µg		Total		Placebo	50 µg		100 µg		Total			
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=200)	
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
COVID-19 Symptomatic, n(%)																
No	96 (96.0)	97 (97.0)	100 (100)	197 (98.5)	100 (100)	99 (99.0)	97 (97.0)	196 (98.0)								
Yes	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)								
Symptoms of Potential COVID-19 [1], n(%)	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)								
Cough	1 (1.0)	0	0	0	0	0	0	0								
Shortness of Breath	0	0	0	0	0	0	0	0								
Fever	1 (1.0)	0	0	0	0	0	0	0								
Sore Throat	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)								
Chest Tightness/Pressure	0	0	0	0	0	0	0	0								
Headache	1 (1.0)	0	0	0	0	0	0	0								
Lethargy	0	0	0	0	0	0	0	0								
Myalgia	0	0	0	0	0	0	0	0								
Anosmia	0	0	0	0	0	0	0	0								
Dysgeusia	0	0	0	0	0	0	0	0								
Repeated Shaking with Chills	0	0	0	0	0	0	0	0								
Chills	1 (1.0)	0	0	0	0	0	0	0								
Other	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)								

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 43								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	97 (97.0)	95 (95.0)	99 (99.0)	194 (97.0)	100 (100)	99 (99.0)	97 (97.0)	196 (98.0)
Yes	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Reason for Exposure [1], n(%)								
Social Setting	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Family Member	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Health Care Facility	0	0	0	0	0	0	0	0
Work	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Travel	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0
Length of Exposure (Days)								
n	0	1	1	2	0	0	0	0
Mean (SD)		1.0 (NA)	3.0 (NA)	2.0 (1.41)				
Median		1.0	3.0	2.0				
Min, Max		1, 1	3, 3	1, 3				

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	97 (97.0)	95 (95.0)	100 (100)	195 (97.5)	100 (100)	99 (99.0)	97 (97.0)	196 (98.0)
Yes	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Symptoms of Potential COVID-19 [1], n(%)	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Cough	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	0	0	0	0
Sore Throat	0	0	0	0	0	0	0	0
Chest Tightness/Pressure	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Headache	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Lethargy	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Myalgia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Day 57								
Exposed or Potentially Exposed to COVID-19, n(%)								
No	95 (95.0)	95 (95.0)	98 (98.0)	193 (96.5)	97 (97.0)	99 (99.0)	98 (98.0)	197 (98.5)
Yes	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	3 (3.0)	0	1 (1.0)	1 (0.5)
Close Contact with Person Having SARS-COV-2 Infection or Covid-19, n(%)	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	3 (3.0)	0	1 (1.0)	1 (0.5)
Reason for Exposure [1], n(%)								
Social Setting	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Family Member	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Health Care Facility	0	0	0	0	0	0	0	0
Work	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Travel	0	0	0	0	0	0	0	0
Other	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Length of Exposure (Days)								
n	2	1	2	3	3	0	1	1
Mean (SD)	6.0 (7.07)	1.0 (NA)	2.0 (1.41)	1.7 (1.15)	7.7 (5.86)		1.0 (NA)	1.0 (NA)
Median	6.0	1.0	2.0	1.0	10.0		1.0	1.0
Min, Max	1, 11	1, 1	1, 3	1, 3	1, 12		1, 1	1, 1

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.1
Summary of SARS-CoV-2 or COVID-19 Exposure and Symptoms Assessment
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
	(N=100)	(N=100)	(N=100)	(N=200)	(N=100)	(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
COVID-19 Symptomatic, n(%)								
No	96 (96.0)	95 (95.0)	99 (99.0)	194 (97.0)	99 (99.0)	99 (99.0)	99 (99.0)	198 (99.0)
Yes	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Symptoms of Potential COVID-19 [1], n(%)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Cough	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Shortness of Breath	0	0	0	0	0	0	0	0
Fever	0	0	0	0	1 (1.0)	0	0	0
Sore Throat	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Chest Tightness/Pressure	0	0	0	0	0	0	0	0
Headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Lethargy	0	0	0	0	0	0	0	0
Myalgia	0	0	0	0	1 (1.0)	0	0	0
Anosmia	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	0	0
Repeated Shaking with Chills	0	0	0	0	0	0	0	0
Chills	0	0	0	0	0	0	0	0
Other	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0

Percentages are based on the number of safety subjects.

[1] Subjects can be counted in more than one category.

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Table 14.2.3.2.2
Summary of Time from SARS-CoV-2 or COVID-19 Exposure to First Symptoms
Safety Set

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Time from Exposure to First Symptoms (Days)				
n	3	2	1	3
Mean (SD)	5.3 (5.13)	9.0 (5.66)	9.0 (NA)	9.0 (4.00)
Median	4.0	9.0	9.0	9.0
Min, Max	1, 11	5, 13	9, 9	5, 13

Time from exposure to the first symptoms is defined as the time between the date of the first symptom and the last exposure date prior to the first symptom.

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Table 14.2.3.2.2
Summary of Time from SARS-CoV-2 or COVID-19 Exposure to First Symptoms
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Time from Exposure to First Symptoms (Days)								
n	2	2	1	3	1	0	0	0
Mean (SD)	2.5 (2.12)	9.0 (5.66)	9.0 (NA)	9.0 (4.00)	11.0 (NA)			
Median	2.5	9.0	9.0	9.0	11.0			
Min, Max	1, 4	5, 13	9, 9	5, 13	11, 11			

Time from exposure to the first symptoms is defined as the time between the date of the first symptom and the last exposure date prior to the first symptom.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Adverse Reactions - N1	199	200	200	400
Any Solicited Adverse Reactions	77 (38.7)	142 (71.0)	176 (88.0)	318 (79.5)
95% CI	31.9, 45.8	64.2, 77.2	82.7, 92.2	75.2, 83.4
Grade 1	55 (27.6)	105 (52.5)	149 (74.5)	254 (63.5)
Grade 2	15 (7.5)	30 (15.0)	24 (12.0)	54 (13.5)
Grade 3	4 (2.0)	5 (2.5)	2 (1.0)	7 (1.8)
Grade 4	0	0	0	0
Solicited Local Adverse Reactions - N1	199	200	200	400
Any Solicited Local Adverse Reactions	27 (13.6)	131 (65.5)	168 (84.0)	299 (74.8)
95% CI	9.1, 19.1	58.5, 72.1	78.2, 88.8	70.2, 78.9
Grade 1	26 (13.1)	124 (62.0)	157 (78.5)	281 (70.3)
Grade 2	1 (0.5)	6 (3.0)	10 (5.0)	16 (4.0)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Pain - N1	199	200	199	399
Any	21 (10.6)	131 (65.5)	166 (83.4)	297 (74.4)
Grade 1	21 (10.6)	125 (62.5)	155 (77.9)	280 (70.2)
Grade 2	0	5 (2.5)	10 (5.0)	15 (3.8)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0
Erythema (Redness) - N1	199	200	199	399
Any	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Grade 1	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Swelling (Hardness) - N1	199	200	200	400
Any	1 (0.5)	8 (4.0)	8 (4.0)	16 (4.0)
Grade 1	1 (0.5)	7 (3.5)	8 (4.0)	15 (3.8)
Grade 2	0	1 (0.5)	0	1 (0.3)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Lymphadenopathy - N1 [1]	199	200	199	399
Any	5 (2.5)	10 (5.0)	18 (9.0)	28 (7.0)
Grade 1	4 (2.0)	10 (5.0)	16 (8.0)	26 (6.5)
Grade 2	1 (0.5)	0	2 (1.0)	2 (0.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions - N1	199	200	199	399
Any Solicited Systemic Adverse Reactions	64 (32.2)	83 (41.5)	89 (44.7)	172 (43.1)
95% CI	25.7, 39.1	34.6, 48.7	37.7, 51.9	38.2, 48.1
Grade 1	42 (21.1)	50 (25.0)	69 (34.7)	119 (29.8)
Grade 2	15 (7.5)	26 (13.0)	18 (9.0)	44 (11.0)
Grade 3	4 (2.0)	4 (2.0)	1 (0.5)	5 (1.3)
Grade 4	0	0	0	0
Fever - N1	199	200	199	399
Any	0	0	1 (0.5)	1 (0.3)
Grade 1	0	0	0	0
Grade 2	0	0	1 (0.5)	1 (0.3)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Headache - N1	199	200	199	399
Any	36 (18.1)	58 (29.0)	43 (21.6)	101 (25.3)
Grade 1	30 (15.1)	42 (21.0)	35 (17.6)	77 (19.3)
Grade 2	2 (1.0)	13 (6.5)	8 (4.0)	21 (5.3)
Grade 3	4 (2.0)	3 (1.5)	0	3 (0.8)
Grade 4	0	0	0	0
Fatigue - N1	199	200	199	399
Any	35 (17.6)	48 (24.0)	50 (25.1)	98 (24.6)
Grade 1	25 (12.6)	30 (15.0)	38 (19.1)	68 (17.0)
Grade 2	10 (5.0)	17 (8.5)	11 (5.5)	28 (7.0)
Grade 3	0	1 (0.5)	1 (0.5)	2 (0.5)
Grade 4	0	0	0	0
Myalgia - N1	199	200	199	399
Any	14 (7.0)	21 (10.5)	28 (14.1)	49 (12.3)
Grade 1	12 (6.0)	14 (7.0)	23 (11.6)	37 (9.3)
Grade 2	2 (1.0)	7 (3.5)	4 (2.0)	11 (2.8)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Arthralgia - N1	199	200	199	399
Any	10 (5.0)	18 (9.0)	18 (9.0)	36 (9.0)
Grade 1	7 (3.5)	14 (7.0)	15 (7.5)	29 (7.3)
Grade 2	3 (1.5)	4 (2.0)	2 (1.0)	6 (1.5)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Nausea/Vomiting - N1	199	200	199	399
Any	10 (5.0)	11 (5.5)	6 (3.0)	17 (4.3)
Grade 1	5 (2.5)	10 (5.0)	5 (2.5)	15 (3.8)
Grade 2	5 (2.5)	1 (0.5)	0	1 (0.3)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Chills - N1	199	200	199	399
Any	6 (3.0)	13 (6.5)	10 (5.0)	23 (5.8)
Grade 1	5 (2.5)	10 (5.0)	6 (3.0)	16 (4.0)
Grade 2	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	199	200	199	399
Any	5 (2.5)	6 (3.0)	5 (2.5)	11 (2.8)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=99) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Solicited Adverse Reactions - N1	100	100	100	200	99	100	100	200
Any Solicited Adverse Reactions	36 (36.0)	79 (79.0)	91 (91.0)	170 (85.0)	41 (41.4)	63 (63.0)	85 (85.0)	148 (74.0)
95% CI	26.6, 46.2	69.7, 86.5	83.6, 95.8	79.3, 89.6	31.6, 51.8	52.8, 72.4	76.5, 91.4	67.3, 79.9
Grade 1	26 (26.0)	56 (56.0)	76 (76.0)	132 (66.0)	29 (29.3)	49 (49.0)	73 (73.0)	122 (61.0)
Grade 2	7 (7.0)	20 (20.0)	13 (13.0)	33 (16.5)	8 (8.1)	10 (10.0)	11 (11.0)	21 (10.5)
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	3 (3.0)	4 (4.0)	1 (1.0)	5 (2.5)
Grade 4	0	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	200	99	100	100	200
Any Solicited Local Adverse Reactions	17 (17.0)	73 (73.0)	87 (87.0)	160 (80.0)	10 (10.1)	58 (58.0)	81 (81.0)	139 (69.5)
95% CI	10.2, 25.8	63.2, 81.4	78.8, 92.9	73.8, 85.3	5.0, 17.8	47.7, 67.8	71.9, 88.2	62.6, 75.8
Grade 1	16 (16.0)	67 (67.0)	77 (77.0)	144 (72.0)	10 (10.1)	57 (57.0)	80 (80.0)	137 (68.5)
Grade 2	1 (1.0)	6 (6.0)	9 (9.0)	15 (7.5)	0	0	1 (1.0)	1 (0.5)
Grade 3	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=99) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Pain - N1	100	100	100	200	99	100	99	199
Any	14 (14.0)	73 (73.0)	86 (86.0)	159 (79.5)	7 (7.1)	58 (58.0)	80 (80.8)	138 (69.3)
Grade 1	14 (14.0)	68 (68.0)	76 (76.0)	144 (72.0)	7 (7.1)	57 (57.0)	79 (79.8)	136 (68.3)
Grade 2	0	5 (5.0)	9 (9.0)	14 (7.0)	0	0	1 (1.0)	1 (0.5)
Grade 3	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	200	99	100	99	199
Any	0	2 (2.0)	3 (3.0)	5 (2.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Grade 1	0	2 (2.0)	3 (3.0)	5 (2.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Swelling (Hardness)- N1	100	100	100	200	99	100	100	200
Any	0	5 (5.0)	5 (5.0)	10 (5.0)	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
Grade 1	0	4 (4.0)	5 (5.0)	9 (4.5)	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
Grade 2	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1 [1]	100	100	100	200	99	100	99	199
Any	4 (4.0)	7 (7.0)	15 (15.0)	22 (11.0)	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)
Grade 1	3 (3.0)	7 (7.0)	14 (14.0)	21 (10.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Grade 2	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=99) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Solicited Systemic Adverse Reactions - N1	100	100	100	200	99	100	99	199
Any Solicited Systemic Adverse Reactions	30 (30.0)	46 (46.0)	52 (52.0)	98 (49.0)	34 (34.3)	37 (37.0)	37 (37.4)	74 (37.2)
95% CI	21.2, 40.0	36.0, 56.3	41.8, 62.1	41.9, 56.1	25.1, 44.6	27.6, 47.2	27.9, 47.7	30.5, 44.3
Grade 1	20 (20.0)	26 (26.0)	44 (44.0)	70 (35.0)	22 (22.2)	24 (24.0)	25 (25.3)	49 (24.6)
Grade 2	7 (7.0)	16 (16.0)	7 (7.0)	23 (11.5)	8 (8.1)	10 (10.0)	11 (11.1)	21 (10.6)
Grade 3	1 (1.0)	1 (1.0)	0	1 (0.5)	3 (3.0)	3 (3.0)	1 (1.0)	4 (2.0)
Grade 4	0	0	0	0	0	0	0	0
Fever - N1	100	100	100	200	99	100	99	199
Any	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Headache - N1	100	100	100	200	99	100	99	199
Any	18 (18.0)	29 (29.0)	25 (25.0)	54 (27.0)	18 (18.2)	29 (29.0)	18 (18.2)	47 (23.6)
Grade 1	16 (16.0)	19 (19.0)	21 (21.0)	40 (20.0)	14 (14.1)	23 (23.0)	14 (14.1)	37 (18.6)
Grade 2	1 (1.0)	9 (9.0)	4 (4.0)	13 (6.5)	1 (1.0)	4 (4.0)	4 (4.0)	8 (4.0)
Grade 3	1 (1.0)	1 (1.0)	0	1 (0.5)	3 (3.0)	2 (2.0)	0	2 (1.0)
Grade 4	0	0	0	0	0	0	0	0
Fatigue - N1	100	100	100	200	99	100	99	199
Any	17 (17.0)	24 (24.0)	30 (30.0)	54 (27.0)	18 (18.2)	24 (24.0)	20 (20.2)	44 (22.1)
Grade 1	13 (13.0)	15 (15.0)	25 (25.0)	40 (20.0)	12 (12.1)	15 (15.0)	13 (13.1)	28 (14.1)
Grade 2	4 (4.0)	9 (9.0)	5 (5.0)	14 (7.0)	6 (6.1)	8 (8.0)	6 (6.1)	14 (7.0)
Grade 3	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0	0
Myalgia - N1	100	100	100	200	99	100	99	199
Any	6 (6.0)	11 (11.0)	16 (16.0)	27 (13.5)	8 (8.1)	10 (10.0)	12 (12.1)	22 (11.1)
Grade 1	5 (5.0)	8 (8.0)	15 (15.0)	23 (11.5)	7 (7.1)	6 (6.0)	8 (8.1)	14 (7.0)
Grade 2	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	4 (4.0)	3 (3.0)	7 (3.5)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Arthralgia - N1	100	100	100	200	99	100	99	199
Any	4 (4.0)	7 (7.0)	9 (9.0)	16 (8.0)	6 (6.1)	11 (11.0)	9 (9.1)	20 (10.1)
Grade 1	2 (2.0)	5 (5.0)	9 (9.0)	14 (7.0)	5 (5.1)	9 (9.0)	6 (6.1)	15 (7.5)
Grade 2	2 (2.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	100	200	99	100	99	199
Any	5 (5.0)	6 (6.0)	3 (3.0)	9 (4.5)	5 (5.1)	5 (5.0)	3 (3.0)	8 (4.0)
Grade 1	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)	3 (3.0)	5 (5.0)	2 (2.0)	7 (3.5)
Grade 2	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	0	0	0
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Chills - N1	100	100	100	200	99	100	99	199
Any	4 (4.0)	8 (8.0)	5 (5.0)	13 (6.5)	2 (2.0)	5 (5.0)	5 (5.1)	10 (5.0)
Grade 1	3 (3.0)	5 (5.0)	5 (5.0)	10 (5.0)	2 (2.0)	5 (5.0)	1 (1.0)	6 (3.0)
Grade 2	1 (1.0)	3 (3.0)	0	3 (1.5)	0	0	3 (3.0)	3 (1.5)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Rash - N1	100	100	100	200	99	100	99	199
Any	4 (4.0)	4 (4.0)	4 (4.0)	8 (4.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Adverse Reactions - N1	194	195	198	393
Any Solicited Adverse Reactions	66 (34.0)	171 (87.7)	178 (89.9)	349 (88.8)
95% CI	27.4, 41.2	82.2, 92.0	84.8, 93.7	85.3, 91.7
Grade 1	53 (27.3)	90 (46.2)	64 (32.3)	154 (39.2)
Grade 2	10 (5.2)	60 (30.8)	83 (41.9)	143 (36.4)
Grade 3	2 (1.0)	21 (10.8)	31 (15.7)	52 (13.2)
Grade 4	0	0	0	0
Solicited Local Adverse Reactions - N1	194	195	198	393
Any Solicited Local Adverse Reactions	16 (8.2)	156 (80.0)	170 (85.9)	326 (83.0)
95% CI	4.8, 13.0	73.7, 85.4	80.2, 90.4	78.9, 86.5
Grade 1	16 (8.2)	127 (65.1)	129 (65.2)	256 (65.1)
Grade 2	0	27 (13.8)	34 (17.2)	61 (15.5)
Grade 3	0	2 (1.0)	7 (3.5)	9 (2.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Pain - N1	194	195	198	393
Any	15 (7.7)	155 (79.5)	169 (85.4)	324 (82.4)
Grade 1	15 (7.7)	131 (67.2)	140 (70.7)	271 (69.0)
Grade 2	0	22 (11.3)	28 (14.1)	50 (12.7)
Grade 3	0	2 (1.0)	1 (0.5)	3 (0.8)
Grade 4	0	0	0	0
Erythema (Redness) - N1	194	195	198	393
Any	0	10 (5.1)	15 (7.6)	25 (6.4)
Grade 1	0	5 (2.6)	7 (3.5)	12 (3.1)
Grade 2	0	5 (2.6)	3 (1.5)	8 (2.0)
Grade 3	0	0	5 (2.5)	5 (1.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Swelling (Hardness) - N1	194	195	198	393
Any	1 (0.5)	12 (6.2)	21 (10.6)	33 (8.4)
Grade 1	1 (0.5)	6 (3.1)	14 (7.1)	20 (5.1)
Grade 2	0	6 (3.1)	6 (3.0)	12 (3.1)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Lymphadenopathy - N1 [1]	194	195	198	393
Any	1 (0.5)	19 (9.7)	20 (10.1)	39 (9.9)
Grade 1	1 (0.5)	12 (6.2)	17 (8.6)	29 (7.4)
Grade 2	0	7 (3.6)	3 (1.5)	10 (2.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Systemic Adverse Reactions - N1	194	195	198	393
Any Solicited Systemic Adverse Reactions	58 (29.9)	135 (69.2)	153 (77.3)	288 (73.3)
95% CI	23.5, 36.9	62.2, 75.6	70.8, 82.9	68.6, 77.6
Grade 1	45 (23.2)	55 (28.2)	56 (28.3)	111 (28.2)
Grade 2	10 (5.2)	58 (29.7)	72 (36.4)	130 (33.1)
Grade 3	2 (1.0)	20 (10.3)	25 (12.6)	45 (11.5)
Grade 4	0	0	0	0
Fever - N1	194	195	198	393
Any	1 (0.5)	12 (6.2)	26 (13.1)	38 (9.7)
Grade 1	1 (0.5)	7 (3.6)	19 (9.6)	26 (6.6)
Grade 2	0	3 (1.5)	3 (1.5)	6 (1.5)
Grade 3	0	2 (1.0)	4 (2.0)	6 (1.5)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Headache - N1	194	195	198	393
Any	33 (17.0)	96 (49.2)	104 (52.5)	200 (50.9)
Grade 1	33 (17.0)	65 (33.3)	56 (28.3)	121 (30.8)
Grade 2	0	22 (11.3)	39 (19.7)	61 (15.5)
Grade 3	0	9 (4.6)	9 (4.5)	18 (4.6)
Grade 4	0	0	0	0
Fatigue - N1	194	195	198	393
Any	41 (21.1)	104 (53.3)	128 (64.6)	232 (59.0)
Grade 1	33 (17.0)	44 (22.6)	44 (22.2)	88 (22.4)
Grade 2	6 (3.1)	49 (25.1)	66 (33.3)	115 (29.3)
Grade 3	2 (1.0)	11 (5.6)	18 (9.1)	29 (7.4)
Grade 4	0	0	0	0
Myalgia - N1	194	195	198	393
Any	15 (7.7)	81 (41.5)	104 (52.5)	185 (47.1)
Grade 1	12 (6.2)	36 (18.5)	35 (17.7)	71 (18.1)
Grade 2	3 (1.5)	35 (17.9)	54 (27.3)	89 (22.6)
Grade 3	0	10 (5.1)	15 (7.6)	25 (6.4)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Arthralgia - N1	194	195	198	393
Any	13 (6.7)	68 (34.9)	77 (38.9)	145 (36.9)
Grade 1	11 (5.7)	32 (16.4)	32 (16.2)	64 (16.3)
Grade 2	2 (1.0)	29 (14.9)	37 (18.7)	66 (16.8)
Grade 3	0	7 (3.6)	8 (4.0)	15 (3.8)
Grade 4	0	0	0	0
Nausea/Vomiting - N1	194	195	198	393
Any	2 (1.0)	25 (12.8)	41 (20.7)	66 (16.8)
Grade 1	2 (1.0)	18 (9.2)	25 (12.6)	43 (10.9)
Grade 2	0	7 (3.6)	16 (8.1)	23 (5.9)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Chills - N1	194	195	198	393
Any	5 (2.6)	49 (25.1)	78 (39.4)	127 (32.3)
Grade 1	4 (2.1)	22 (11.3)	30 (15.2)	52 (13.2)
Grade 2	1 (0.5)	24 (12.3)	47 (23.7)	71 (18.1)
Grade 3	0	3 (1.5)	1 (0.5)	4 (1.0)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Rash - N1	194	195	198	393
Any	1 (0.5)	10 (5.1)	6 (3.0)	16 (4.1)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)		50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Solicited Adverse Reactions - N1	94	97	99	196	100	98	99	197
Any Solicited Adverse Reactions	28 (29.8)	86 (88.7)	92 (92.9)	178 (90.8)	38 (38.0)	85 (86.7)	86 (86.9)	171 (86.8)
95% CI	20.8, 40.1	80.6, 94.2	86.0, 97.1	85.9, 94.5	28.5, 48.3	78.4, 92.7	78.6, 92.8	81.3, 91.2
Grade 1	22 (23.4)	44 (45.4)	26 (26.3)	70 (35.7)	31 (31.0)	46 (46.9)	38 (38.4)	84 (42.6)
Grade 2	4 (4.3)	31 (32.0)	48 (48.5)	79 (40.3)	6 (6.0)	29 (29.6)	35 (35.4)	64 (32.5)
Grade 3	2 (2.1)	11 (11.3)	18 (18.2)	29 (14.8)	0	10 (10.2)	13 (13.1)	23 (11.7)
Grade 4	0	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	94	97	99	196	100	98	99	197
Any Solicited Local Adverse Reactions	10 (10.6)	78 (80.4)	89 (89.9)	167 (85.2)	6 (6.0)	78 (79.6)	81 (81.8)	159 (80.7)
95% CI	5.2, 18.7	71.1, 87.8	82.2, 95.0	79.4, 89.9	2.2, 12.6	70.3, 87.1	72.8, 88.9	74.5, 86.0
Grade 1	10 (10.6)	61 (62.9)	62 (62.6)	123 (62.8)	6 (6.0)	66 (67.3)	67 (67.7)	133 (67.5)
Grade 2	0	15 (15.5)	25 (25.3)	40 (20.4)	0	12 (12.2)	9 (9.1)	21 (10.7)
Grade 3	0	2 (2.1)	2 (2.0)	4 (2.0)	0	0	5 (5.1)	5 (2.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)		50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Pain - N1	94	97	99	196	100	98	99	197
Any	9 (9.6)	78 (80.4)	89 (89.9)	167 (85.2)	6 (6.0)	77 (78.6)	80 (80.8)	157 (79.7)
Grade 1	9 (9.6)	64 (66.0)	65 (65.7)	129 (65.8)	6 (6.0)	67 (68.4)	75 (75.8)	142 (72.1)
Grade 2	0	12 (12.4)	23 (23.2)	35 (17.9)	0	10 (10.2)	5 (5.1)	15 (7.6)
Grade 3	0	2 (2.1)	1 (1.0)	3 (1.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Erythema (Redness) - N1	94	97	99	196	100	98	99	197
Any	0	5 (5.2)	8 (8.1)	13 (6.6)	0	5 (5.1)	7 (7.1)	12 (6.1)
Grade 1	0	3 (3.1)	5 (5.1)	8 (4.1)	0	2 (2.0)	2 (2.0)	4 (2.0)
Grade 2	0	2 (2.1)	2 (2.0)	4 (2.0)	0	3 (3.1)	1 (1.0)	4 (2.0)
Grade 3	0	0	1 (1.0)	1 (0.5)	0	0	4 (4.0)	4 (2.0)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=94) n (%)	50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)	Placebo (N=100) n (%)	50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Swelling (Hardness)- N1	94	97	99	196	100	98	99	197
Any	1 (1.1)	6 (6.2)	11 (11.1)	17 (8.7)	0	6 (6.1)	10 (10.1)	16 (8.1)
Grade 1	1 (1.1)	3 (3.1)	10 (10.1)	13 (6.6)	0	3 (3.1)	4 (4.0)	7 (3.6)
Grade 2	0	3 (3.1)	1 (1.0)	4 (2.0)	0	3 (3.1)	5 (5.1)	8 (4.1)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1 [1]	94	97	99	196	100	98	99	197
Any	1 (1.1)	7 (7.2)	10 (10.1)	17 (8.7)	0	12 (12.2)	10 (10.1)	22 (11.2)
Grade 1	1 (1.1)	4 (4.1)	7 (7.1)	11 (5.6)	0	8 (8.2)	10 (10.1)	18 (9.1)
Grade 2	0	3 (3.1)	3 (3.0)	6 (3.1)	0	4 (4.1)	0	4 (2.0)
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=94) n (%)	50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)	Placebo (N=100) n (%)	50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Solicited Systemic Adverse Reactions - N1	94	97	99	196	100	98	99	197
Any Solicited Systemic Adverse Reactions	23 (24.5)	69 (71.1)	78 (78.8)	147 (75.0)	35 (35.0)	66 (67.3)	75 (75.8)	141 (71.6)
95% CI	16.2, 34.4	61.0, 79.9	69.4, 86.4	68.3, 80.9	25.7, 45.2	57.1, 76.5	66.1, 83.8	64.7, 77.8
Grade 1	17 (18.1)	27 (27.8)	21 (21.2)	48 (24.5)	28 (28.0)	28 (28.6)	35 (35.4)	63 (32.0)
Grade 2	4 (4.3)	30 (30.9)	41 (41.4)	71 (36.2)	6 (6.0)	28 (28.6)	31 (31.3)	59 (29.9)
Grade 3	2 (2.1)	10 (10.3)	16 (16.2)	26 (13.3)	0	10 (10.2)	9 (9.1)	19 (9.6)
Grade 4	0	0	0	0	0	0	0	0
Fever - N1	94	97	99	196	100	98	99	197
Any	1 (1.1)	7 (7.2)	15 (15.2)	22 (11.2)	0	5 (5.1)	11 (11.1)	16 (8.1)
Grade 1	1 (1.1)	3 (3.1)	10 (10.1)	13 (6.6)	0	4 (4.1)	9 (9.1)	13 (6.6)
Grade 2	0	2 (2.1)	2 (2.0)	4 (2.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Grade 3	0	2 (2.1)	3 (3.0)	5 (2.6)	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=94) n (%)	50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)	Placebo (N=100) n (%)	50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Headache - N1	94	97	99	196	100	98	99	197
Any	14 (14.9)	49 (50.5)	55 (55.6)	104 (53.1)	19 (19.0)	47 (48.0)	49 (49.5)	96 (48.7)
Grade 1	14 (14.9)	31 (32.0)	24 (24.2)	55 (28.1)	19 (19.0)	34 (34.7)	32 (32.3)	66 (33.5)
Grade 2	0	15 (15.5)	27 (27.3)	42 (21.4)	0	7 (7.1)	12 (12.1)	19 (9.6)
Grade 3	0	3 (3.1)	4 (4.0)	7 (3.6)	0	6 (6.1)	5 (5.1)	11 (5.6)
Grade 4	0	0	0	0	0	0	0	0
Fatigue - N1	94	97	99	196	100	98	99	197
Any	19 (20.2)	44 (45.4)	65 (65.7)	109 (55.6)	22 (22.0)	60 (61.2)	63 (63.6)	123 (62.4)
Grade 1	16 (17.0)	17 (17.5)	16 (16.2)	33 (16.8)	17 (17.0)	27 (27.6)	28 (28.3)	55 (27.9)
Grade 2	1 (1.1)	22 (22.7)	38 (38.4)	60 (30.6)	5 (5.0)	27 (27.6)	28 (28.3)	55 (27.9)
Grade 3	2 (2.1)	5 (5.2)	11 (11.1)	16 (8.2)	0	6 (6.1)	7 (7.1)	13 (6.6)
Grade 4	0	0	0	0	0	0	0	0
Myalgia - N1	94	97	99	196	100	98	99	197
Any	4 (4.3)	42 (43.3)	57 (57.6)	99 (50.5)	11 (11.0)	39 (39.8)	47 (47.5)	86 (43.7)
Grade 1	2 (2.1)	18 (18.6)	17 (17.2)	35 (17.9)	10 (10.0)	18 (18.4)	18 (18.2)	36 (18.3)
Grade 2	2 (2.1)	17 (17.5)	29 (29.3)	46 (23.5)	1 (1.0)	18 (18.4)	25 (25.3)	43 (21.8)
Grade 3	0	7 (7.2)	11 (11.1)	18 (9.2)	0	3 (3.1)	4 (4.0)	7 (3.6)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=94) n (%)	50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)	Placebo (N=100) n (%)	50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Arthralgia - N1	94	97	99	196	100	98	99	197
Any	3 (3.2)	30 (30.9)	39 (39.4)	69 (35.2)	10 (10.0)	38 (38.8)	38 (38.4)	76 (38.6)
Grade 1	1 (1.1)	15 (15.5)	11 (11.1)	26 (13.3)	10 (10.0)	17 (17.3)	21 (21.2)	38 (19.3)
Grade 2	2 (2.1)	10 (10.3)	22 (22.2)	32 (16.3)	0	19 (19.4)	15 (15.2)	34 (17.3)
Grade 3	0	5 (5.2)	6 (6.1)	11 (5.6)	0	2 (2.0)	2 (2.0)	4 (2.0)
Grade 4	0	0	0	0	0	0	0	0
Nausea/Vomiting - N1	94	97	99	196	100	98	99	197
Any	2 (2.1)	19 (19.6)	28 (28.3)	47 (24.0)	0	6 (6.1)	13 (13.1)	19 (9.6)
Grade 1	2 (2.1)	15 (15.5)	18 (18.2)	33 (16.8)	0	3 (3.1)	7 (7.1)	10 (5.1)
Grade 2	0	4 (4.1)	10 (10.1)	14 (7.1)	0	3 (3.1)	6 (6.1)	9 (4.6)
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Chills - N1	94	97	99	196	100	98	99	197
Any	2 (2.1)	28 (28.9)	47 (47.5)	75 (38.3)	3 (3.0)	21 (21.4)	31 (31.3)	52 (26.4)
Grade 1	1 (1.1)	9 (9.3)	18 (18.2)	27 (13.8)	3 (3.0)	13 (13.3)	12 (12.1)	25 (12.7)
Grade 2	1 (1.1)	17 (17.5)	28 (28.3)	45 (23.0)	0	7 (7.1)	19 (19.2)	26 (13.2)
Grade 3	0	2 (2.1)	1 (1.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=97) n (%)	100 µg (N=99) n (%)	Total (N=196) n (%)		50 µg (N=98) n (%)	100 µg (N=99) n (%)	Total (N=197) n (%)
Rash - N1	94	97	99	196	100	98	99	197
Any	0	7 (7.2)	4 (4.0)	11 (5.6)	1 (1.0)	3 (3.1)	2 (2.0)	5 (2.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event.
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Adverse Reactions - N1	200	200	200	400
Any Solicited Adverse Reactions	103 (51.5)	182 (91.0)	192 (96.0)	374 (93.5)
95% CI	44.3, 58.6	86.1, 94.6	92.3, 98.3	90.6, 95.7
Grade 1	72 (36.0)	95 (47.5)	69 (34.5)	164 (41.0)
Grade 2	21 (10.5)	61 (30.5)	90 (45.0)	151 (37.8)
Grade 3	6 (3.0)	25 (12.5)	32 (16.0)	57 (14.3)
Grade 4	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	200	400
Any Solicited Local Adverse Reactions	38 (19.0)	171 (85.5)	185 (92.5)	356 (89.0)
95% CI	13.8, 25.1	79.8, 90.1	87.9, 95.7	85.5, 91.9
Grade 1	37 (18.5)	139 (69.5)	137 (68.5)	276 (69.0)
Grade 2	1 (0.5)	29 (14.5)	40 (20.0)	69 (17.3)
Grade 3	0	3 (1.5)	8 (4.0)	11 (2.8)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Pain - N1	200	200	200	400
Any	32 (16.0)	171 (85.5)	183 (91.5)	354 (88.5)
Grade 1	32 (16.0)	144 (72.0)	147 (73.5)	291 (72.8)
Grade 2	0	24 (12.0)	34 (17.0)	58 (14.5)
Grade 3	0	3 (1.5)	2 (1.0)	5 (1.3)
Grade 4	0	0	0	0
Erythema (Redness) - N1	200	200	200	400
Any	1 (0.5)	12 (6.0)	19 (9.5)	31 (7.8)
Grade 1	1 (0.5)	7 (3.5)	11 (5.5)	18 (4.5)
Grade 2	0	5 (2.5)	3 (1.5)	8 (2.0)
Grade 3	0	0	5 (2.5)	5 (1.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Swelling (Hardness) - N1	200	200	200	400
Any	2 (1.0)	16 (8.0)	25 (12.5)	41 (10.3)
Grade 1	2 (1.0)	10 (5.0)	18 (9.0)	28 (7.0)
Grade 2	0	6 (3.0)	6 (3.0)	12 (3.0)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Lymphadenopathy - N1 [1]	200	200	200	400
Any	5 (2.5)	24 (12.0)	32 (16.0)	56 (14.0)
Grade 1	4 (2.0)	17 (8.5)	28 (14.0)	45 (11.3)
Grade 2	1 (0.5)	7 (3.5)	4 (2.0)	11 (2.8)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions - N1	200	200	200	400
Any Solicited Systemic Adverse Reactions	91 (45.5)	148 (74.0)	167 (83.5)	315 (78.8)
95% CI	38.5, 52.7	67.3, 79.9	77.6, 88.4	74.4, 82.7
Grade 1	60 (30.0)	66 (33.0)	61 (30.5)	127 (31.8)
Grade 2	21 (10.5)	58 (29.0)	79 (39.5)	137 (34.3)
Grade 3	6 (3.0)	23 (11.5)	26 (13.0)	49 (12.3)
Grade 4	0	0	0	0
Fever - N1	200	200	200	400
Any	1 (0.5)	12 (6.0)	26 (13.0)	38 (9.5)
Grade 1	1 (0.5)	7 (3.5)	18 (9.0)	25 (6.3)
Grade 2	0	3 (1.5)	4 (2.0)	7 (1.8)
Grade 3	0	2 (1.0)	4 (2.0)	6 (1.5)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Headache - N1	200	200	200	400
Any	59 (29.5)	111 (55.5)	115 (57.5)	226 (56.5)
Grade 1	53 (26.5)	72 (36.0)	64 (32.0)	136 (34.0)
Grade 2	2 (1.0)	28 (14.0)	42 (21.0)	70 (17.5)
Grade 3	4 (2.0)	11 (5.5)	9 (4.5)	20 (5.0)
Grade 4	0	0	0	0
Fatigue - N1	200	200	200	400
Any	61 (30.5)	113 (56.5)	138 (69.0)	251 (62.8)
Grade 1	47 (23.5)	51 (25.5)	47 (23.5)	98 (24.5)
Grade 2	12 (6.0)	50 (25.0)	72 (36.0)	122 (30.5)
Grade 3	2 (1.0)	12 (6.0)	19 (9.5)	31 (7.8)
Grade 4	0	0	0	0
Myalgia - N1	200	200	200	400
Any	26 (13.0)	87 (43.5)	111 (55.5)	198 (49.5)
Grade 1	21 (10.5)	41 (20.5)	39 (19.5)	80 (20.0)
Grade 2	5 (2.5)	36 (18.0)	56 (28.0)	92 (23.0)
Grade 3	0	10 (5.0)	16 (8.0)	26 (6.5)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Arthralgia - N1	200	200	200	400
Any	21 (10.5)	74 (37.0)	79 (39.5)	153 (38.3)
Grade 1	16 (8.0)	36 (18.0)	31 (15.5)	67 (16.8)
Grade 2	5 (2.5)	31 (15.5)	39 (19.5)	70 (17.5)
Grade 3	0	7 (3.5)	9 (4.5)	16 (4.0)
Grade 4	0	0	0	0
Nausea/Vomiting - N1	200	200	200	400
Any	11 (5.5)	31 (15.5)	43 (21.5)	74 (18.5)
Grade 1	6 (3.0)	23 (11.5)	26 (13.0)	49 (12.3)
Grade 2	5 (2.5)	8 (4.0)	16 (8.0)	24 (6.0)
Grade 3	0	0	1 (0.5)	1 (0.3)
Grade 4	0	0	0	0
Chills - N1	200	200	200	400
Any	11 (5.5)	52 (26.0)	83 (41.5)	135 (33.8)
Grade 1	9 (4.5)	25 (12.5)	31 (15.5)	56 (14.0)
Grade 2	2 (1.0)	24 (12.0)	50 (25.0)	74 (18.5)
Grade 3	0	3 (1.5)	2 (1.0)	5 (1.3)
Grade 4	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	200	200	200	400
Any	6 (3.0)	14 (7.0)	11 (5.5)	25 (6.3)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Solicited Adverse Reactions - N1	100	100	100	200	100	100	100	200
Any Solicited Adverse Reactions	48 (48.0)	92 (92.0)	95 (95.0)	187 (93.5)	55 (55.0)	90 (90.0)	97 (97.0)	187 (93.5)
95% CI	37.9, 58.2	84.8, 96.5	88.7, 98.4	89.1, 96.5	44.7, 65.0	82.4, 95.1	91.5, 99.4	89.1, 96.5
Grade 1	33 (33.0)	46 (46.0)	26 (26.0)	72 (36.0)	39 (39.0)	49 (49.0)	43 (43.0)	92 (46.0)
Grade 2	10 (10.0)	33 (33.0)	50 (50.0)	83 (41.5)	11 (11.0)	28 (28.0)	40 (40.0)	68 (34.0)
Grade 3	3 (3.0)	12 (12.0)	18 (18.0)	30 (15.0)	3 (3.0)	13 (13.0)	14 (14.0)	27 (13.5)
Grade 4	0	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	200	100	100	100	200
Any Solicited Local Adverse Reactions	23 (23.0)	86 (86.0)	93 (93.0)	179 (89.5)	15 (15.0)	85 (85.0)	92 (92.0)	177 (88.5)
95% CI	15.2, 32.5	77.6, 92.1	86.1, 97.1	84.4, 93.4	8.6, 23.5	76.5, 91.4	84.8, 96.5	83.2, 92.6
Grade 1	22 (22.0)	67 (67.0)	59 (59.0)	126 (63.0)	15 (15.0)	72 (72.0)	78 (78.0)	150 (75.0)
Grade 2	1 (1.0)	17 (17.0)	31 (31.0)	48 (24.0)	0	12 (12.0)	9 (9.0)	21 (10.5)
Grade 3	0	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	5 (5.0)	6 (3.0)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Pain - N1	100	100	100	200	100	100	100	200
Any	20 (20.0)	86 (86.0)	93 (93.0)	179 (89.5)	12 (12.0)	85 (85.0)	90 (90.0)	175 (87.5)
Grade 1	20 (20.0)	70 (70.0)	62 (62.0)	132 (66.0)	12 (12.0)	74 (74.0)	85 (85.0)	159 (79.5)
Grade 2	0	14 (14.0)	29 (29.0)	43 (21.5)	0	10 (10.0)	5 (5.0)	15 (7.5)
Grade 3	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	200	100	100	100	200
Any	0	5 (5.0)	10 (10.0)	15 (7.5)	1 (1.0)	7 (7.0)	9 (9.0)	16 (8.0)
Grade 1	0	3 (3.0)	7 (7.0)	10 (5.0)	1 (1.0)	4 (4.0)	4 (4.0)	8 (4.0)
Grade 2	0	2 (2.0)	2 (2.0)	4 (2.0)	0	3 (3.0)	1 (1.0)	4 (2.0)
Grade 3	0	0	1 (1.0)	1 (0.5)	0	0	4 (4.0)	4 (2.0)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Swelling (Hardness)- N1	100	100	100	200	100	100	100	200
Any	1 (1.0)	8 (8.0)	13 (13.0)	21 (10.5)	1 (1.0)	8 (8.0)	12 (12.0)	20 (10.0)
Grade 1	1 (1.0)	5 (5.0)	12 (12.0)	17 (8.5)	1 (1.0)	5 (5.0)	6 (6.0)	11 (5.5)
Grade 2	0	3 (3.0)	1 (1.0)	4 (2.0)	0	3 (3.0)	5 (5.0)	8 (4.0)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1 [1]	100	100	100	200	100	100	100	200
Any	4 (4.0)	11 (11.0)	19 (19.0)	30 (15.0)	1 (1.0)	13 (13.0)	13 (13.0)	26 (13.0)
Grade 1	3 (3.0)	8 (8.0)	16 (16.0)	24 (12.0)	1 (1.0)	9 (9.0)	12 (12.0)	21 (10.5)
Grade 2	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)	0	4 (4.0)	1 (1.0)	5 (2.5)
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Solicited Systemic Adverse Reactions - N1	100	100	100	200	100	100	100	200
Any Solicited Systemic Adverse Reactions	40 (40.0)	76 (76.0)	84 (84.0)	160 (80.0)	51 (51.0)	72 (72.0)	83 (83.0)	155 (77.5)
95% CI	30.3, 50.3	66.4, 84.0	75.3, 90.6	73.8, 85.3	40.8, 61.1	62.1, 80.5	74.2, 89.8	71.1, 83.1
Grade 1	25 (25.0)	33 (33.0)	25 (25.0)	58 (29.0)	35 (35.0)	33 (33.0)	36 (36.0)	69 (34.5)
Grade 2	10 (10.0)	31 (31.0)	42 (42.0)	73 (36.5)	11 (11.0)	27 (27.0)	37 (37.0)	64 (32.0)
Grade 3	3 (3.0)	11 (11.0)	16 (16.0)	27 (13.5)	3 (3.0)	12 (12.0)	10 (10.0)	22 (11.0)
Grade 4	0	0	0	0	0	0	0	0
Fever - N1	100	100	100	200	100	100	100	200
Any	1 (1.0)	7 (7.0)	15 (15.0)	22 (11.0)	0	5 (5.0)	11 (11.0)	16 (8.0)
Grade 1	1 (1.0)	3 (3.0)	10 (10.0)	13 (6.5)	0	4 (4.0)	8 (8.0)	12 (6.0)
Grade 2	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	2 (2.0)	3 (1.5)
Grade 3	0	2 (2.0)	3 (3.0)	5 (2.5)	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Headache - N1	100	100	100	200	100	100	100	200
Any	28 (28.0)	58 (58.0)	60 (60.0)	118 (59.0)	31 (31.0)	53 (53.0)	55 (55.0)	108 (54.0)
Grade 1	26 (26.0)	35 (35.0)	28 (28.0)	63 (31.5)	27 (27.0)	37 (37.0)	36 (36.0)	73 (36.5)
Grade 2	1 (1.0)	19 (19.0)	28 (28.0)	47 (23.5)	1 (1.0)	9 (9.0)	14 (14.0)	23 (11.5)
Grade 3	1 (1.0)	4 (4.0)	4 (4.0)	8 (4.0)	3 (3.0)	7 (7.0)	5 (5.0)	12 (6.0)
Grade 4	0	0	0	0	0	0	0	0
Fatigue - N1	100	100	100	200	100	100	100	200
Any	28 (28.0)	50 (50.0)	70 (70.0)	120 (60.0)	33 (33.0)	63 (63.0)	68 (68.0)	131 (65.5)
Grade 1	22 (22.0)	21 (21.0)	19 (19.0)	40 (20.0)	25 (25.0)	30 (30.0)	28 (28.0)	58 (29.0)
Grade 2	4 (4.0)	24 (24.0)	40 (40.0)	64 (32.0)	8 (8.0)	26 (26.0)	32 (32.0)	58 (29.0)
Grade 3	2 (2.0)	5 (5.0)	11 (11.0)	16 (8.0)	0	7 (7.0)	8 (8.0)	15 (7.5)
Grade 4	0	0	0	0	0	0	0	0
Myalgia - N1	100	100	100	200	100	100	100	200
Any	10 (10.0)	46 (46.0)	59 (59.0)	105 (52.5)	16 (16.0)	41 (41.0)	52 (52.0)	93 (46.5)
Grade 1	7 (7.0)	22 (22.0)	19 (19.0)	41 (20.5)	14 (14.0)	19 (19.0)	20 (20.0)	39 (19.5)
Grade 2	3 (3.0)	17 (17.0)	29 (29.0)	46 (23.0)	2 (2.0)	19 (19.0)	27 (27.0)	46 (23.0)
Grade 3	0	7 (7.0)	11 (11.0)	18 (9.0)	0	3 (3.0)	5 (5.0)	8 (4.0)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Arthralgia - N1	100	100	100	200	100	100	100	200
Any	7 (7.0)	32 (32.0)	39 (39.0)	71 (35.5)	14 (14.0)	42 (42.0)	40 (40.0)	82 (41.0)
Grade 1	3 (3.0)	16 (16.0)	11 (11.0)	27 (13.5)	13 (13.0)	20 (20.0)	20 (20.0)	40 (20.0)
Grade 2	4 (4.0)	11 (11.0)	22 (22.0)	33 (16.5)	1 (1.0)	20 (20.0)	17 (17.0)	37 (18.5)
Grade 3	0	5 (5.0)	6 (6.0)	11 (5.5)	0	2 (2.0)	3 (3.0)	5 (2.5)
Grade 4	0	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	100	200	100	100	100	200
Any	6 (6.0)	20 (20.0)	28 (28.0)	48 (24.0)	5 (5.0)	11 (11.0)	15 (15.0)	26 (13.0)
Grade 1	3 (3.0)	15 (15.0)	18 (18.0)	33 (16.5)	3 (3.0)	8 (8.0)	8 (8.0)	16 (8.0)
Grade 2	3 (3.0)	5 (5.0)	10 (10.0)	15 (7.5)	2 (2.0)	3 (3.0)	6 (6.0)	9 (4.5)
Grade 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0	0
Chills - N1	100	100	100	200	100	100	100	200
Any	6 (6.0)	30 (30.0)	48 (48.0)	78 (39.0)	5 (5.0)	22 (22.0)	35 (35.0)	57 (28.5)
Grade 1	4 (4.0)	11 (11.0)	19 (19.0)	30 (15.0)	5 (5.0)	14 (14.0)	12 (12.0)	26 (13.0)
Grade 2	2 (2.0)	17 (17.0)	28 (28.0)	45 (22.5)	0	7 (7.0)	22 (22.0)	29 (14.5)
Grade 3	0	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0	0

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.1.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade
Solicited Safety Set

Solicited Adverse Reaction Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Rash - N1	100	100	100	200	100	100	100	200
Any	4 (4.0)	10 (10.0)	8 (8.0)	18 (9.0)	2 (2.0)	4 (4.0)	3 (3.0)	7 (3.5)

CI = Confidence intervals. N1 = Number of exposed subjects who submitted any data for the event
Percentages are based on the number of exposed subjects who submitted any data for the event (N1).
95% CI is calculated using the Clopper-Pearson method.
In eDiary, rash is not reported by grade.
[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	199	197	194	192	194	192	196
Any Solicited Adverse Reactions	31 (15.6)	32 (16.2)	23 (11.9)	15 (7.8)	18 (9.3)	20 (10.4)	16 (8.2)
95% CI	10.8, 21.4	11.4, 22.2	7.7, 17.3	4.4, 12.6	5.6, 14.3	6.5, 15.6	4.7, 12.9
Grade 1	27 (13.6)	25 (12.7)	18 (9.3)	11 (5.7)	15 (7.7)	15 (7.8)	11 (5.6)
Grade 2	4 (2.0)	5 (2.5)	2 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)	3 (1.5)
Grade 3	0	0	2 (1.0)	0	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	198	196	193	191	194	192	196
Any Solicited Local Adverse Reactions	14 (7.1)	8 (4.1)	2 (1.0)	3 (1.6)	5 (2.6)	4 (2.1)	3 (1.5)
95% CI	3.9, 11.6	1.8, 7.9	0.1, 3.7	0.3, 4.5	0.8, 5.9	0.6, 5.2	0.3, 4.4
Grade 1	14 (7.1)	8 (4.1)	2 (1.0)	3 (1.6)	5 (2.6)	3 (1.6)	3 (1.5)
Grade 2	0	0	0	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	198	196	193	191	194	192	196
Any	11 (5.6)	6 (3.1)	1 (0.5)	1 (0.5)	3 (1.5)	2 (1.0)	0
Grade 1	11 (5.6)	6 (3.1)	1 (0.5)	1 (0.5)	3 (1.5)	2 (1.0)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	198	196	193	191	194	192	196
Any	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 1	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	198	196	193	191	194	192	196
Any	0	1 (0.5)	0	0	0	0	0
Grade 1	0	1 (0.5)	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	198	196	193	191	194	192	196
Any	2 (1.0)	0	0	1 (0.5)	1 (0.5)	2 (1.0)	2 (1.0)
Grade 1	2 (1.0)	0	0	1 (0.5)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 2	0	0	0	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	199	196	194	192	194	192	196
Any Solicited Systemic Adverse Reactions	21 (10.6)	25 (12.8)	21 (10.8)	12 (6.3)	14 (7.2)	18 (9.4)	14 (7.1)
95% CI	6.7, 15.7	8.4, 18.3	6.8, 16.1	3.3, 10.7	4.0, 11.8	5.7, 14.4	4.0, 11.7
Grade 1	17 (8.5)	18 (9.2)	16 (8.2)	8 (4.2)	11 (5.7)	13 (6.8)	9 (4.6)
Grade 2	4 (2.0)	5 (2.6)	2 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)	3 (1.5)
Grade 3	0	0	2 (1.0)	0	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	199	195	193	191	193	190	194
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	198	196	193	191	194	192	196
Any	9 (4.5)	12 (6.1)	8 (4.1)	4 (2.1)	9 (4.6)	8 (4.2)	6 (3.1)
Grade 1	9 (4.5)	12 (6.1)	6 (3.1)	3 (1.6)	8 (4.1)	6 (3.1)	4 (2.0)
Grade 2	0	0	0	1 (0.5)	1 (0.5)	0	1 (0.5)
Grade 3	0	0	2 (1.0)	0	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	198	196	193	191	194	192	196
Any	16 (8.1)	12 (6.1)	10 (5.2)	6 (3.1)	6 (3.1)	10 (5.2)	8 (4.1)
Grade 1	13 (6.6)	8 (4.1)	10 (5.2)	4 (2.1)	5 (2.6)	8 (4.2)	6 (3.1)
Grade 2	3 (1.5)	4 (2.0)	0	2 (1.0)	1 (0.5)	2 (1.0)	2 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	198	196	193	191	194	192	196
Any	3 (1.5)	3 (1.5)	5 (2.6)	4 (2.1)	2 (1.0)	4 (2.1)	4 (2.0)
Grade 1	3 (1.5)	2 (1.0)	5 (2.6)	3 (1.6)	2 (1.0)	3 (1.6)	4 (2.0)
Grade 2	0	1 (0.5)	0	1 (0.5)	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	198	196	193	191	194	192	196
Any	1 (0.5)	3 (1.5)	3 (1.6)	3 (1.6)	3 (1.5)	3 (1.6)	4 (2.0)
Grade 1	1 (0.5)	2 (1.0)	2 (1.0)	3 (1.6)	3 (1.5)	2 (1.0)	4 (2.0)
Grade 2	0	1 (0.5)	1 (0.5)	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	198	196	193	191	194	192	196
Any	2 (1.0)	2 (1.0)	2 (1.0)	0	0	3 (1.6)	3 (1.5)
Grade 1	1 (0.5)	2 (1.0)	1 (0.5)	0	0	2 (1.0)	1 (0.5)
Grade 2	1 (0.5)	0	1 (0.5)	0	0	1 (0.5)	2 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=199)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	198	196	193	191	194	192	196
Any	2 (1.0)	2 (1.0)	2 (1.0)	0	0	0	0
Grade 1	2 (1.0)	1 (0.5)	2 (1.0)	0	0	0	0
Grade 2	0	1 (0.5)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	198	196	193	191	194	192	196
Any	0	2 (1.0)	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	197	195	195	193	192	194
Any Solicited Adverse Reactions	82 (41.0)	120 (60.9)	73 (37.4)	37 (19.0)	26 (13.5)	25 (13.0)	21 (10.8)
95% CI	34.1, 48.2	53.7, 67.8	30.6, 44.6	13.7, 25.2	9.0, 19.1	8.6, 18.6	6.8, 16.1
Grade 1	71 (35.5)	107 (54.3)	64 (32.8)	26 (13.3)	20 (10.4)	18 (9.4)	16 (8.2)
Grade 2	8 (4.0)	13 (6.6)	7 (3.6)	9 (4.6)	3 (1.6)	3 (1.6)	2 (1.0)
Grade 3	2 (1.0)	0	0	1 (0.5)	1 (0.5)	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	196	193	195	192	192	192
Any Solicited Local Adverse Reactions	71 (35.5)	116 (59.2)	55 (28.5)	15 (7.7)	5 (2.6)	2 (1.0)	0
95% CI	28.9, 42.6	52.0, 66.1	22.2, 35.4	4.4, 12.4	0.9, 6.0	0.1, 3.7	0.0, 1.9
Grade 1	68 (34.0)	111 (56.6)	55 (28.5)	15 (7.7)	5 (2.6)	2 (1.0)	0
Grade 2	2 (1.0)	5 (2.6)	0	0	0	0	0
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	196	193	195	192	192	192
Any	70 (35.0)	116 (59.2)	55 (28.5)	14 (7.2)	4 (2.1)	2 (1.0)	0
Grade 1	68 (34.0)	111 (56.6)	55 (28.5)	14 (7.2)	4 (2.1)	2 (1.0)	0
Grade 2	1 (0.5)	5 (2.6)	0	0	0	0	0
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	196	193	195	192	192	192
Any	1 (0.5)	3 (1.5)	2 (1.0)	1 (0.5)	0	0	0
Grade 1	1 (0.5)	3 (1.5)	2 (1.0)	1 (0.5)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	196	193	195	192	192	192
Any	2 (1.0)	7 (3.6)	2 (1.0)	1 (0.5)	0	0	0
Grade 1	1 (0.5)	7 (3.6)	2 (1.0)	1 (0.5)	0	0	0
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	200	196	193	195	192	192	192
Any	3 (1.5)	6 (3.1)	2 (1.0)	1 (0.5)	1 (0.5)	0	0
Grade 1	3 (1.5)	6 (3.1)	2 (1.0)	1 (0.5)	1 (0.5)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	197	195	195	193	192	194
Any Solicited Systemic Adverse Reactions	33 (16.5)	37 (18.8)	34 (17.4)	27 (13.8)	24 (12.4)	24 (12.5)	21 (10.8)
95% CI	11.6, 22.4	13.6, 24.9	12.4, 23.5	9.3, 19.5	8.1, 17.9	8.2, 18.0	6.8, 16.1
Grade 1	24 (12.0)	27 (13.7)	25 (12.8)	16 (8.2)	18 (9.3)	17 (8.9)	16 (8.2)
Grade 2	7 (3.5)	10 (5.1)	7 (3.6)	9 (4.6)	3 (1.6)	3 (1.6)	2 (1.0)
Grade 3	1 (0.5)	0	0	1 (0.5)	1 (0.5)	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	195	194	194	190	189	191
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	197	193	195	191	191	193
Any	17 (8.5)	17 (8.6)	20 (10.4)	12 (6.2)	11 (5.8)	15 (7.9)	13 (6.7)
Grade 1	15 (7.5)	12 (6.1)	17 (8.8)	6 (3.1)	11 (5.8)	12 (6.3)	11 (5.7)
Grade 2	1 (0.5)	5 (2.5)	3 (1.6)	5 (2.6)	0	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	0	0	1 (0.5)	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	197	193	195	191	191	193
Any	13 (6.5)	24 (12.2)	20 (10.4)	17 (8.7)	12 (6.3)	10 (5.2)	8 (4.1)
Grade 1	9 (4.5)	21 (10.7)	15 (7.8)	12 (6.2)	9 (4.7)	8 (4.2)	7 (3.6)
Grade 2	4 (2.0)	3 (1.5)	5 (2.6)	5 (2.6)	2 (1.0)	2 (1.0)	1 (0.5)
Grade 3	0	0	0	0	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	197	193	195	191	191	192
Any	6 (3.0)	14 (7.1)	9 (4.7)	4 (2.1)	4 (2.1)	1 (0.5)	1 (0.5)
Grade 1	3 (1.5)	11 (5.6)	8 (4.1)	3 (1.5)	3 (1.6)	1 (0.5)	1 (0.5)
Grade 2	3 (1.5)	3 (1.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	197	193	195	191	191	192
Any	6 (3.0)	10 (5.1)	9 (4.7)	6 (3.1)	4 (2.1)	4 (2.1)	3 (1.6)
Grade 1	5 (2.5)	9 (4.6)	8 (4.1)	6 (3.1)	3 (1.6)	3 (1.6)	3 (1.6)
Grade 2	1 (0.5)	1 (0.5)	1 (0.5)	0	1 (0.5)	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	197	193	195	191	191	192
Any	4 (2.0)	2 (1.0)	3 (1.6)	2 (1.0)	2 (1.0)	0	0
Grade 1	3 (1.5)	2 (1.0)	3 (1.6)	2 (1.0)	2 (1.0)	0	0
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Chills - N1	200	197	193	195	191	191	192
Any	8 (4.0)	3 (1.5)	3 (1.6)	2 (1.0)	1 (0.5)	0	0
Grade 1	6 (3.0)	2 (1.0)	3 (1.6)	2 (1.0)	1 (0.5)	0	0
Grade 2	2 (1.0)	1 (0.5)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	197	193	195	191	191	192
Any	1 (0.5)	2 (1.0)	2 (1.0)	1 (0.5)	3 (1.6)	3 (1.6)	3 (1.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	199	199	196	196	189	192	195
Any Solicited Adverse Reactions	99 (49.7)	153 (76.9)	94 (48.0)	45 (23.0)	24 (12.7)	18 (9.4)	20 (10.3)
95% CI	42.6, 56.9	70.4, 82.6	40.8, 55.2	17.3, 29.5	8.3, 18.3	5.7, 14.4	6.4, 15.4
Grade 1	93 (46.7)	139 (69.8)	85 (43.4)	39 (19.9)	23 (12.2)	17 (8.9)	18 (9.2)
Grade 2	5 (2.5)	11 (5.5)	8 (4.1)	3 (1.5)	0	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	199	199	196	196	189	192	194
Any Solicited Local Adverse Reactions	92 (46.2)	149 (74.9)	85 (43.4)	29 (14.8)	6 (3.2)	7 (3.6)	5 (2.6)
95% CI	39.2, 53.4	68.3, 80.7	36.3, 50.6	10.1, 20.6	1.2, 6.8	1.5, 7.4	0.8, 5.9
Grade 1	90 (45.2)	141 (70.9)	82 (41.8)	29 (14.8)	6 (3.2)	7 (3.6)	5 (2.6)
Grade 2	2 (1.0)	7 (3.5)	3 (1.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	199	198	195	195	189	192	194
Any	92 (46.2)	146 (73.7)	84 (43.1)	24 (12.3)	6 (3.2)	3 (1.6)	3 (1.5)
Grade 1	90 (45.2)	138 (69.7)	81 (41.5)	24 (12.3)	6 (3.2)	3 (1.6)	3 (1.5)
Grade 2	2 (1.0)	7 (3.5)	3 (1.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	199	198	195	195	189	192	194
Any	0	2 (1.0)	4 (2.1)	2 (1.0)	0	0	0
Grade 1	0	2 (1.0)	4 (2.1)	2 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	199	199	196	196	189	192	194
Any	0	4 (2.0)	6 (3.1)	3 (1.5)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 1	0	4 (2.0)	6 (3.1)	3 (1.5)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	199	198	195	195	189	192	194
Any	6 (3.0)	7 (3.5)	5 (2.6)	3 (1.5)	1 (0.5)	5 (2.6)	3 (1.5)
Grade 1	4 (2.0)	6 (3.0)	4 (2.1)	3 (1.5)	1 (0.5)	5 (2.6)	3 (1.5)
Grade 2	2 (1.0)	1 (0.5)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	199	198	195	195	189	192	195
Any Solicited Systemic Adverse Reactions	38 (19.1)	47 (23.7)	29 (14.9)	23 (11.8)	18 (9.5)	14 (7.3)	15 (7.7)
95% CI	13.9, 25.3	18.0, 30.3	10.2, 20.7	7.6, 17.2	5.7, 14.6	4.0, 11.9	4.4, 12.4
Grade 1	32 (16.1)	39 (19.7)	23 (11.8)	17 (8.7)	17 (9.0)	13 (6.8)	13 (6.7)
Grade 2	5 (2.5)	6 (3.0)	5 (2.6)	3 (1.5)	0	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	199	195	195	194	187	191	189
Any	0	0	1 (0.5)	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	199	197	194	194	188	192	194
Any	14 (7.0)	23 (11.7)	9 (4.6)	10 (5.2)	5 (2.7)	8 (4.2)	7 (3.6)
Grade 1	13 (6.5)	19 (9.6)	7 (3.6)	9 (4.6)	5 (2.7)	8 (4.2)	6 (3.1)
Grade 2	1 (0.5)	4 (2.0)	2 (1.0)	1 (0.5)	0	0	1 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	199	197	194	194	188	192	193
Any	21 (10.6)	26 (13.2)	21 (10.8)	14 (7.2)	13 (6.9)	9 (4.7)	7 (3.6)
Grade 1	16 (8.0)	21 (10.7)	19 (9.8)	11 (5.7)	12 (6.4)	8 (4.2)	7 (3.6)
Grade 2	4 (2.0)	4 (2.0)	1 (0.5)	2 (1.0)	0	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	199	197	194	194	188	192	193
Any	9 (4.5)	19 (9.6)	10 (5.2)	5 (2.6)	3 (1.6)	3 (1.6)	2 (1.0)
Grade 1	8 (4.0)	16 (8.1)	9 (4.6)	3 (1.5)	2 (1.1)	2 (1.0)	2 (1.0)
Grade 2	0	2 (1.0)	0	1 (0.5)	0	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	199	197	194	194	188	192	193
Any	4 (2.0)	12 (6.1)	6 (3.1)	4 (2.1)	3 (1.6)	1 (0.5)	0
Grade 1	3 (1.5)	10 (5.1)	5 (2.6)	3 (1.5)	2 (1.1)	0	0
Grade 2	0	1 (0.5)	0	0	0	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	199	197	194	194	188	192	193
Any	0	2 (1.0)	3 (1.5)	1 (0.5)	1 (0.5)	0	2 (1.0)
Grade 1	0	2 (1.0)	2 (1.0)	0	1 (0.5)	0	2 (1.0)
Grade 2	0	0	1 (0.5)	0	0	0	0
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	199	197	194	194	188	192	193
Any	4 (2.0)	6 (3.0)	3 (1.5)	1 (0.5)	1 (0.5)	0	1 (0.5)
Grade 1	3 (1.5)	5 (2.5)	1 (0.5)	0	1 (0.5)	0	1 (0.5)
Grade 2	1 (0.5)	1 (0.5)	2 (1.0)	0	0	0	0
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	199	197	194	194	188	192	193
Any	1 (0.5)	2 (1.0)	0	2 (1.0)	0	0	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	399	396	391	391	382	384	389
Any Solicited Adverse Reactions	181 (45.4)	273 (68.9)	167 (42.7)	82 (21.0)	50 (13.1)	43 (11.2)	41 (10.5)
95% CI	40.4, 50.4	64.1, 73.5	37.8, 47.8	17.0, 25.3	9.9, 16.9	8.2, 14.8	7.7, 14.0
Grade 1	164 (41.1)	246 (62.1)	149 (38.1)	65 (16.6)	43 (11.3)	35 (9.1)	34 (8.7)
Grade 2	13 (3.3)	24 (6.1)	15 (3.8)	12 (3.1)	3 (0.8)	4 (1.0)	3 (0.8)
Grade 3	3 (0.8)	2 (0.5)	1 (0.3)	2 (0.5)	2 (0.5)	2 (0.5)	1 (0.3)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	399	395	389	391	381	384	386
Any Solicited Local Adverse Reactions	163 (40.9)	265 (67.1)	140 (36.0)	44 (11.3)	11 (2.9)	9 (2.3)	5 (1.3)
95% CI	36.0, 45.9	62.2, 71.7	31.2, 41.0	8.3, 14.8	1.4, 5.1	1.1, 4.4	0.4, 3.0
Grade 1	158 (39.6)	252 (63.8)	137 (35.2)	44 (11.3)	11 (2.9)	9 (2.3)	5 (1.3)
Grade 2	4 (1.0)	12 (3.0)	3 (0.8)	0	0	0	0
Grade 3	1 (0.3)	1 (0.3)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	399	394	388	390	381	384	386
Any	162 (40.6)	262 (66.5)	139 (35.8)	38 (9.7)	10 (2.6)	5 (1.3)	3 (0.8)
Grade 1	158 (39.6)	249 (63.2)	136 (35.1)	38 (9.7)	10 (2.6)	5 (1.3)	3 (0.8)
Grade 2	3 (0.8)	12 (3.0)	3 (0.8)	0	0	0	0
Grade 3	1 (0.3)	1 (0.3)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	399	394	388	390	381	384	386
Any	1 (0.3)	5 (1.3)	6 (1.5)	3 (0.8)	0	0	0
Grade 1	1 (0.3)	5 (1.3)	6 (1.5)	3 (0.8)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	399	395	389	391	381	384	386
Any	2 (0.5)	11 (2.8)	8 (2.1)	4 (1.0)	1 (0.3)	1 (0.3)	2 (0.5)
Grade 1	1 (0.3)	11 (2.8)	8 (2.1)	4 (1.0)	1 (0.3)	1 (0.3)	2 (0.5)
Grade 2	1 (0.3)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	399	394	388	390	381	384	386
Any	9 (2.3)	13 (3.3)	7 (1.8)	4 (1.0)	2 (0.5)	5 (1.3)	3 (0.8)
Grade 1	7 (1.8)	12 (3.0)	6 (1.5)	4 (1.0)	2 (0.5)	5 (1.3)	3 (0.8)
Grade 2	2 (0.5)	1 (0.3)	1 (0.3)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	399	395	390	390	382	384	389
Any Solicited Systemic Adverse Reactions	71 (17.8)	84 (21.3)	63 (16.2)	50 (12.8)	42 (11.0)	38 (9.9)	36 (9.3)
95% CI	14.2, 21.9	17.3, 25.6	12.6, 20.2	9.7, 16.6	8.0, 14.6	7.1, 13.3	6.6, 12.6
Grade 1	56 (14.0)	66 (16.7)	48 (12.3)	33 (8.5)	35 (9.2)	30 (7.8)	29 (7.5)
Grade 2	12 (3.0)	16 (4.1)	12 (3.1)	12 (3.1)	3 (0.8)	4 (1.0)	3 (0.8)
Grade 3	2 (0.5)	1 (0.3)	1 (0.3)	2 (0.5)	2 (0.5)	2 (0.5)	1 (0.3)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	399	390	389	388	377	380	380
Any	0	0	1 (0.3)	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (0.3)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	399	394	387	389	379	383	387
Any	31 (7.8)	40 (10.2)	29 (7.5)	22 (5.7)	16 (4.2)	23 (6.0)	20 (5.2)
Grade 1	28 (7.0)	31 (7.9)	24 (6.2)	15 (3.9)	16 (4.2)	20 (5.2)	17 (4.4)
Grade 2	2 (0.5)	9 (2.3)	5 (1.3)	6 (1.5)	0	1 (0.3)	2 (0.5)
Grade 3	1 (0.3)	0	0	1 (0.3)	0	2 (0.5)	1 (0.3)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	399	394	387	389	379	383	386
Any	34 (8.5)	50 (12.7)	41 (10.6)	31 (8.0)	25 (6.6)	19 (5.0)	15 (3.9)
Grade 1	25 (6.3)	42 (10.7)	34 (8.8)	23 (5.9)	21 (5.5)	16 (4.2)	14 (3.6)
Grade 2	8 (2.0)	7 (1.8)	6 (1.6)	7 (1.8)	2 (0.5)	3 (0.8)	1 (0.3)
Grade 3	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	2 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	399	394	387	389	379	383	385
Any	15 (3.8)	33 (8.4)	19 (4.9)	9 (2.3)	7 (1.8)	4 (1.0)	3 (0.8)
Grade 1	11 (2.8)	27 (6.9)	17 (4.4)	6 (1.5)	5 (1.3)	3 (0.8)	3 (0.8)
Grade 2	3 (0.8)	5 (1.3)	1 (0.3)	2 (0.5)	1 (0.3)	1 (0.3)	0
Grade 3	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	399	394	387	389	379	383	385
Any	10 (2.5)	22 (5.6)	15 (3.9)	10 (2.6)	7 (1.8)	5 (1.3)	3 (0.8)
Grade 1	8 (2.0)	19 (4.8)	13 (3.4)	9 (2.3)	5 (1.3)	3 (0.8)	3 (0.8)
Grade 2	1 (0.3)	2 (0.5)	1 (0.3)	0	1 (0.3)	2 (0.5)	0
Grade 3	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	1 (0.3)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	399	394	387	389	379	383	385
Any	4 (1.0)	4 (1.0)	6 (1.6)	3 (0.8)	3 (0.8)	0	2 (0.5)
Grade 1	3 (0.8)	4 (1.0)	5 (1.3)	2 (0.5)	3 (0.8)	0	2 (0.5)
Grade 2	1 (0.3)	0	1 (0.3)	0	0	0	0
Grade 3	0	0	0	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	399	394	387	389	379	383	385
Any	12 (3.0)	9 (2.3)	6 (1.6)	3 (0.8)	2 (0.5)	0	1 (0.3)
Grade 1	9 (2.3)	7 (1.8)	4 (1.0)	2 (0.5)	2 (0.5)	0	1 (0.3)
Grade 2	3 (0.8)	2 (0.5)	2 (0.5)	0	0	0	0
Grade 3	0	0	0	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	399	394	387	389	379	383	385
Any	2 (0.5)	4 (1.0)	2 (0.5)	3 (0.8)	3 (0.8)	3 (0.8)	4 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	98	99	93	97	96	98
Any Solicited Adverse Reactions	16 (16.0)	16 (16.3)	8 (8.1)	7 (7.5)	11 (11.3)	9 (9.4)	9 (9.2)
95% CI	9.4, 24.7	9.6, 25.2	3.6, 15.3	3.1, 14.9	5.8, 19.4	4.4, 17.1	4.3, 16.7
Grade 1	16 (16.0)	12 (12.2)	5 (5.1)	4 (4.3)	9 (9.3)	5 (5.2)	5 (5.1)
Grade 2	0	2 (2.0)	2 (2.0)	2 (2.2)	1 (1.0)	2 (2.1)	2 (2.0)
Grade 3	0	0	0	0	0	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	99	98	98	92	97	96	98
Any Solicited Local Adverse Reactions	11 (11.1)	3 (3.1)	0	1 (1.1)	2 (2.1)	1 (1.0)	2 (2.0)
95% CI	5.7, 19.0	0.6, 8.7	0.0, 3.7	0.0, 5.9	0.3, 7.3	0.0, 5.7	0.2, 7.2
Grade 1	11 (11.1)	3 (3.1)	0	1 (1.1)	2 (2.1)	0	2 (2.0)
Grade 2	0	0	0	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	99	98	98	92	97	96	98
Any	9 (9.1)	3 (3.1)	0	1 (1.1)	2 (2.1)	1 (1.0)	0
Grade 1	9 (9.1)	3 (3.1)	0	1 (1.1)	2 (2.1)	1 (1.0)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	99	98	98	92	97	96	98
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	99	98	98	92	97	96	98
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	99	98	98	92	97	96	98
Any	2 (2.0)	0	0	0	0	1 (1.0)	2 (2.0)
Grade 1	2 (2.0)	0	0	0	0	0	2 (2.0)
Grade 2	0	0	0	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	98	99	93	97	96	98
Any Solicited Systemic Adverse Reactions	9 (9.0)	13 (13.3)	8 (8.1)	6 (6.5)	10 (10.3)	9 (9.4)	8 (8.2)
95% CI	4.2, 16.4	7.3, 21.6	3.6, 15.3	2.4, 13.5	5.1, 18.1	4.4, 17.1	3.6, 15.5
Grade 1	9 (9.0)	9 (9.2)	5 (5.1)	3 (3.2)	8 (8.2)	5 (5.2)	4 (4.1)
Grade 2	0	2 (2.0)	2 (2.0)	2 (2.2)	1 (1.0)	2 (2.1)	2 (2.0)
Grade 3	0	0	0	0	0	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	98	99	93	97	96	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	99	98	98	92	97	96	98
Any	4 (4.0)	6 (6.1)	2 (2.0)	1 (1.1)	7 (7.2)	3 (3.1)	4 (4.1)
Grade 1	4 (4.0)	6 (6.1)	2 (2.0)	0	6 (6.2)	2 (2.1)	3 (3.1)
Grade 2	0	0	0	1 (1.1)	1 (1.0)	0	0
Grade 3	0	0	0	0	0	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	99	98	98	92	97	96	98
Any	6 (6.1)	6 (6.1)	5 (5.1)	4 (4.3)	4 (4.1)	7 (7.3)	5 (5.1)
Grade 1	6 (6.1)	4 (4.1)	5 (5.1)	2 (2.2)	4 (4.1)	5 (5.2)	4 (4.1)
Grade 2	0	2 (2.0)	0	2 (2.2)	0	2 (2.1)	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Myalgia - N1	99	98	98	92	97	96	98
Any	1 (1.0)	0	1 (1.0)	3 (3.3)	1 (1.0)	3 (3.1)	2 (2.0)
Grade 1	1 (1.0)	0	1 (1.0)	2 (2.2)	1 (1.0)	2 (2.1)	2 (2.0)
Grade 2	0	0	0	1 (1.1)	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	99	98	98	92	97	96	98
Any	0	2 (2.0)	1 (1.0)	1 (1.1)	2 (2.1)	2 (2.1)	2 (2.0)
Grade 1	0	2 (2.0)	0	1 (1.1)	2 (2.1)	1 (1.0)	2 (2.0)
Grade 2	0	0	1 (1.0)	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	99	98	98	92	97	96	98
Any	0	2 (2.0)	1 (1.0)	0	0	2 (2.1)	1 (1.0)
Grade 1	0	2 (2.0)	0	0	0	1 (1.0)	0
Grade 2	0	0	1 (1.0)	0	0	1 (1.0)	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	99	98	98	92	97	96	98
Any	1 (1.0)	2 (2.0)	1 (1.0)	0	0	0	0
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	99	98	98	92	97	96	98
Any	0	2 (2.0)	1 (1.0)	1 (1.1)	1 (1.0)	1 (1.0)	1 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	98	98	97	96	95	98
Any Solicited Adverse Reactions	51 (51.0)	67 (68.4)	42 (42.9)	18 (18.6)	10 (10.4)	6 (6.3)	9 (9.2)
95% CI	40.8, 61.1	58.2, 77.4	32.9, 53.3	11.4, 27.7	5.1, 18.3	2.4, 13.2	4.3, 16.7
Grade 1	43 (43.0)	59 (60.2)	36 (36.7)	14 (14.4)	7 (7.3)	4 (4.2)	6 (6.1)
Grade 2	6 (6.0)	8 (8.2)	5 (5.1)	4 (4.1)	2 (2.1)	1 (1.1)	2 (2.0)
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	98	97	97	96	95	98
Any Solicited Local Adverse Reactions	46 (46.0)	63 (64.3)	36 (37.1)	10 (10.3)	2 (2.1)	0	0
95% CI	36.0, 56.3	54.0, 73.7	27.5, 47.5	5.1, 18.1	0.3, 7.3	0.0, 3.8	0.0, 3.7
Grade 1	44 (44.0)	58 (59.2)	36 (37.1)	10 (10.3)	2 (2.1)	0	0
Grade 2	2 (2.0)	5 (5.1)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	98	97	97	96	95	98
Any	46 (46.0)	63 (64.3)	36 (37.1)	9 (9.3)	2 (2.1)	0	0
Grade 1	45 (45.0)	58 (59.2)	36 (37.1)	9 (9.3)	2 (2.1)	0	0
Grade 2	1 (1.0)	5 (5.1)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	98	97	97	96	95	98
Any	0	2 (2.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 1	0	2 (2.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	98	97	97	96	95	98
Any	2 (2.0)	4 (4.1)	2 (2.1)	1 (1.0)	0	0	0
Grade 1	1 (1.0)	4 (4.1)	2 (2.1)	1 (1.0)	0	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	98	97	97	96	95	98
Any	3 (3.0)	4 (4.1)	2 (2.1)	1 (1.0)	0	0	0
Grade 1	3 (3.0)	4 (4.1)	2 (2.1)	1 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	98	98	97	96	95	98
Any Solicited Systemic Adverse Reactions	21 (21.0)	18 (18.4)	16 (16.3)	12 (12.4)	9 (9.4)	6 (6.3)	9 (9.2)
95% CI	13.5, 30.3	11.3, 27.5	9.6, 25.2	6.6, 20.6	4.4, 17.1	2.4, 13.2	4.3, 16.7
Grade 1	14 (14.0)	13 (13.3)	10 (10.2)	8 (8.2)	6 (6.3)	4 (4.2)	6 (6.1)
Grade 2	5 (5.0)	5 (5.1)	5 (5.1)	4 (4.1)	2 (2.1)	1 (1.1)	2 (2.0)
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	96	98	97	94	92	96
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	98	97	97	96	95	98
Any	9 (9.0)	9 (9.2)	12 (12.4)	6 (6.2)	4 (4.2)	3 (3.2)	7 (7.1)
Grade 1	7 (7.0)	6 (6.1)	9 (9.3)	3 (3.1)	4 (4.2)	3 (3.2)	6 (6.1)
Grade 2	1 (1.0)	3 (3.1)	3 (3.1)	3 (3.1)	0	0	1 (1.0)
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	98	97	97	96	95	98
Any	8 (8.0)	10 (10.2)	9 (9.3)	8 (8.2)	4 (4.2)	2 (2.1)	3 (3.1)
Grade 1	5 (5.0)	10 (10.2)	6 (6.2)	6 (6.2)	3 (3.1)	2 (2.1)	2 (2.0)
Grade 2	3 (3.0)	0	3 (3.1)	2 (2.1)	1 (1.0)	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	98	97	97	96	95	98
Any	4 (4.0)	8 (8.2)	4 (4.1)	1 (1.0)	1 (1.0)	0	0
Grade 1	2 (2.0)	7 (7.1)	4 (4.1)	1 (1.0)	0	0	0
Grade 2	2 (2.0)	1 (1.0)	0	0	1 (1.0)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	98	97	97	96	95	98
Any	4 (4.0)	4 (4.1)	3 (3.1)	1 (1.0)	1 (1.0)	1 (1.1)	0
Grade 1	3 (3.0)	4 (4.1)	3 (3.1)	1 (1.0)	0	0	0
Grade 2	1 (1.0)	0	0	0	1 (1.0)	1 (1.1)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	98	97	97	96	95	98
Any	4 (4.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0
Grade 1	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	98	97	97	96	95	98
Any	6 (6.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 1	4 (4.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 2	2 (2.0)	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	98	97	97	96	95	98
Any	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)	1 (1.1)	1 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	99	97	98	93	95	98
Any Solicited Adverse Reactions	57 (57.0)	83 (83.8)	52 (53.6)	21 (21.4)	12 (12.9)	9 (9.5)	12 (12.2)
95% CI	46.7, 66.9	75.1, 90.5	43.2, 63.8	13.8, 30.9	6.8, 21.5	4.4, 17.2	6.5, 20.4
Grade 1	55 (55.0)	72 (72.7)	48 (49.5)	19 (19.4)	12 (12.9)	9 (9.5)	11 (11.2)
Grade 2	2 (2.0)	9 (9.1)	4 (4.1)	0	0	0	1 (1.0)
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	99	97	98	93	95	98
Any Solicited Local Adverse Reactions	53 (53.0)	81 (81.8)	46 (47.4)	13 (13.3)	4 (4.3)	7 (7.4)	5 (5.1)
95% CI	42.8, 63.1	72.8, 88.9	37.2, 57.8	7.3, 21.6	1.2, 10.6	3.0, 14.6	1.7, 11.5
Grade 1	52 (52.0)	73 (73.7)	43 (44.3)	13 (13.3)	4 (4.3)	7 (7.4)	5 (5.1)
Grade 2	1 (1.0)	7 (7.1)	3 (3.1)	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	99	97	98	93	95	98
Any	53 (53.0)	80 (80.8)	46 (47.4)	9 (9.2)	4 (4.3)	3 (3.2)	3 (3.1)
Grade 1	52 (52.0)	72 (72.7)	43 (44.3)	9 (9.2)	4 (4.3)	3 (3.2)	3 (3.1)
Grade 2	1 (1.0)	7 (7.1)	3 (3.1)	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	99	97	98	93	95	98
Any	0	2 (2.0)	2 (2.1)	1 (1.0)	0	0	0
Grade 1	0	2 (2.0)	2 (2.1)	1 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	99	97	98	93	95	98
Any	0	3 (3.0)	3 (3.1)	1 (1.0)	1 (1.1)	1 (1.1)	2 (2.0)
Grade 1	0	3 (3.0)	3 (3.1)	1 (1.0)	1 (1.1)	1 (1.1)	2 (2.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	99	97	98	93	95	98
Any	5 (5.0)	6 (6.1)	4 (4.1)	3 (3.1)	1 (1.1)	5 (5.3)	3 (3.1)
Grade 1	4 (4.0)	5 (5.1)	3 (3.1)	3 (3.1)	1 (1.1)	5 (5.3)	3 (3.1)
Grade 2	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	99	97	98	93	95	98
Any Solicited Systemic Adverse Reactions	24 (24.0)	28 (28.3)	17 (17.5)	12 (12.2)	8 (8.6)	5 (5.3)	7 (7.1)
95% CI	16.0, 33.6	19.7, 38.2	10.6, 26.6	6.5, 20.4	3.8, 16.2	1.7, 11.9	2.9, 14.2
Grade 1	22 (22.0)	23 (23.2)	16 (16.5)	10 (10.2)	8 (8.6)	5 (5.3)	6 (6.1)
Grade 2	2 (2.0)	4 (4.0)	1 (1.0)	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	98	97	97	92	95	95
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	99	97	98	93	95	98
Any	7 (7.0)	16 (16.2)	5 (5.2)	5 (5.1)	2 (2.2)	3 (3.2)	5 (5.1)
Grade 1	7 (7.0)	13 (13.1)	4 (4.1)	5 (5.1)	2 (2.2)	3 (3.2)	4 (4.1)
Grade 2	0	3 (3.0)	1 (1.0)	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	99	97	98	93	95	98
Any	13 (13.0)	15 (15.2)	13 (13.4)	7 (7.1)	7 (7.5)	4 (4.2)	3 (3.1)
Grade 1	11 (11.0)	12 (12.1)	13 (13.4)	7 (7.1)	7 (7.5)	4 (4.2)	3 (3.1)
Grade 2	2 (2.0)	3 (3.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	99	97	98	93	95	98
Any	7 (7.0)	11 (11.1)	4 (4.1)	1 (1.0)	0	1 (1.1)	0
Grade 1	7 (7.0)	10 (10.1)	4 (4.1)	1 (1.0)	0	1 (1.1)	0
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	99	97	98	93	95	98
Any	3 (3.0)	5 (5.1)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 1	3 (3.0)	5 (5.1)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	99	97	98	93	95	98
Any	0	1 (1.0)	1 (1.0)	0	0	0	1 (1.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	99	97	98	93	95	98
Any	2 (2.0)	3 (3.0)	0	0	0	0	1 (1.0)
Grade 1	2 (2.0)	3 (3.0)	0	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	99	97	98	93	95	98
Any	1 (1.0)	2 (2.0)	0	2 (2.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	197	195	195	189	190	196
Any Solicited Adverse Reactions	108 (54.0)	150 (76.1)	94 (48.2)	39 (20.0)	22 (11.6)	15 (7.9)	21 (10.7)
95% CI	46.8, 61.1	69.6, 81.9	41.0, 55.5	14.6, 26.3	7.4, 17.1	4.5, 12.7	6.8, 15.9
Grade 1	98 (49.0)	131 (66.5)	84 (43.1)	33 (16.9)	19 (10.1)	13 (6.8)	17 (8.7)
Grade 2	8 (4.0)	17 (8.6)	9 (4.6)	4 (2.1)	2 (1.1)	1 (0.5)	3 (1.5)
Grade 3	1 (0.5)	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	197	194	195	189	190	196
Any Solicited Local Adverse Reactions	99 (49.5)	144 (73.1)	82 (42.3)	23 (11.8)	6 (3.2)	7 (3.7)	5 (2.6)
95% CI	42.4, 56.6	66.3, 79.2	35.2, 49.6	7.6, 17.2	1.2, 6.8	1.5, 7.4	0.8, 5.9
Grade 1	96 (48.0)	131 (66.5)	79 (40.7)	23 (11.8)	6 (3.2)	7 (3.7)	5 (2.6)
Grade 2	3 (1.5)	12 (6.1)	3 (1.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	197	194	195	189	190	196
Any	99 (49.5)	143 (72.6)	82 (42.3)	18 (9.2)	6 (3.2)	3 (1.6)	3 (1.5)
Grade 1	97 (48.5)	130 (66.0)	79 (40.7)	18 (9.2)	6 (3.2)	3 (1.6)	3 (1.5)
Grade 2	2 (1.0)	12 (6.1)	3 (1.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	197	194	195	189	190	196
Any	0	4 (2.0)	3 (1.5)	2 (1.0)	0	0	0
Grade 1	0	4 (2.0)	3 (1.5)	2 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	197	194	195	189	190	196
Any	2 (1.0)	7 (3.6)	5 (2.6)	2 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 1	1 (0.5)	7 (3.6)	5 (2.6)	2 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	200	197	194	195	189	190	196
Any	8 (4.0)	10 (5.1)	6 (3.1)	4 (2.1)	1 (0.5)	5 (2.6)	3 (1.5)
Grade 1	7 (3.5)	9 (4.6)	5 (2.6)	4 (2.1)	1 (0.5)	5 (2.6)	3 (1.5)
Grade 2	1 (0.5)	1 (0.5)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	197	195	195	189	190	196
Any Solicited Systemic Adverse Reactions	45 (22.5)	46 (23.4)	33 (16.9)	24 (12.3)	17 (9.0)	11 (5.8)	16 (8.2)
95% CI	16.9, 28.9	17.6, 29.9	11.9, 22.9	8.0, 17.8	5.3, 14.0	2.9, 10.1	4.7, 12.9
Grade 1	36 (18.0)	36 (18.3)	26 (13.3)	18 (9.2)	14 (7.4)	9 (4.7)	12 (6.1)
Grade 2	7 (3.5)	9 (4.6)	6 (3.1)	4 (2.1)	2 (1.1)	1 (0.5)	3 (1.5)
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	194	195	194	186	187	191
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	197	194	195	189	190	196
Any	16 (8.0)	25 (12.7)	17 (8.8)	11 (5.6)	6 (3.2)	6 (3.2)	12 (6.1)
Grade 1	14 (7.0)	19 (9.6)	13 (6.7)	8 (4.1)	6 (3.2)	6 (3.2)	10 (5.1)
Grade 2	1 (0.5)	6 (3.0)	4 (2.1)	3 (1.5)	0	0	2 (1.0)
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	197	194	195	189	190	196
Any	21 (10.5)	25 (12.7)	22 (11.3)	15 (7.7)	11 (5.8)	6 (3.2)	6 (3.1)
Grade 1	16 (8.0)	22 (11.2)	19 (9.8)	13 (6.7)	10 (5.3)	6 (3.2)	5 (2.6)
Grade 2	5 (2.5)	3 (1.5)	3 (1.5)	2 (1.0)	1 (0.5)	0	1 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Myalgia - N1	200	197	194	195	189	190	196
Any	11 (5.5)	19 (9.6)	8 (4.1)	2 (1.0)	1 (0.5)	1 (0.5)	0
Grade 1	9 (4.5)	17 (8.6)	8 (4.1)	2 (1.0)	0	1 (0.5)	0
Grade 2	2 (1.0)	2 (1.0)	0	0	1 (0.5)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	197	194	195	189	190	196
Any	7 (3.5)	9 (4.6)	5 (2.6)	2 (1.0)	2 (1.1)	1 (0.5)	0
Grade 1	6 (3.0)	9 (4.6)	5 (2.6)	2 (1.0)	1 (0.5)	0	0
Grade 2	1 (0.5)	0	0	0	1 (0.5)	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	197	194	195	189	190	196
Any	4 (2.0)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	0	1 (0.5)
Grade 1	3 (1.5)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	0	1 (0.5)
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	197	194	195	189	190	196
Any	8 (4.0)	5 (2.5)	1 (0.5)	1 (0.5)	0	0	1 (0.5)
Grade 1	6 (3.0)	4 (2.0)	1 (0.5)	1 (0.5)	0	0	1 (0.5)
Grade 2	2 (1.0)	1 (0.5)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	197	194	195	189	190	196
Any	2 (1.0)	3 (1.5)	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	99	99	95	99	97	96	98
Any Solicited Adverse Reactions	15 (15.2)	16 (16.2)	15 (15.8)	8 (8.1)	7 (7.2)	11 (11.5)	7 (7.1)
95% CI	8.7, 23.8	9.5, 24.9	9.1, 24.7	3.6, 15.3	3.0, 14.3	5.9, 19.6	2.9, 14.2
Grade 1	11 (11.1)	13 (13.1)	13 (13.7)	7 (7.1)	6 (6.2)	10 (10.4)	6 (6.1)
Grade 2	4 (4.0)	3 (3.0)	0	0	1 (1.0)	0	1 (1.0)
Grade 3	0	0	2 (2.1)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	99	98	95	99	97	96	98
Any Solicited Local Adverse Reactions	3 (3.0)	5 (5.1)	2 (2.1)	2 (2.0)	3 (3.1)	3 (3.1)	1 (1.0)
95% CI	0.6, 8.6	1.7, 11.5	0.3, 7.4	0.2, 7.1	0.6, 8.8	0.6, 8.9	0.0, 5.6
Grade 1	3 (3.0)	5 (5.1)	2 (2.1)	2 (2.0)	3 (3.1)	3 (3.1)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	99	98	95	99	97	96	98
Any	2 (2.0)	3 (3.1)	1 (1.1)	0	1 (1.0)	1 (1.0)	0
Grade 1	2 (2.0)	3 (3.1)	1 (1.1)	0	1 (1.0)	1 (1.0)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	99	98	95	99	97	96	98
Any	1 (1.0)	1 (1.0)	1 (1.1)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 1	1 (1.0)	1 (1.0)	1 (1.1)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	99	98	95	99	97	96	98
Any	0	1 (1.0)	0	0	0	0	0
Grade 1	0	1 (1.0)	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	99	98	95	99	97	96	98
Any	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 1	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	99	98	95	99	97	96	98
Any Solicited Systemic Adverse Reactions	12 (12.1)	12 (12.2)	13 (13.7)	6 (6.1)	4 (4.1)	9 (9.4)	6 (6.1)
95% CI	6.4, 20.2	6.5, 20.4	7.5, 22.3	2.3, 12.7	1.1, 10.2	4.4, 17.1	2.3, 12.9
Grade 1	8 (8.1)	9 (9.2)	11 (11.6)	5 (5.1)	3 (3.1)	8 (8.3)	5 (5.1)
Grade 2	4 (4.0)	3 (3.1)	0	0	1 (1.0)	0	1 (1.0)
Grade 3	0	0	2 (2.1)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	99	97	94	98	96	94	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	99	98	95	99	97	96	98
Any	5 (5.1)	6 (6.1)	6 (6.3)	3 (3.0)	2 (2.1)	5 (5.2)	2 (2.0)
Grade 1	5 (5.1)	6 (6.1)	4 (4.2)	3 (3.0)	2 (2.1)	4 (4.2)	1 (1.0)
Grade 2	0	0	0	0	0	0	1 (1.0)
Grade 3	0	0	2 (2.1)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	99	98	95	99	97	96	98
Any	10 (10.1)	6 (6.1)	5 (5.3)	2 (2.0)	2 (2.1)	3 (3.1)	3 (3.1)
Grade 1	7 (7.1)	4 (4.1)	5 (5.3)	2 (2.0)	1 (1.0)	3 (3.1)	2 (2.0)
Grade 2	3 (3.0)	2 (2.0)	0	0	1 (1.0)	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	99	98	95	99	97	96	98
Any	2 (2.0)	3 (3.1)	4 (4.2)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 1	2 (2.0)	2 (2.0)	4 (4.2)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	99	98	95	99	97	96	98
Any	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 1	1 (1.0)	0	2 (2.1)	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	99	98	95	99	97	96	98
Any	2 (2.0)	0	1 (1.1)	0	0	1 (1.0)	2 (2.0)
Grade 1	1 (1.0)	0	1 (1.1)	0	0	1 (1.0)	1 (1.0)
Grade 2	1 (1.0)	0	0	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	99	98	95	99	97	96	98
Any	1 (1.0)	0	1 (1.1)	0	0	0	0
Grade 1	1 (1.0)	0	1 (1.1)	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	99	98	95	99	97	96	98
Any	0	0	0	1 (1.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	99	97	98	97	97	96
Any Solicited Adverse Reactions	31 (31.0)	53 (53.5)	31 (32.0)	19 (19.4)	16 (16.5)	19 (19.6)	12 (12.5)
95% CI	22.1, 41.0	43.2, 63.6	22.9, 42.2	12.1, 28.6	9.7, 25.4	12.2, 28.9	6.6, 20.8
Grade 1	28 (28.0)	48 (48.5)	28 (28.9)	12 (12.2)	13 (13.4)	14 (14.4)	10 (10.4)
Grade 2	2 (2.0)	5 (5.1)	2 (2.1)	5 (5.1)	1 (1.0)	2 (2.1)	0
Grade 3	1 (1.0)	0	0	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	98	96	98	96	97	94
Any Solicited Local Adverse Reactions	25 (25.0)	53 (54.1)	19 (19.8)	5 (5.1)	3 (3.1)	2 (2.1)	0
95% CI	16.9, 34.7	43.7, 64.2	12.4, 29.2	1.7, 11.5	0.6, 8.9	0.3, 7.3	0.0, 3.8
Grade 1	24 (24.0)	53 (54.1)	19 (19.8)	5 (5.1)	3 (3.1)	2 (2.1)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	98	96	98	96	97	94
Any	24 (24.0)	53 (54.1)	19 (19.8)	5 (5.1)	2 (2.1)	2 (2.1)	0
Grade 1	23 (23.0)	53 (54.1)	19 (19.8)	5 (5.1)	2 (2.1)	2 (2.1)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	98	96	98	96	97	94
Any	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	98	96	98	96	97	94
Any	0	3 (3.1)	0	0	0	0	0
Grade 1	0	3 (3.1)	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	98	96	98	96	97	94
Any	0	2 (2.0)	0	0	1 (1.0)	0	0
Grade 1	0	2 (2.0)	0	0	1 (1.0)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	99	97	98	97	97	96
Any Solicited Systemic Adverse Reactions	12 (12.0)	19 (19.2)	18 (18.6)	15 (15.3)	15 (15.5)	18 (18.6)	12 (12.5)
95% CI	6.4, 20.0	12.0, 28.3	11.4, 27.7	8.8, 24.0	8.9, 24.2	11.4, 27.7	6.6, 20.8
Grade 1	10 (10.0)	14 (14.1)	15 (15.5)	8 (8.2)	12 (12.4)	13 (13.4)	10 (10.4)
Grade 2	2 (2.0)	5 (5.1)	2 (2.1)	5 (5.1)	1 (1.0)	2 (2.1)	0
Grade 3	0	0	0	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	99	96	97	96	97	95
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	99	96	98	95	96	95
Any	8 (8.0)	8 (8.1)	8 (8.3)	6 (6.1)	7 (7.4)	12 (12.5)	6 (6.3)
Grade 1	8 (8.0)	6 (6.1)	8 (8.3)	3 (3.1)	7 (7.4)	9 (9.4)	5 (5.3)
Grade 2	0	2 (2.0)	0	2 (2.0)	0	1 (1.0)	0
Grade 3	0	0	0	1 (1.0)	0	2 (2.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	99	96	98	95	96	95
Any	5 (5.0)	14 (14.1)	11 (11.5)	9 (9.2)	8 (8.4)	8 (8.3)	5 (5.3)
Grade 1	4 (4.0)	11 (11.1)	9 (9.4)	6 (6.1)	6 (6.3)	6 (6.3)	5 (5.3)
Grade 2	1 (1.0)	3 (3.0)	2 (2.1)	3 (3.1)	1 (1.1)	2 (2.1)	0
Grade 3	0	0	0	0	1 (1.1)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Myalgia - N1	100	99	96	98	95	96	94
Any	2 (2.0)	6 (6.1)	5 (5.2)	3 (3.1)	3 (3.2)	1 (1.0)	1 (1.1)
Grade 1	1 (1.0)	4 (4.0)	4 (4.2)	2 (2.0)	3 (3.2)	1 (1.0)	1 (1.1)
Grade 2	1 (1.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	99	96	98	95	96	94
Any	2 (2.0)	6 (6.1)	6 (6.3)	5 (5.1)	3 (3.2)	3 (3.1)	3 (3.2)
Grade 1	2 (2.0)	5 (5.1)	5 (5.2)	5 (5.1)	3 (3.2)	3 (3.1)	3 (3.2)
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	99	96	98	95	96	94
Any	0	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 1	0	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	99	96	98	95	96	94
Any	2 (2.0)	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 1	2 (2.0)	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.1)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	99	96	98	95	96	94
Any	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.1)	2 (2.1)	2 (2.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	99	100	99	98	96	97	97
Any Solicited Adverse Reactions	42 (42.4)	70 (70.0)	42 (42.4)	24 (24.5)	12 (12.5)	9 (9.3)	8 (8.2)
95% CI	32.5, 52.8	60.0, 78.8	32.5, 52.8	16.4, 34.2	6.6, 20.8	4.3, 16.9	3.6, 15.6
Grade 1	38 (38.4)	67 (67.0)	37 (37.4)	20 (20.4)	11 (11.5)	8 (8.2)	7 (7.2)
Grade 2	3 (3.0)	2 (2.0)	4 (4.0)	3 (3.1)	0	1 (1.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	99	100	99	98	96	97	96
Any Solicited Local Adverse Reactions	39 (39.4)	68 (68.0)	39 (39.4)	16 (16.3)	2 (2.1)	0	0
95% CI	29.7, 49.7	57.9, 77.0	29.7, 49.7	9.6, 25.2	0.3, 7.3	0.0, 3.7	0.0, 3.8
Grade 1	38 (38.4)	68 (68.0)	39 (39.4)	16 (16.3)	2 (2.1)	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	99	99	98	97	96	97	96
Any	39 (39.4)	66 (66.7)	38 (38.8)	15 (15.5)	2 (2.1)	0	0
Grade 1	38 (38.4)	66 (66.7)	38 (38.8)	15 (15.5)	2 (2.1)	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	99	99	98	97	96	97	96
Any	0	0	2 (2.0)	1 (1.0)	0	0	0
Grade 1	0	0	2 (2.0)	1 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	99	100	99	98	96	97	96
Any	0	1 (1.0)	3 (3.0)	2 (2.0)	0	0	0
Grade 1	0	1 (1.0)	3 (3.0)	2 (2.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	99	99	98	97	96	97	96
Any	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	99	99	98	97	96	97	97
Any Solicited Systemic Adverse Reactions	14 (14.1)	19 (19.2)	12 (12.2)	11 (11.3)	10 (10.4)	9 (9.3)	8 (8.2)
95% CI	8.0, 22.6	12.0, 28.3	6.5, 20.4	5.8, 19.4	5.1, 18.3	4.3, 16.9	3.6, 15.6
Grade 1	10 (10.1)	16 (16.2)	7 (7.1)	7 (7.2)	9 (9.4)	8 (8.2)	7 (7.2)
Grade 2	3 (3.0)	2 (2.0)	4 (4.1)	3 (3.1)	0	1 (1.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Fever - N1	99	97	98	97	95	96	94
Any	0	0	1 (1.0)	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	99	98	97	96	95	97	96
Any	7 (7.1)	7 (7.1)	4 (4.1)	5 (5.2)	3 (3.2)	5 (5.2)	2 (2.1)
Grade 1	6 (6.1)	6 (6.1)	3 (3.1)	4 (4.2)	3 (3.2)	5 (5.2)	2 (2.1)
Grade 2	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	99	98	97	96	95	97	95
Any	8 (8.1)	11 (11.2)	8 (8.2)	7 (7.3)	6 (6.3)	5 (5.2)	4 (4.2)
Grade 1	5 (5.1)	9 (9.2)	6 (6.2)	4 (4.2)	5 (5.3)	4 (4.1)	4 (4.2)
Grade 2	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.1)	0	1 (1.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.1)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	99	98	97	96	95	97	95
Any	2 (2.0)	8 (8.2)	6 (6.2)	4 (4.2)	3 (3.2)	2 (2.1)	2 (2.1)
Grade 1	1 (1.0)	6 (6.1)	5 (5.2)	2 (2.1)	2 (2.1)	1 (1.0)	2 (2.1)
Grade 2	0	1 (1.0)	0	1 (1.0)	0	1 (1.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.1)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	99	98	97	96	95	97	95
Any	1 (1.0)	7 (7.1)	4 (4.1)	3 (3.1)	2 (2.1)	1 (1.0)	0
Grade 1	0	5 (5.1)	3 (3.1)	2 (2.1)	1 (1.1)	0	0
Grade 2	0	1 (1.0)	0	0	0	1 (1.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.1)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	99	98	97	96	95	97	95
Any	0	1 (1.0)	2 (2.1)	1 (1.0)	1 (1.1)	0	1 (1.1)
Grade 1	0	1 (1.0)	1 (1.0)	0	1 (1.1)	0	1 (1.1)
Grade 2	0	0	1 (1.0)	0	0	0	0
Grade 3	0	0	0	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	99	98	97	96	95	97	95
Any	2 (2.0)	3 (3.1)	3 (3.1)	1 (1.0)	1 (1.1)	0	0
Grade 1	1 (1.0)	2 (2.0)	1 (1.0)	0	1 (1.1)	0	0
Grade 2	1 (1.0)	1 (1.0)	2 (2.1)	0	0	0	0
Grade 3	0	0	0	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	99	98	97	96	95	97	95
Any	0	0	0	0	0	0	1 (1.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	199	199	196	196	193	194	193
Any Solicited Adverse Reactions	73 (36.7)	123 (61.8)	73 (37.2)	43 (21.9)	28 (14.5)	28 (14.4)	20 (10.4)
95% CI	30.0, 43.8	54.7, 68.6	30.5, 44.4	16.4, 28.4	9.9, 20.3	9.8, 20.2	6.4, 15.6
Grade 1	66 (33.2)	115 (57.8)	65 (33.2)	32 (16.3)	24 (12.4)	22 (11.3)	17 (8.8)
Grade 2	5 (2.5)	7 (3.5)	6 (3.1)	8 (4.1)	1 (0.5)	3 (1.5)	0
Grade 3	2 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)	2 (1.0)	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	199	198	195	196	192	194	190
Any Solicited Local Adverse Reactions	64 (32.2)	121 (61.1)	58 (29.7)	21 (10.7)	5 (2.6)	2 (1.0)	0
95% CI	25.7, 39.1	53.9, 67.9	23.4, 36.7	6.8, 15.9	0.9, 6.0	0.1, 3.7	0.0, 1.9
Grade 1	62 (31.2)	121 (61.1)	58 (29.7)	21 (10.7)	5 (2.6)	2 (1.0)	0
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	199	197	194	195	192	194	190
Any	63 (31.7)	119 (60.4)	57 (29.4)	20 (10.3)	4 (2.1)	2 (1.0)	0
Grade 1	61 (30.7)	119 (60.4)	57 (29.4)	20 (10.3)	4 (2.1)	2 (1.0)	0
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	199	197	194	195	192	194	190
Any	1 (0.5)	1 (0.5)	3 (1.5)	1 (0.5)	0	0	0
Grade 1	1 (0.5)	1 (0.5)	3 (1.5)	1 (0.5)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	199	198	195	196	192	194	190
Any	0	4 (2.0)	3 (1.5)	2 (1.0)	0	0	0
Grade 1	0	4 (2.0)	3 (1.5)	2 (1.0)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	199	197	194	195	192	194	190
Any	1 (0.5)	3 (1.5)	1 (0.5)	0	1 (0.5)	0	0
Grade 1	0	3 (1.5)	1 (0.5)	0	1 (0.5)	0	0
Grade 2	1 (0.5)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	199	198	195	195	193	194	193
Any Solicited Systemic Adverse Reactions	26 (13.1)	38 (19.2)	30 (15.4)	26 (13.3)	25 (13.0)	27 (13.9)	20 (10.4)
95% CI	8.7, 18.6	14.0, 25.4	10.6, 21.2	8.9, 18.9	8.6, 18.5	9.4, 19.6	6.4, 15.6
Grade 1	20 (10.1)	30 (15.2)	22 (11.3)	15 (7.7)	21 (10.9)	21 (10.8)	17 (8.8)
Grade 2	5 (2.5)	7 (3.5)	6 (3.1)	8 (4.1)	1 (0.5)	3 (1.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	2 (1.0)	2 (1.0)	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	199	196	194	194	191	193	189
Any	0	0	1 (0.5)	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	199	197	193	194	190	193	191
Any	15 (7.5)	15 (7.6)	12 (6.2)	11 (5.7)	10 (5.3)	17 (8.8)	8 (4.2)
Grade 1	14 (7.0)	12 (6.1)	11 (5.7)	7 (3.6)	10 (5.3)	14 (7.3)	7 (3.7)
Grade 2	1 (0.5)	3 (1.5)	1 (0.5)	3 (1.5)	0	1 (0.5)	0
Grade 3	0	0	0	1 (0.5)	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	199	197	193	194	190	193	190
Any	13 (6.5)	25 (12.7)	19 (9.8)	16 (8.2)	14 (7.4)	13 (6.7)	9 (4.7)
Grade 1	9 (4.5)	20 (10.2)	15 (7.8)	10 (5.2)	11 (5.8)	10 (5.2)	9 (4.7)
Grade 2	3 (1.5)	4 (2.0)	3 (1.6)	5 (2.6)	1 (0.5)	3 (1.6)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	2 (1.1)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	199	197	193	194	190	193	189
Any	4 (2.0)	14 (7.1)	11 (5.7)	7 (3.6)	6 (3.2)	3 (1.6)	3 (1.6)
Grade 1	2 (1.0)	10 (5.1)	9 (4.7)	4 (2.1)	5 (2.6)	2 (1.0)	3 (1.6)
Grade 2	1 (0.5)	3 (1.5)	1 (0.5)	2 (1.0)	0	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	199	197	193	194	190	193	189
Any	3 (1.5)	13 (6.6)	10 (5.2)	8 (4.1)	5 (2.6)	4 (2.1)	3 (1.6)
Grade 1	2 (1.0)	10 (5.1)	8 (4.1)	7 (3.6)	4 (2.1)	3 (1.6)	3 (1.6)
Grade 2	0	2 (1.0)	1 (0.5)	0	0	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	199	197	193	194	190	193	189
Any	0	2 (1.0)	4 (2.1)	2 (1.0)	2 (1.1)	0	1 (0.5)
Grade 1	0	2 (1.0)	3 (1.6)	1 (0.5)	2 (1.1)	0	1 (0.5)
Grade 2	0	0	1 (0.5)	0	0	0	0
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Grade and Day of Reporting
First Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	199	197	193	194	190	193	189
Any	4 (2.0)	4 (2.0)	5 (2.6)	2 (1.0)	2 (1.1)	0	0
Grade 1	3 (1.5)	3 (1.5)	3 (1.6)	1 (0.5)	2 (1.1)	0	0
Grade 2	1 (0.5)	1 (0.5)	2 (1.0)	0	0	0	0
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	199	197	193	194	190	193	189
Any	0	1 (0.5)	1 (0.5)	1 (0.5)	2 (1.1)	2 (1.0)	3 (1.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	193	190	181	183	181	183	184
Any Solicited Adverse Reactions	24 (12.4)	27 (14.2)	24 (13.3)	15 (8.2)	18 (9.9)	12 (6.6)	15 (8.2)
95% CI	8.1, 17.9	9.6, 20.0	8.7, 19.1	4.7, 13.2	6.0, 15.3	3.4, 11.2	4.6, 13.1
Grade 1	20 (10.4)	23 (12.1)	20 (11.0)	13 (7.1)	15 (8.3)	10 (5.5)	13 (7.1)
Grade 2	3 (1.6)	3 (1.6)	3 (1.7)	1 (0.5)	1 (0.6)	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.6)	1 (0.5)	2 (1.1)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	193	190	181	183	181	183	184
Any Solicited Local Adverse Reactions	11 (5.7)	5 (2.6)	3 (1.7)	3 (1.6)	2 (1.1)	2 (1.1)	3 (1.6)
95% CI	2.9, 10.0	0.9, 6.0	0.3, 4.8	0.3, 4.7	0.1, 3.9	0.1, 3.9	0.3, 4.7
Grade 1	11 (5.7)	5 (2.6)	3 (1.7)	3 (1.6)	2 (1.1)	2 (1.1)	3 (1.6)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	193	190	181	183	181	183	184
Any	11 (5.7)	4 (2.1)	3 (1.7)	2 (1.1)	2 (1.1)	2 (1.1)	3 (1.6)
Grade 1	11 (5.7)	4 (2.1)	3 (1.7)	2 (1.1)	2 (1.1)	2 (1.1)	3 (1.6)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	193	190	181	183	181	183	184
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	193	190	181	183	181	183	184
Any	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 1	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	193	190	181	183	181	183	184
Any	0	1 (0.5)	0	1 (0.5)	0	0	0
Grade 1	0	1 (0.5)	0	1 (0.5)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	193	190	181	183	181	183	184
Any Solicited Systemic Adverse Reactions	18 (9.3)	24 (12.6)	23 (12.7)	13 (7.1)	17 (9.4)	11 (6.0)	12 (6.5)
95% CI	5.6, 14.3	8.3, 18.2	8.2, 18.5	3.8, 11.8	5.6, 14.6	3.0, 10.5	3.4, 11.1
Grade 1	14 (7.3)	20 (10.5)	19 (10.5)	11 (6.0)	14 (7.7)	9 (4.9)	10 (5.4)
Grade 2	3 (1.6)	3 (1.6)	3 (1.7)	1 (0.5)	1 (0.6)	1 (0.5)	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.6)	1 (0.5)	2 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	193	188	179	180	179	182	180
Any	0	0	0	0	1 (0.6)	0	0
Grade 1	0	0	0	0	1 (0.6)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	193	189	181	183	181	183	184
Any	10 (5.2)	12 (6.3)	6 (3.3)	5 (2.7)	8 (4.4)	5 (2.7)	5 (2.7)
Grade 1	10 (5.2)	12 (6.3)	6 (3.3)	5 (2.7)	8 (4.4)	5 (2.7)	5 (2.7)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	193	189	181	183	181	183	184
Any	11 (5.7)	18 (9.5)	16 (8.8)	10 (5.5)	10 (5.5)	2 (1.1)	7 (3.8)
Grade 1	7 (3.6)	14 (7.4)	14 (7.7)	9 (4.9)	9 (5.0)	1 (0.5)	5 (2.7)
Grade 2	3 (1.6)	3 (1.6)	1 (0.6)	0	0	0	0
Grade 3	1 (0.5)	1 (0.5)	1 (0.6)	1 (0.5)	1 (0.6)	1 (0.5)	2 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	193	189	181	183	181	183	184
Any	2 (1.0)	6 (3.2)	5 (2.8)	4 (2.2)	1 (0.6)	4 (2.2)	4 (2.2)
Grade 1	2 (1.0)	6 (3.2)	3 (1.7)	3 (1.6)	1 (0.6)	4 (2.2)	4 (2.2)
Grade 2	0	0	2 (1.1)	1 (0.5)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	193	189	181	183	181	183	184
Any	1 (0.5)	5 (2.6)	4 (2.2)	1 (0.5)	3 (1.7)	4 (2.2)	4 (2.2)
Grade 1	1 (0.5)	5 (2.6)	2 (1.1)	1 (0.5)	3 (1.7)	4 (2.2)	4 (2.2)
Grade 2	0	0	2 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	193	189	181	183	181	183	184
Any	0	1 (0.5)	0	0	2 (1.1)	0	0
Grade 1	0	1 (0.5)	0	0	2 (1.1)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=194)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	193	189	181	183	181	183	184
Any	0	1 (0.5)	1 (0.6)	1 (0.5)	3 (1.7)	1 (0.5)	0
Grade 1	0	1 (0.5)	1 (0.6)	1 (0.5)	2 (1.1)	0	0
Grade 2	0	0	0	0	1 (0.6)	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	193	189	181	183	181	183	184
Any	0	0	0	0	1 (0.6)	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	192	193	185	180	181	182	190
Any Solicited Adverse Reactions	97 (50.5)	158 (81.9)	112 (60.5)	64 (35.6)	45 (24.9)	33 (18.1)	31 (16.3)
95% CI	43.2, 57.8	75.7, 87.0	53.1, 67.6	28.6, 43.0	18.7, 31.8	12.8, 24.5	11.4, 22.4
Grade 1	78 (40.6)	88 (45.6)	89 (48.1)	49 (27.2)	35 (19.3)	21 (11.5)	19 (10.0)
Grade 2	12 (6.3)	53 (27.5)	16 (8.6)	8 (4.4)	5 (2.8)	5 (2.7)	4 (2.1)
Grade 3	6 (3.1)	17 (8.8)	7 (3.8)	5 (2.8)	4 (2.2)	5 (2.7)	5 (2.6)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	192	193	185	180	180	182	190
Any Solicited Local Adverse Reactions	90 (46.9)	144 (74.6)	91 (49.2)	41 (22.8)	21 (11.7)	10 (5.5)	4 (2.1)
95% CI	39.7, 54.2	67.9, 80.6	41.8, 56.6	16.9, 29.6	7.4, 17.3	2.7, 9.9	0.6, 5.3
Grade 1	79 (41.1)	119 (61.7)	81 (43.8)	37 (20.6)	18 (10.0)	8 (4.4)	2 (1.1)
Grade 2	10 (5.2)	23 (11.9)	9 (4.9)	3 (1.7)	2 (1.1)	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.6)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Pain - N1	192	193	185	180	180	182	190
Any	88 (45.8)	144 (74.6)	89 (48.1)	39 (21.7)	18 (10.0)	6 (3.3)	4 (2.1)
Grade 1	78 (40.6)	122 (63.2)	84 (45.4)	37 (20.6)	16 (8.9)	4 (2.2)	2 (1.1)
Grade 2	9 (4.7)	20 (10.4)	4 (2.2)	1 (0.6)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.6)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	192	193	185	180	180	182	190
Any	1 (0.5)	7 (3.6)	8 (4.3)	4 (2.2)	1 (0.6)	0	0
Grade 1	0	5 (2.6)	3 (1.6)	2 (1.1)	0	0	0
Grade 2	1 (0.5)	2 (1.0)	5 (2.7)	2 (1.1)	1 (0.6)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	192	193	185	180	180	182	190
Any	0	9 (4.7)	9 (4.9)	7 (3.9)	6 (3.3)	2 (1.1)	0
Grade 1	0	6 (3.1)	6 (3.2)	5 (2.8)	5 (2.8)	2 (1.1)	0
Grade 2	0	3 (1.6)	3 (1.6)	2 (1.1)	1 (0.6)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lymphadenopathy - N1 [1]	192	193	185	180	180	182	190
Any	5 (2.6)	13 (6.7)	8 (4.3)	4 (2.2)	3 (1.7)	5 (2.7)	1 (0.5)
Grade 1	5 (2.6)	7 (3.6)	6 (3.2)	4 (2.2)	3 (1.7)	5 (2.7)	1 (0.5)
Grade 2	0	6 (3.1)	2 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	192	193	185	180	181	182	190
Any Solicited Systemic Adverse Reactions	40 (20.8)	114 (59.1)	64 (34.6)	46 (25.6)	33 (18.2)	27 (14.8)	29 (15.3)
95% CI	15.3, 27.3	51.8, 66.1	27.8, 41.9	19.4, 32.6	12.9, 24.6	10.0, 20.8	10.5, 21.2
Grade 1	24 (12.5)	46 (23.8)	45 (24.3)	34 (18.9)	26 (14.4)	17 (9.3)	19 (10.0)
Grade 2	8 (4.2)	51 (26.4)	12 (6.5)	5 (2.8)	3 (1.7)	4 (2.2)	3 (1.6)
Grade 3	6 (3.1)	16 (8.3)	7 (3.8)	5 (2.8)	3 (1.7)	4 (2.2)	4 (2.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	191	192	183	178	179	182	188
Any	2 (1.0)	12 (6.3)	0	0	0	0	0
Grade 1	1 (0.5)	7 (3.6)	0	0	0	0	0
Grade 2	0	3 (1.6)	0	0	0	0	0
Grade 3	1 (0.5)	2 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	192	193	185	180	180	181	190
Any	26 (13.5)	76 (39.4)	34 (18.4)	30 (16.7)	17 (9.4)	15 (8.3)	15 (7.9)
Grade 1	21 (10.9)	50 (25.9)	27 (14.6)	25 (13.9)	14 (7.8)	11 (6.1)	12 (6.3)
Grade 2	3 (1.6)	21 (10.9)	6 (3.2)	4 (2.2)	3 (1.7)	3 (1.7)	2 (1.1)
Grade 3	2 (1.0)	5 (2.6)	1 (0.5)	1 (0.6)	0	1 (0.6)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	192	193	185	180	181	181	190
Any	27 (14.1)	90 (46.6)	41 (22.2)	24 (13.3)	17 (9.4)	15 (8.3)	13 (6.8)
Grade 1	18 (9.4)	38 (19.7)	27 (14.6)	18 (10.0)	13 (7.2)	8 (4.4)	9 (4.7)
Grade 2	5 (2.6)	43 (22.3)	10 (5.4)	4 (2.2)	2 (1.1)	5 (2.8)	2 (1.1)
Grade 3	4 (2.1)	9 (4.7)	4 (2.2)	2 (1.1)	2 (1.1)	2 (1.1)	2 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	192	193	185	180	181	181	190
Any	17 (8.9)	72 (37.3)	30 (16.2)	19 (10.6)	11 (6.1)	9 (5.0)	8 (4.2)
Grade 1	8 (4.2)	28 (14.5)	19 (10.3)	14 (7.8)	9 (5.0)	7 (3.9)	6 (3.2)
Grade 2	4 (2.1)	34 (17.6)	5 (2.7)	3 (1.7)	1 (0.6)	1 (0.6)	1 (0.5)
Grade 3	5 (2.6)	10 (5.2)	6 (3.2)	2 (1.1)	1 (0.6)	1 (0.6)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	192	193	185	180	181	181	190
Any	12 (6.3)	59 (30.6)	29 (15.7)	13 (7.2)	11 (6.1)	8 (4.4)	6 (3.2)
Grade 1	5 (2.6)	26 (13.5)	20 (10.8)	9 (5.0)	8 (4.4)	6 (3.3)	4 (2.1)
Grade 2	4 (2.1)	26 (13.5)	4 (2.2)	1 (0.6)	1 (0.6)	0	0
Grade 3	3 (1.6)	7 (3.6)	5 (2.7)	3 (1.7)	2 (1.1)	2 (1.1)	2 (1.1)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	192	193	185	180	180	181	190
Any	3 (1.6)	18 (9.3)	6 (3.2)	3 (1.7)	1 (0.6)	3 (1.7)	1 (0.5)
Grade 1	3 (1.6)	13 (6.7)	5 (2.7)	2 (1.1)	1 (0.6)	2 (1.1)	1 (0.5)
Grade 2	0	5 (2.6)	1 (0.5)	1 (0.6)	0	1 (0.6)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=195)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	192	193	185	180	180	181	190
Any	9 (4.7)	44 (22.8)	13 (7.0)	4 (2.2)	2 (1.1)	1 (0.6)	0
Grade 1	3 (1.6)	19 (9.8)	11 (5.9)	3 (1.7)	1 (0.6)	1 (0.6)	0
Grade 2	5 (2.6)	23 (11.9)	1 (0.5)	1 (0.6)	1 (0.6)	0	0
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	192	193	185	180	180	181	190
Any	3 (1.6)	2 (1.0)	3 (1.6)	2 (1.1)	2 (1.1)	3 (1.7)	3 (1.6)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010202.sas 19NOV2020 02:13 Database Lock Date: 05NOV2020

Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	197	198	191	189	189	189	196
Any Solicited Adverse Reactions	110 (55.8)	171 (86.4)	119 (62.3)	65 (34.4)	45 (23.8)	36 (19.0)	24 (12.2)
95% CI	48.6, 62.9	80.8, 90.8	55.0, 69.2	27.6, 41.6	17.9, 30.5	13.7, 25.4	8.0, 17.7
Grade 1	92 (46.7)	70 (35.4)	82 (42.9)	43 (22.8)	33 (17.5)	28 (14.8)	17 (8.7)
Grade 2	13 (6.6)	77 (38.9)	23 (12.0)	8 (4.2)	6 (3.2)	2 (1.1)	4 (2.0)
Grade 3	5 (2.5)	24 (12.1)	14 (7.3)	13 (6.9)	5 (2.6)	5 (2.6)	3 (1.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	197	198	191	189	188	188	196
Any Solicited Local Adverse Reactions	102 (51.8)	161 (81.3)	100 (52.4)	48 (25.4)	22 (11.7)	13 (6.9)	8 (4.1)
95% CI	44.6, 58.9	75.2, 86.5	45.0, 59.6	19.4, 32.2	7.5, 17.2	3.7, 11.5	1.8, 7.9
Grade 1	98 (49.7)	131 (66.2)	89 (46.6)	39 (20.6)	22 (11.7)	13 (6.9)	8 (4.1)
Grade 2	4 (2.0)	28 (14.1)	9 (4.7)	4 (2.1)	0	0	0
Grade 3	0	2 (1.0)	2 (1.0)	5 (2.6)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	197	198	191	189	188	188	196
Any	101 (51.3)	161 (81.3)	95 (49.7)	44 (23.3)	19 (10.1)	10 (5.3)	6 (3.1)
Grade 1	97 (49.2)	135 (68.2)	90 (47.1)	40 (21.2)	19 (10.1)	10 (5.3)	6 (3.1)
Grade 2	4 (2.0)	25 (12.6)	4 (2.1)	3 (1.6)	0	0	0
Grade 3	0	1 (0.5)	1 (0.5)	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	197	198	191	189	188	188	196
Any	1 (0.5)	6 (3.0)	9 (4.7)	9 (4.8)	3 (1.6)	0	0
Grade 1	1 (0.5)	6 (3.0)	5 (2.6)	4 (2.1)	3 (1.6)	0	0
Grade 2	0	0	3 (1.6)	1 (0.5)	0	0	0
Grade 3	0	0	1 (0.5)	4 (2.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	197	198	191	189	188	188	196
Any	7 (3.6)	13 (6.6)	12 (6.3)	9 (4.8)	5 (2.7)	4 (2.1)	3 (1.5)
Grade 1	6 (3.0)	9 (4.5)	9 (4.7)	9 (4.8)	5 (2.7)	4 (2.1)	3 (1.5)
Grade 2	1 (0.5)	3 (1.5)	3 (1.6)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	197	198	191	189	188	188	196
Any	6 (3.0)	9 (4.5)	10 (5.2)	7 (3.7)	0	0	0
Grade 1	4 (2.0)	6 (3.0)	10 (5.2)	7 (3.7)	0	0	0
Grade 2	2 (1.0)	3 (1.5)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	197	198	191	189	189	189	196
Any Solicited Systemic Adverse Reactions	50 (25.4)	140 (70.7)	65 (34.0)	37 (19.6)	29 (15.3)	29 (15.3)	18 (9.2)
95% CI	19.5, 32.1	63.8, 76.9	27.3, 41.2	14.2, 26.0	10.5, 21.3	10.5, 21.3	5.5, 14.1
Grade 1	33 (16.8)	49 (24.7)	35 (18.3)	22 (11.6)	17 (9.0)	21 (11.1)	11 (5.6)
Grade 2	11 (5.6)	69 (34.8)	17 (8.9)	6 (3.2)	6 (3.2)	2 (1.1)	4 (2.0)
Grade 3	5 (2.5)	22 (11.1)	12 (6.3)	8 (4.2)	5 (2.6)	5 (2.6)	3 (1.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	197	197	189	188	187	187	195
Any	3 (1.5)	21 (10.7)	6 (3.2)	2 (1.1)	1 (0.5)	1 (0.5)	0
Grade 1	2 (1.0)	15 (7.6)	3 (1.6)	1 (0.5)	1 (0.5)	0	0
Grade 2	0	2 (1.0)	1 (0.5)	0	0	1 (0.5)	0
Grade 3	1 (0.5)	4 (2.0)	2 (1.1)	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	197	197	189	189	188	188	196
Any	28 (14.2)	93 (47.2)	36 (19.0)	16 (8.5)	16 (8.5)	17 (9.0)	12 (6.1)
Grade 1	23 (11.7)	49 (24.9)	23 (12.2)	10 (5.3)	10 (5.3)	13 (6.9)	8 (4.1)
Grade 2	3 (1.5)	36 (18.3)	9 (4.8)	3 (1.6)	3 (1.6)	1 (0.5)	2 (1.0)
Grade 3	2 (1.0)	8 (4.1)	4 (2.1)	3 (1.6)	3 (1.6)	3 (1.6)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	197	197	190	189	188	189	196
Any	33 (16.8)	113 (57.4)	50 (26.3)	20 (10.6)	15 (8.0)	10 (5.3)	9 (4.6)
Grade 1	21 (10.7)	38 (19.3)	29 (15.3)	13 (6.9)	11 (5.9)	6 (3.2)	4 (2.0)
Grade 2	11 (5.6)	60 (30.5)	13 (6.8)	5 (2.6)	3 (1.6)	3 (1.6)	4 (2.0)
Grade 3	1 (0.5)	15 (7.6)	8 (4.2)	2 (1.1)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	197	197	190	189	188	188	196
Any	25 (12.7)	98 (49.7)	30 (15.8)	9 (4.8)	8 (4.3)	5 (2.7)	8 (4.1)
Grade 1	15 (7.6)	34 (17.3)	12 (6.3)	5 (2.6)	4 (2.1)	2 (1.1)	6 (3.1)
Grade 2	8 (4.1)	49 (24.9)	10 (5.3)	1 (0.5)	2 (1.1)	1 (0.5)	1 (0.5)
Grade 3	2 (1.0)	15 (7.6)	8 (4.2)	3 (1.6)	2 (1.1)	2 (1.1)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	197	197	189	189	188	188	196
Any	15 (7.6)	72 (36.5)	22 (11.6)	9 (4.8)	7 (3.7)	8 (4.3)	4 (2.0)
Grade 1	8 (4.1)	30 (15.2)	11 (5.8)	5 (2.6)	3 (1.6)	6 (3.2)	4 (2.0)
Grade 2	6 (3.0)	34 (17.3)	6 (3.2)	2 (1.1)	3 (1.6)	1 (0.5)	0
Grade 3	1 (0.5)	8 (4.1)	5 (2.6)	2 (1.1)	1 (0.5)	1 (0.5)	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	197	197	189	189	188	188	196
Any	8 (4.1)	30 (15.2)	9 (4.8)	2 (1.1)	3 (1.6)	2 (1.1)	3 (1.5)
Grade 1	5 (2.5)	21 (10.7)	6 (3.2)	2 (1.1)	3 (1.6)	1 (0.5)	2 (1.0)
Grade 2	3 (1.5)	9 (4.6)	3 (1.6)	0	0	1 (0.5)	1 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=198)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	197	197	189	189	188	188	196
Any	14 (7.1)	71 (36.0)	14 (7.4)	4 (2.1)	2 (1.1)	1 (0.5)	2 (1.0)
Grade 1	11 (5.6)	29 (14.7)	6 (3.2)	2 (1.1)	2 (1.1)	1 (0.5)	0
Grade 2	3 (1.5)	41 (20.8)	8 (4.2)	2 (1.1)	0	0	2 (1.0)
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	197	197	189	189	188	188	196
Any	1 (0.5)	4 (2.0)	2 (1.1)	2 (1.1)	2 (1.1)	1 (0.5)	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	389	391	376	369	370	371	386
Any Solicited Adverse Reactions	207 (53.2)	329 (84.1)	231 (61.4)	129 (35.0)	90 (24.3)	69 (18.6)	55 (14.2)
95% CI	48.1, 58.3	80.1, 87.6	56.3, 66.4	30.1, 40.1	20.0, 29.0	14.8, 22.9	10.9, 18.1
Grade 1	170 (43.7)	158 (40.4)	171 (45.5)	92 (24.9)	68 (18.4)	49 (13.2)	36 (9.3)
Grade 2	25 (6.4)	130 (33.2)	39 (10.4)	16 (4.3)	11 (3.0)	7 (1.9)	8 (2.1)
Grade 3	11 (2.8)	41 (10.5)	21 (5.6)	18 (4.9)	9 (2.4)	10 (2.7)	8 (2.1)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	389	391	376	369	368	370	386
Any Solicited Local Adverse Reactions	192 (49.4)	305 (78.0)	191 (50.8)	89 (24.1)	43 (11.7)	23 (6.2)	12 (3.1)
95% CI	44.3, 54.4	73.6, 82.0	45.6, 56.0	19.8, 28.8	8.6, 15.4	4.0, 9.2	1.6, 5.4
Grade 1	177 (45.5)	250 (63.9)	170 (45.2)	76 (20.6)	40 (10.9)	21 (5.7)	10 (2.6)
Grade 2	14 (3.6)	51 (13.0)	18 (4.8)	7 (1.9)	2 (0.5)	1 (0.3)	1 (0.3)
Grade 3	1 (0.3)	4 (1.0)	3 (0.8)	6 (1.6)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	389	391	376	369	368	370	386
Any	189 (48.6)	305 (78.0)	184 (48.9)	83 (22.5)	37 (10.1)	16 (4.3)	10 (2.6)
Grade 1	175 (45.0)	257 (65.7)	174 (46.3)	77 (20.9)	35 (9.5)	14 (3.8)	8 (2.1)
Grade 2	13 (3.3)	45 (11.5)	8 (2.1)	4 (1.1)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 3	1 (0.3)	3 (0.8)	2 (0.5)	2 (0.5)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	389	391	376	369	368	370	386
Any	2 (0.5)	13 (3.3)	17 (4.5)	13 (3.5)	4 (1.1)	0	0
Grade 1	1 (0.3)	11 (2.8)	8 (2.1)	6 (1.6)	3 (0.8)	0	0
Grade 2	1 (0.3)	2 (0.5)	8 (2.1)	3 (0.8)	1 (0.3)	0	0
Grade 3	0	0	1 (0.3)	4 (1.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	389	391	376	369	368	370	386
Any	7 (1.8)	22 (5.6)	21 (5.6)	16 (4.3)	11 (3.0)	6 (1.6)	3 (0.8)
Grade 1	6 (1.5)	15 (3.8)	15 (4.0)	14 (3.8)	10 (2.7)	6 (1.6)	3 (0.8)
Grade 2	1 (0.3)	6 (1.5)	6 (1.6)	2 (0.5)	1 (0.3)	0	0
Grade 3	0	1 (0.3)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	389	391	376	369	368	370	386
Any	11 (2.8)	22 (5.6)	18 (4.8)	11 (3.0)	3 (0.8)	5 (1.4)	1 (0.3)
Grade 1	9 (2.3)	13 (3.3)	16 (4.3)	11 (3.0)	3 (0.8)	5 (1.4)	1 (0.3)
Grade 2	2 (0.5)	9 (2.3)	2 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	389	391	376	369	370	371	386
Any Solicited Systemic Adverse Reactions	90 (23.1)	254 (65.0)	129 (34.3)	83 (22.5)	62 (16.8)	56 (15.1)	47 (12.2)
95% CI	19.0, 27.7	60.0, 69.7	29.5, 39.3	18.3, 27.1	13.1, 21.0	11.6, 19.1	9.1, 15.9
Grade 1	57 (14.7)	95 (24.3)	80 (21.3)	56 (15.2)	43 (11.6)	38 (10.2)	30 (7.8)
Grade 2	19 (4.9)	120 (30.7)	29 (7.7)	11 (3.0)	9 (2.4)	6 (1.6)	7 (1.8)
Grade 3	11 (2.8)	38 (9.7)	19 (5.1)	13 (3.5)	8 (2.2)	9 (2.4)	7 (1.8)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	388	389	372	366	366	369	383
Any	5 (1.3)	33 (8.5)	6 (1.6)	2 (0.5)	1 (0.3)	1 (0.3)	0
Grade 1	3 (0.8)	22 (5.7)	3 (0.8)	1 (0.3)	1 (0.3)	0	0
Grade 2	0	5 (1.3)	1 (0.3)	0	0	1 (0.3)	0
Grade 3	2 (0.5)	6 (1.5)	2 (0.5)	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	389	390	374	369	368	369	386
Any	54 (13.9)	169 (43.3)	70 (18.7)	46 (12.5)	33 (9.0)	32 (8.7)	27 (7.0)
Grade 1	44 (11.3)	99 (25.4)	50 (13.4)	35 (9.5)	24 (6.5)	24 (6.5)	20 (5.2)
Grade 2	6 (1.5)	57 (14.6)	15 (4.0)	7 (1.9)	6 (1.6)	4 (1.1)	4 (1.0)
Grade 3	4 (1.0)	13 (3.3)	5 (1.3)	4 (1.1)	3 (0.8)	4 (1.1)	3 (0.8)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	389	390	375	369	369	370	386
Any	60 (15.4)	203 (52.1)	91 (24.3)	44 (11.9)	32 (8.7)	25 (6.8)	22 (5.7)
Grade 1	39 (10.0)	76 (19.5)	56 (14.9)	31 (8.4)	24 (6.5)	14 (3.8)	13 (3.4)
Grade 2	16 (4.1)	103 (26.4)	23 (6.1)	9 (2.4)	5 (1.4)	8 (2.2)	6 (1.6)
Grade 3	5 (1.3)	24 (6.2)	12 (3.2)	4 (1.1)	3 (0.8)	3 (0.8)	3 (0.8)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	389	390	375	369	369	369	386
Any	42 (10.8)	170 (43.6)	60 (16.0)	28 (7.6)	19 (5.1)	14 (3.8)	16 (4.1)
Grade 1	23 (5.9)	62 (15.9)	31 (8.3)	19 (5.1)	13 (3.5)	9 (2.4)	12 (3.1)
Grade 2	12 (3.1)	83 (21.3)	15 (4.0)	4 (1.1)	3 (0.8)	2 (0.5)	2 (0.5)
Grade 3	7 (1.8)	25 (6.4)	14 (3.7)	5 (1.4)	3 (0.8)	3 (0.8)	2 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	389	390	374	369	369	369	386
Any	27 (6.9)	131 (33.6)	51 (13.6)	22 (6.0)	18 (4.9)	16 (4.3)	10 (2.6)
Grade 1	13 (3.3)	56 (14.4)	31 (8.3)	14 (3.8)	11 (3.0)	12 (3.3)	8 (2.1)
Grade 2	10 (2.6)	60 (15.4)	10 (2.7)	3 (0.8)	4 (1.1)	1 (0.3)	0
Grade 3	4 (1.0)	15 (3.8)	10 (2.7)	5 (1.4)	3 (0.8)	3 (0.8)	2 (0.5)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	389	390	374	369	368	369	386
Any	11 (2.8)	48 (12.3)	15 (4.0)	5 (1.4)	4 (1.1)	5 (1.4)	4 (1.0)
Grade 1	8 (2.1)	34 (8.7)	11 (2.9)	4 (1.1)	4 (1.1)	3 (0.8)	3 (0.8)
Grade 2	3 (0.8)	14 (3.6)	4 (1.1)	1 (0.3)	0	2 (0.5)	1 (0.3)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=393)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	389	390	374	369	368	369	386
Any	23 (5.9)	115 (29.5)	27 (7.2)	8 (2.2)	4 (1.1)	2 (0.5)	2 (0.5)
Grade 1	14 (3.6)	48 (12.3)	17 (4.5)	5 (1.4)	3 (0.8)	2 (0.5)	0
Grade 2	8 (2.1)	64 (16.4)	9 (2.4)	3 (0.8)	1 (0.3)	0	2 (0.5)
Grade 3	1 (0.3)	3 (0.8)	1 (0.3)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	389	390	374	369	368	369	386
Any	4 (1.0)	6 (1.5)	5 (1.3)	4 (1.1)	4 (1.1)	4 (1.1)	3 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	94	93	87	89	84	88	87
Any Solicited Adverse Reactions	11 (11.7)	13 (14.0)	10 (11.5)	9 (10.1)	10 (11.9)	6 (6.8)	8 (9.2)
95% CI	6.0, 20.0	7.7, 22.7	5.7, 20.1	4.7, 18.3	5.9, 20.8	2.5, 14.3	4.1, 17.3
Grade 1	10 (10.6)	11 (11.8)	7 (8.0)	8 (9.0)	8 (9.5)	4 (4.5)	6 (6.9)
Grade 2	0	1 (1.1)	2 (2.3)	0	1 (1.2)	1 (1.1)	0
Grade 3	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.1)	2 (2.3)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	94	93	87	89	84	88	87
Any Solicited Local Adverse Reactions	6 (6.4)	5 (5.4)	3 (3.4)	3 (3.4)	2 (2.4)	2 (2.3)	2 (2.3)
95% CI	2.4, 13.4	1.8, 12.1	0.7, 9.7	0.7, 9.5	0.3, 8.3	0.3, 8.0	0.3, 8.1
Grade 1	6 (6.4)	5 (5.4)	3 (3.4)	3 (3.4)	2 (2.4)	2 (2.3)	2 (2.3)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	94	93	87	89	84	88	87
Any	6 (6.4)	4 (4.3)	3 (3.4)	2 (2.2)	2 (2.4)	2 (2.3)	2 (2.3)
Grade 1	6 (6.4)	4 (4.3)	3 (3.4)	2 (2.2)	2 (2.4)	2 (2.3)	2 (2.3)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	94	93	87	89	84	88	87
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	94	93	87	89	84	88	87
Any	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.1)	1 (1.1)
Grade 1	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.1)	1 (1.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	94	93	87	89	84	88	87
Any	0	1 (1.1)	0	1 (1.1)	0	0	0
Grade 1	0	1 (1.1)	0	1 (1.1)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	94	93	87	89	84	88	87
Any Solicited Systemic Adverse Reactions	7 (7.4)	10 (10.8)	9 (10.3)	7 (7.9)	9 (10.7)	5 (5.7)	6 (6.9)
95% CI	3.0, 14.7	5.3, 18.9	4.8, 18.7	3.2, 15.5	5.0, 19.4	1.9, 12.8	2.6, 14.4
Grade 1	6 (6.4)	8 (8.6)	6 (6.9)	6 (6.7)	7 (8.3)	3 (3.4)	4 (4.6)
Grade 2	0	1 (1.1)	2 (2.3)	0	1 (1.2)	1 (1.1)	0
Grade 3	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.1)	2 (2.3)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	94	93	87	87	83	88	86
Any	0	0	0	0	1 (1.2)	0	0
Grade 1	0	0	0	0	1 (1.2)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	94	92	87	89	84	88	87
Any	4 (4.3)	5 (5.4)	2 (2.3)	4 (4.5)	5 (6.0)	3 (3.4)	4 (4.6)
Grade 1	4 (4.3)	5 (5.4)	2 (2.3)	4 (4.5)	5 (6.0)	3 (3.4)	4 (4.6)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	94	92	87	89	84	88	87
Any	5 (5.3)	7 (7.6)	6 (6.9)	5 (5.6)	6 (7.1)	1 (1.1)	3 (3.4)
Grade 1	4 (4.3)	5 (5.4)	5 (5.7)	4 (4.5)	5 (6.0)	0	1 (1.1)
Grade 2	0	1 (1.1)	0	0	0	0	0
Grade 3	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.2)	1 (1.1)	2 (2.3)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	94	92	87	89	84	88	87
Any	0	1 (1.1)	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Grade 1	0	1 (1.1)	0	0	0	1 (1.1)	1 (1.1)
Grade 2	0	0	2 (2.3)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	94	92	87	89	84	88	87
Any	0	0	2 (2.3)	0	0	1 (1.1)	1 (1.1)
Grade 1	0	0	0	0	0	1 (1.1)	1 (1.1)
Grade 2	0	0	2 (2.3)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	94	92	87	89	84	88	87
Any	0	1 (1.1)	0	0	2 (2.4)	0	0
Grade 1	0	1 (1.1)	0	0	2 (2.4)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=94)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	94	92	87	89	84	88	87
Any	0	0	1 (1.1)	0	1 (1.2)	1 (1.1)	0
Grade 1	0	0	1 (1.1)	0	0	0	0
Grade 2	0	0	0	0	1 (1.2)	1 (1.1)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	94	92	87	89	84	88	87
Any	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	96	96	90	85	87	91	95
Any Solicited Adverse Reactions	55 (57.3)	80 (83.3)	48 (53.3)	27 (31.8)	20 (23.0)	18 (19.8)	18 (18.9)
95% CI	46.8, 67.3	74.4, 90.2	42.5, 63.9	22.1, 42.8	14.6, 33.2	12.2, 29.4	11.6, 28.3
Grade 1	43 (44.8)	45 (46.9)	37 (41.1)	19 (22.4)	14 (16.1)	9 (9.9)	10 (10.5)
Grade 2	7 (7.3)	25 (26.0)	5 (5.6)	3 (3.5)	2 (2.3)	4 (4.4)	3 (3.2)
Grade 3	4 (4.2)	10 (10.4)	6 (6.7)	3 (3.5)	3 (3.4)	3 (3.3)	4 (4.2)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	96	96	90	85	86	91	95
Any Solicited Local Adverse Reactions	51 (53.1)	75 (78.1)	38 (42.2)	16 (18.8)	7 (8.1)	3 (3.3)	2 (2.1)
95% CI	42.7, 63.4	68.5, 85.9	31.9, 53.1	11.2, 28.8	3.3, 16.1	0.7, 9.3	0.3, 7.4
Grade 1	44 (45.8)	61 (63.5)	34 (37.8)	15 (17.6)	6 (7.0)	2 (2.2)	1 (1.1)
Grade 2	6 (6.3)	12 (12.5)	3 (3.3)	0	0	0	0
Grade 3	1 (1.0)	2 (2.1)	1 (1.1)	1 (1.2)	1 (1.2)	1 (1.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	96	96	90	85	86	91	95
Any	51 (53.1)	75 (78.1)	37 (41.1)	15 (17.6)	5 (5.8)	2 (2.2)	2 (2.1)
Grade 1	45 (46.9)	63 (65.6)	35 (38.9)	14 (16.5)	4 (4.7)	1 (1.1)	1 (1.1)
Grade 2	5 (5.2)	10 (10.4)	1 (1.1)	0	0	0	0
Grade 3	1 (1.0)	2 (2.1)	1 (1.1)	1 (1.2)	1 (1.2)	1 (1.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	96	96	90	85	86	91	95
Any	1 (1.0)	4 (4.2)	4 (4.4)	1 (1.2)	0	0	0
Grade 1	0	3 (3.1)	2 (2.2)	1 (1.2)	0	0	0
Grade 2	1 (1.0)	1 (1.0)	2 (2.2)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	96	96	90	85	86	91	95
Any	0	5 (5.2)	4 (4.4)	2 (2.4)	2 (2.3)	0	0
Grade 1	0	3 (3.1)	3 (3.3)	2 (2.4)	2 (2.3)	0	0
Grade 2	0	2 (2.1)	1 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	96	96	90	85	86	91	95
Any	2 (2.1)	5 (5.2)	3 (3.3)	1 (1.2)	0	1 (1.1)	0
Grade 1	2 (2.1)	2 (2.1)	2 (2.2)	1 (1.2)	0	1 (1.1)	0
Grade 2	0	3 (3.1)	1 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	96	96	90	85	87	91	95
Any Solicited Systemic Adverse Reactions	22 (22.9)	55 (57.3)	29 (32.2)	22 (25.9)	16 (18.4)	16 (17.6)	17 (17.9)
95% CI	15.0, 32.6	46.8, 67.3	22.8, 42.9	17.0, 36.5	10.9, 28.1	10.4, 27.0	10.8, 27.1
Grade 1	11 (11.5)	21 (21.9)	19 (21.1)	14 (16.5)	11 (12.6)	8 (8.8)	10 (10.5)
Grade 2	5 (5.2)	24 (25.0)	4 (4.4)	3 (3.5)	2 (2.3)	4 (4.4)	3 (3.2)
Grade 3	4 (4.2)	9 (9.4)	6 (6.7)	3 (3.5)	2 (2.3)	2 (2.2)	3 (3.2)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	95	95	89	83	85	91	93
Any	2 (2.1)	7 (7.4)	0	0	0	0	0
Grade 1	1 (1.1)	3 (3.2)	0	0	0	0	0
Grade 2	0	2 (2.1)	0	0	0	0	0
Grade 3	1 (1.1)	2 (2.1)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	96	96	90	85	86	90	95
Any	14 (14.6)	38 (39.6)	20 (22.2)	18 (21.2)	10 (11.6)	8 (8.9)	11 (11.6)
Grade 1	11 (11.5)	23 (24.0)	15 (16.7)	15 (17.6)	8 (9.3)	5 (5.6)	8 (8.4)
Grade 2	2 (2.1)	13 (13.5)	4 (4.4)	3 (3.5)	2 (2.3)	3 (3.3)	2 (2.1)
Grade 3	1 (1.0)	2 (2.1)	1 (1.1)	0	0	0	1 (1.1)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	96	96	90	85	87	90	95
Any	10 (10.4)	38 (39.6)	15 (16.7)	11 (12.9)	7 (8.0)	9 (10.0)	7 (7.4)
Grade 1	5 (5.2)	13 (13.5)	10 (11.1)	8 (9.4)	5 (5.7)	4 (4.4)	4 (4.2)
Grade 2	3 (3.1)	21 (21.9)	2 (2.2)	2 (2.4)	1 (1.1)	4 (4.4)	2 (2.1)
Grade 3	2 (2.1)	4 (4.2)	3 (3.3)	1 (1.2)	1 (1.1)	1 (1.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	96	96	90	85	87	90	95
Any	11 (11.5)	35 (36.5)	14 (15.6)	10 (11.8)	6 (6.9)	5 (5.6)	5 (5.3)
Grade 1	6 (6.3)	12 (12.5)	7 (7.8)	7 (8.2)	5 (5.7)	4 (4.4)	3 (3.2)
Grade 2	1 (1.0)	16 (16.7)	2 (2.2)	1 (1.2)	0	0	1 (1.1)
Grade 3	4 (4.2)	7 (7.3)	5 (5.6)	2 (2.4)	1 (1.1)	1 (1.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	96	96	90	85	87	90	95
Any	7 (7.3)	24 (25.0)	14 (15.6)	7 (8.2)	6 (6.9)	5 (5.6)	3 (3.2)
Grade 1	3 (3.1)	11 (11.5)	8 (8.9)	3 (3.5)	4 (4.6)	3 (3.3)	1 (1.1)
Grade 2	1 (1.0)	8 (8.3)	1 (1.1)	1 (1.2)	0	0	0
Grade 3	3 (3.1)	5 (5.2)	5 (5.6)	3 (3.5)	2 (2.3)	2 (2.2)	2 (2.1)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	96	96	90	85	86	90	95
Any	2 (2.1)	14 (14.6)	4 (4.4)	1 (1.2)	1 (1.2)	2 (2.2)	1 (1.1)
Grade 1	2 (2.1)	10 (10.4)	4 (4.4)	1 (1.2)	1 (1.2)	2 (2.2)	1 (1.1)
Grade 2	0	4 (4.2)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=97)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	96	96	90	85	86	90	95
Any	5 (5.2)	26 (27.1)	6 (6.7)	2 (2.4)	0	0	0
Grade 1	2 (2.1)	8 (8.3)	5 (5.6)	2 (2.4)	0	0	0
Grade 2	2 (2.1)	17 (17.7)	0	0	0	0	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.1)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	96	96	90	85	86	90	95
Any	2 (2.1)	1 (1.0)	2 (2.2)	2 (2.4)	2 (2.3)	3 (3.3)	1 (1.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	99	99	92	93	93	93	99
Any Solicited Adverse Reactions	60 (60.6)	89 (89.9)	63 (68.5)	36 (38.7)	21 (22.6)	19 (20.4)	14 (14.1)
95% CI	50.3, 70.3	82.2, 95.0	58.0, 77.8	28.8, 49.4	14.6, 32.4	12.8, 30.1	8.0, 22.6
Grade 1	46 (46.5)	30 (30.3)	41 (44.6)	22 (23.7)	12 (12.9)	14 (15.1)	10 (10.1)
Grade 2	11 (11.1)	43 (43.4)	11 (12.0)	4 (4.3)	4 (4.3)	1 (1.1)	2 (2.0)
Grade 3	3 (3.0)	16 (16.2)	11 (12.0)	9 (9.7)	4 (4.3)	3 (3.2)	2 (2.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	99	99	92	93	93	92	99
Any Solicited Local Adverse Reactions	60 (60.6)	85 (85.9)	50 (54.3)	23 (24.7)	8 (8.6)	7 (7.6)	4 (4.0)
95% CI	50.3, 70.3	77.4, 92.0	43.6, 64.8	16.4, 34.8	3.8, 16.2	3.1, 15.1	1.1, 10.0
Grade 1	56 (56.6)	64 (64.6)	44 (47.8)	19 (20.4)	8 (8.6)	7 (7.6)	4 (4.0)
Grade 2	4 (4.0)	20 (20.2)	5 (5.4)	2 (2.2)	0	0	0
Grade 3	0	1 (1.0)	1 (1.1)	2 (2.2)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	99	99	92	93	93	92	99
Any	59 (59.6)	85 (85.9)	50 (54.3)	22 (23.7)	7 (7.5)	5 (5.4)	2 (2.0)
Grade 1	55 (55.6)	64 (64.6)	46 (50.0)	19 (20.4)	7 (7.5)	5 (5.4)	2 (2.0)
Grade 2	4 (4.0)	20 (20.2)	3 (3.3)	2 (2.2)	0	0	0
Grade 3	0	1 (1.0)	1 (1.1)	1 (1.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	99	99	92	93	93	92	99
Any	1 (1.0)	4 (4.0)	5 (5.4)	2 (2.2)	0	0	0
Grade 1	1 (1.0)	4 (4.0)	3 (3.3)	1 (1.1)	0	0	0
Grade 2	0	0	2 (2.2)	0	0	0	0
Grade 3	0	0	0	1 (1.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	99	99	92	93	93	92	99
Any	4 (4.0)	5 (5.1)	6 (6.5)	4 (4.3)	2 (2.2)	2 (2.2)	2 (2.0)
Grade 1	3 (3.0)	5 (5.1)	6 (6.5)	4 (4.3)	2 (2.2)	2 (2.2)	2 (2.0)
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	99	99	92	93	93	92	99
Any	4 (4.0)	7 (7.1)	4 (4.3)	2 (2.2)	0	0	0
Grade 1	2 (2.0)	4 (4.0)	4 (4.3)	2 (2.2)	0	0	0
Grade 2	2 (2.0)	3 (3.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	99	99	92	93	93	93	99
Any Solicited Systemic Adverse Reactions	26 (26.3)	74 (74.7)	36 (39.1)	24 (25.8)	17 (18.3)	17 (18.3)	12 (12.1)
95% CI	17.9, 36.1	65.0, 82.9	29.1, 49.9	17.3, 35.9	11.0, 27.6	11.0, 27.6	6.4, 20.2
Grade 1	13 (13.1)	20 (20.2)	18 (19.6)	13 (14.0)	8 (8.6)	12 (12.9)	8 (8.1)
Grade 2	9 (9.1)	39 (39.4)	7 (7.6)	3 (3.2)	4 (4.3)	1 (1.1)	2 (2.0)
Grade 3	3 (3.0)	15 (15.2)	10 (10.9)	7 (7.5)	4 (4.3)	3 (3.2)	2 (2.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	99	98	92	92	92	91	98
Any	2 (2.0)	14 (14.3)	3 (3.3)	2 (2.2)	1 (1.1)	1 (1.1)	0
Grade 1	1 (1.0)	10 (10.2)	0	1 (1.1)	1 (1.1)	0	0
Grade 2	0	1 (1.0)	1 (1.1)	0	0	1 (1.1)	0
Grade 3	1 (1.0)	3 (3.1)	2 (2.2)	1 (1.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	99	98	92	93	93	92	99
Any	16 (16.2)	50 (51.0)	18 (19.6)	11 (11.8)	8 (8.6)	9 (9.8)	8 (8.1)
Grade 1	12 (12.1)	20 (20.4)	10 (10.9)	7 (7.5)	4 (4.3)	7 (7.6)	6 (6.1)
Grade 2	3 (3.0)	26 (26.5)	6 (6.5)	2 (2.2)	2 (2.2)	1 (1.1)	1 (1.0)
Grade 3	1 (1.0)	4 (4.1)	2 (2.2)	2 (2.2)	2 (2.2)	1 (1.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	99	98	92	93	93	93	99
Any	18 (18.2)	61 (62.2)	28 (30.4)	13 (14.0)	12 (12.9)	6 (6.5)	7 (7.1)
Grade 1	9 (9.1)	17 (17.3)	16 (17.4)	9 (9.7)	9 (9.7)	4 (4.3)	4 (4.0)
Grade 2	9 (9.1)	35 (35.7)	5 (5.4)	2 (2.2)	2 (2.2)	1 (1.1)	2 (2.0)
Grade 3	0	9 (9.2)	7 (7.6)	2 (2.2)	1 (1.1)	1 (1.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	99	98	92	93	93	92	99
Any	17 (17.2)	52 (53.1)	15 (16.3)	6 (6.5)	7 (7.5)	5 (5.4)	6 (6.1)
Grade 1	9 (9.1)	15 (15.3)	7 (7.6)	3 (3.2)	4 (4.3)	2 (2.2)	4 (4.0)
Grade 2	7 (7.1)	26 (26.5)	2 (2.2)	0	1 (1.1)	1 (1.1)	1 (1.0)
Grade 3	1 (1.0)	11 (11.2)	6 (6.5)	3 (3.2)	2 (2.2)	2 (2.2)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	99	98	92	93	93	92	99
Any	11 (11.1)	37 (37.8)	13 (14.1)	4 (4.3)	3 (3.2)	5 (5.4)	2 (2.0)
Grade 1	5 (5.1)	11 (11.2)	7 (7.6)	1 (1.1)	0	3 (3.3)	2 (2.0)
Grade 2	6 (6.1)	20 (20.4)	2 (2.2)	1 (1.1)	2 (2.2)	1 (1.1)	0
Grade 3	0	6 (6.1)	4 (4.3)	2 (2.2)	1 (1.1)	1 (1.1)	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	99	98	92	93	93	92	99
Any	6 (6.1)	20 (20.4)	6 (6.5)	0	2 (2.2)	1 (1.1)	2 (2.0)
Grade 1	3 (3.0)	14 (14.3)	4 (4.3)	0	2 (2.2)	1 (1.1)	2 (2.0)
Grade 2	3 (3.0)	6 (6.1)	2 (2.2)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	99	98	92	93	93	92	99
Any	10 (10.1)	44 (44.9)	7 (7.6)	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.0)
Grade 1	8 (8.1)	18 (18.4)	2 (2.2)	2 (2.2)	1 (1.1)	1 (1.1)	0
Grade 2	2 (2.0)	25 (25.5)	5 (5.4)	1 (1.1)	0	0	1 (1.0)
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	99	98	92	93	93	92	99
Any	1 (1.0)	3 (3.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	195	195	182	178	180	184	194
Any Solicited Adverse Reactions	115 (59.0)	169 (86.7)	111 (61.0)	63 (35.4)	41 (22.8)	37 (20.1)	32 (16.5)
95% CI	51.7, 66.0	81.1, 91.1	53.5, 68.1	28.4, 42.9	16.9, 29.6	14.6, 26.6	11.6, 22.5
Grade 1	89 (45.6)	75 (38.5)	78 (42.9)	41 (23.0)	26 (14.4)	23 (12.5)	20 (10.3)
Grade 2	18 (9.2)	68 (34.9)	16 (8.8)	7 (3.9)	6 (3.3)	5 (2.7)	5 (2.6)
Grade 3	7 (3.6)	26 (13.3)	17 (9.3)	12 (6.7)	7 (3.9)	6 (3.3)	6 (3.1)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	195	195	182	178	179	183	194
Any Solicited Local Adverse Reactions	111 (56.9)	160 (82.1)	88 (48.4)	39 (21.9)	15 (8.4)	10 (5.5)	6 (3.1)
95% CI	49.7, 64.0	75.9, 87.2	40.9, 55.9	16.1, 28.7	4.8, 13.4	2.7, 9.8	1.1, 6.6
Grade 1	100 (51.3)	125 (64.1)	78 (42.9)	34 (19.1)	14 (7.8)	9 (4.9)	5 (2.6)
Grade 2	10 (5.1)	32 (16.4)	8 (4.4)	2 (1.1)	0	0	0
Grade 3	1 (0.5)	3 (1.5)	2 (1.1)	3 (1.7)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	195	195	182	178	179	183	194
Any	110 (56.4)	160 (82.1)	87 (47.8)	37 (20.8)	12 (6.7)	7 (3.8)	4 (2.1)
Grade 1	100 (51.3)	127 (65.1)	81 (44.5)	33 (18.5)	11 (6.1)	6 (3.3)	3 (1.5)
Grade 2	9 (4.6)	30 (15.4)	4 (2.2)	2 (1.1)	0	0	0
Grade 3	1 (0.5)	3 (1.5)	2 (1.1)	2 (1.1)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	195	195	182	178	179	183	194
Any	2 (1.0)	8 (4.1)	9 (4.9)	3 (1.7)	0	0	0
Grade 1	1 (0.5)	7 (3.6)	5 (2.7)	2 (1.1)	0	0	0
Grade 2	1 (0.5)	1 (0.5)	4 (2.2)	0	0	0	0
Grade 3	0	0	0	1 (0.6)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	195	195	182	178	179	183	194
Any	4 (2.1)	10 (5.1)	10 (5.5)	6 (3.4)	4 (2.2)	2 (1.1)	2 (1.0)
Grade 1	3 (1.5)	8 (4.1)	9 (4.9)	6 (3.4)	4 (2.2)	2 (1.1)	2 (1.0)
Grade 2	1 (0.5)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	195	195	182	178	179	183	194
Any	6 (3.1)	12 (6.2)	7 (3.8)	3 (1.7)	0	1 (0.5)	0
Grade 1	4 (2.1)	6 (3.1)	6 (3.3)	3 (1.7)	0	1 (0.5)	0
Grade 2	2 (1.0)	6 (3.1)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	195	195	182	178	180	184	194
Any Solicited Systemic Adverse Reactions	48 (24.6)	129 (66.2)	65 (35.7)	46 (25.8)	33 (18.3)	33 (17.9)	29 (14.9)
95% CI	18.7, 31.3	59.0, 72.8	28.8, 43.1	19.6, 32.9	13.0, 24.8	12.7, 24.3	10.2, 20.8
Grade 1	24 (12.3)	41 (21.0)	37 (20.3)	27 (15.2)	19 (10.6)	20 (10.9)	18 (9.3)
Grade 2	14 (7.2)	63 (32.3)	11 (6.0)	6 (3.4)	6 (3.3)	5 (2.7)	5 (2.6)
Grade 3	7 (3.6)	24 (12.3)	16 (8.8)	10 (5.6)	6 (3.3)	5 (2.7)	5 (2.6)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	194	193	181	175	177	182	191
Any	4 (2.1)	21 (10.9)	3 (1.7)	2 (1.1)	1 (0.6)	1 (0.5)	0
Grade 1	2 (1.0)	13 (6.7)	0	1 (0.6)	1 (0.6)	0	0
Grade 2	0	3 (1.6)	1 (0.6)	0	0	1 (0.5)	0
Grade 3	2 (1.0)	5 (2.6)	2 (1.1)	1 (0.6)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	195	194	182	178	179	182	194
Any	30 (15.4)	88 (45.4)	38 (20.9)	29 (16.3)	18 (10.1)	17 (9.3)	19 (9.8)
Grade 1	23 (11.8)	43 (22.2)	25 (13.7)	22 (12.4)	12 (6.7)	12 (6.6)	14 (7.2)
Grade 2	5 (2.6)	39 (20.1)	10 (5.5)	5 (2.8)	4 (2.2)	4 (2.2)	3 (1.5)
Grade 3	2 (1.0)	6 (3.1)	3 (1.6)	2 (1.1)	2 (1.1)	1 (0.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	195	194	182	178	180	183	194
Any	28 (14.4)	99 (51.0)	43 (23.6)	24 (13.5)	19 (10.6)	15 (8.2)	14 (7.2)
Grade 1	14 (7.2)	30 (15.5)	26 (14.3)	17 (9.6)	14 (7.8)	8 (4.4)	8 (4.1)
Grade 2	12 (6.2)	56 (28.9)	7 (3.8)	4 (2.2)	3 (1.7)	5 (2.7)	4 (2.1)
Grade 3	2 (1.0)	13 (6.7)	10 (5.5)	3 (1.7)	2 (1.1)	2 (1.1)	2 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	195	194	182	178	180	182	194
Any	28 (14.4)	87 (44.8)	29 (15.9)	16 (9.0)	13 (7.2)	10 (5.5)	11 (5.7)
Grade 1	15 (7.7)	27 (13.9)	14 (7.7)	10 (5.6)	9 (5.0)	6 (3.3)	7 (3.6)
Grade 2	8 (4.1)	42 (21.6)	4 (2.2)	1 (0.6)	1 (0.6)	1 (0.5)	2 (1.0)
Grade 3	5 (2.6)	18 (9.3)	11 (6.0)	5 (2.8)	3 (1.7)	3 (1.6)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	195	194	182	178	180	182	194
Any	18 (9.2)	61 (31.4)	27 (14.8)	11 (6.2)	9 (5.0)	10 (5.5)	5 (2.6)
Grade 1	8 (4.1)	22 (11.3)	15 (8.2)	4 (2.2)	4 (2.2)	6 (3.3)	3 (1.5)
Grade 2	7 (3.6)	28 (14.4)	3 (1.6)	2 (1.1)	2 (1.1)	1 (0.5)	0
Grade 3	3 (1.5)	11 (5.7)	9 (4.9)	5 (2.8)	3 (1.7)	3 (1.6)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	195	194	182	178	179	182	194
Any	8 (4.1)	34 (17.5)	10 (5.5)	1 (0.6)	3 (1.7)	3 (1.6)	3 (1.5)
Grade 1	5 (2.6)	24 (12.4)	8 (4.4)	1 (0.6)	3 (1.7)	3 (1.6)	3 (1.5)
Grade 2	3 (1.5)	10 (5.2)	2 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=196)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	195	194	182	178	179	182	194
Any	15 (7.7)	70 (36.1)	13 (7.1)	5 (2.8)	1 (0.6)	1 (0.5)	1 (0.5)
Grade 1	10 (5.1)	26 (13.4)	7 (3.8)	4 (2.2)	1 (0.6)	1 (0.5)	0
Grade 2	4 (2.1)	42 (21.6)	5 (2.7)	1 (0.6)	0	0	1 (0.5)
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	195	194	182	178	179	182	194
Any	3 (1.5)	4 (2.1)	3 (1.6)	3 (1.7)	3 (1.7)	4 (2.2)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	99	97	94	94	97	95	97
Any Solicited Adverse Reactions	13 (13.1)	14 (14.4)	14 (14.9)	6 (6.4)	8 (8.2)	6 (6.3)	7 (7.2)
95% CI	7.2, 21.4	8.1, 23.0	8.4, 23.7	2.4, 13.4	3.6, 15.6	2.4, 13.2	3.0, 14.3
Grade 1	10 (10.1)	12 (12.4)	13 (13.8)	5 (5.3)	7 (7.2)	6 (6.3)	7 (7.2)
Grade 2	3 (3.0)	2 (2.1)	1 (1.1)	1 (1.1)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	99	97	94	94	97	95	97
Any Solicited Local Adverse Reactions	5 (5.1)	0	0	0	0	0	1 (1.0)
95% CI	1.7, 11.4	0.0, 3.7	0.0, 3.8	0.0, 3.8	0.0, 3.7	0.0, 3.8	0.0, 5.6
Grade 1	5 (5.1)	0	0	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Pain - N1	99	97	94	94	97	95	97
Any	5 (5.1)	0	0	0	0	0	1 (1.0)
Grade 1	5 (5.1)	0	0	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	99	97	94	94	97	95	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	99	97	94	94	97	95	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	99	97	94	94	97	95	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	99	97	94	94	97	95	97
Any Solicited Systemic Adverse Reactions	11 (11.1)	14 (14.4)	14 (14.9)	6 (6.4)	8 (8.2)	6 (6.3)	6 (6.2)
95% CI	5.7, 19.0	8.1, 23.0	8.4, 23.7	2.4, 13.4	3.6, 15.6	2.4, 13.2	2.3, 13.0
Grade 1	8 (8.1)	12 (12.4)	13 (13.8)	5 (5.3)	7 (7.2)	6 (6.3)	6 (6.2)
Grade 2	3 (3.0)	2 (2.1)	1 (1.1)	1 (1.1)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	99	95	92	93	96	94	94
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	99	97	94	94	97	95	97
Any	6 (6.1)	7 (7.2)	4 (4.3)	1 (1.1)	3 (3.1)	2 (2.1)	1 (1.0)
Grade 1	6 (6.1)	7 (7.2)	4 (4.3)	1 (1.1)	3 (3.1)	2 (2.1)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	99	97	94	94	97	95	97
Any	6 (6.1)	11 (11.3)	10 (10.6)	5 (5.3)	4 (4.1)	1 (1.1)	4 (4.1)
Grade 1	3 (3.0)	9 (9.3)	9 (9.6)	5 (5.3)	4 (4.1)	1 (1.1)	4 (4.1)
Grade 2	3 (3.0)	2 (2.1)	1 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	99	97	94	94	97	95	97
Any	2 (2.0)	5 (5.2)	3 (3.2)	4 (4.3)	1 (1.0)	3 (3.2)	3 (3.1)
Grade 1	2 (2.0)	5 (5.2)	3 (3.2)	3 (3.2)	1 (1.0)	3 (3.2)	3 (3.1)
Grade 2	0	0	0	1 (1.1)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	99	97	94	94	97	95	97
Any	1 (1.0)	5 (5.2)	2 (2.1)	1 (1.1)	3 (3.1)	3 (3.2)	3 (3.1)
Grade 1	1 (1.0)	5 (5.2)	2 (2.1)	1 (1.1)	3 (3.1)	3 (3.2)	3 (3.1)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	99	97	94	94	97	95	97
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	99	97	94	94	97	95	97
Any	0	1 (1.0)	0	1 (1.1)	2 (2.1)	0	0
Grade 1	0	1 (1.0)	0	1 (1.1)	2 (2.1)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	99	97	94	94	97	95	97
Any	0	0	0	0	1 (1.0)	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	96	97	95	95	94	91	95
Any Solicited Adverse Reactions	42 (43.8)	78 (80.4)	64 (67.4)	37 (38.9)	25 (26.6)	15 (16.5)	13 (13.7)
95% CI	33.6, 54.3	71.1, 87.8	57.0, 76.6	29.1, 49.5	18.0, 36.7	9.5, 25.7	7.5, 22.3
Grade 1	35 (36.5)	43 (44.3)	52 (54.7)	30 (31.6)	21 (22.3)	12 (13.2)	9 (9.5)
Grade 2	5 (5.2)	28 (28.9)	11 (11.6)	5 (5.3)	3 (3.2)	1 (1.1)	1 (1.1)
Grade 3	2 (2.1)	7 (7.2)	1 (1.1)	2 (2.1)	1 (1.1)	2 (2.2)	1 (1.1)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	96	97	95	95	94	91	95
Any Solicited Local Adverse Reactions	39 (40.6)	69 (71.1)	53 (55.8)	25 (26.3)	14 (14.9)	7 (7.7)	2 (2.1)
95% CI	30.7, 51.1	61.0, 79.9	45.2, 66.0	17.8, 36.4	8.4, 23.7	3.1, 15.2	0.3, 7.4
Grade 1	35 (36.5)	58 (59.8)	47 (49.5)	22 (23.2)	12 (12.8)	6 (6.6)	1 (1.1)
Grade 2	4 (4.2)	11 (11.3)	6 (6.3)	3 (3.2)	2 (2.1)	1 (1.1)	1 (1.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	96	97	95	95	94	91	95
Any	37 (38.5)	69 (71.1)	52 (54.7)	24 (25.3)	13 (13.8)	4 (4.4)	2 (2.1)
Grade 1	33 (34.4)	59 (60.8)	49 (51.6)	23 (24.2)	12 (12.8)	3 (3.3)	1 (1.1)
Grade 2	4 (4.2)	10 (10.3)	3 (3.2)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	96	97	95	95	94	91	95
Any	0	3 (3.1)	4 (4.2)	3 (3.2)	1 (1.1)	0	0
Grade 1	0	2 (2.1)	1 (1.1)	1 (1.1)	0	0	0
Grade 2	0	1 (1.0)	3 (3.2)	2 (2.1)	1 (1.1)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	96	97	95	95	94	91	95
Any	0	4 (4.1)	5 (5.3)	5 (5.3)	4 (4.3)	2 (2.2)	0
Grade 1	0	3 (3.1)	3 (3.2)	3 (3.2)	3 (3.2)	2 (2.2)	0
Grade 2	0	1 (1.0)	2 (2.1)	2 (2.1)	1 (1.1)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	96	97	95	95	94	91	95
Any	3 (3.1)	8 (8.2)	5 (5.3)	3 (3.2)	3 (3.2)	4 (4.4)	1 (1.1)
Grade 1	3 (3.1)	5 (5.2)	4 (4.2)	3 (3.2)	3 (3.2)	4 (4.4)	1 (1.1)
Grade 2	0	3 (3.1)	1 (1.1)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	96	97	95	95	94	91	95
Any Solicited Systemic Adverse Reactions	18 (18.8)	59 (60.8)	35 (36.8)	24 (25.3)	17 (18.1)	11 (12.1)	12 (12.6)
95% CI	11.5, 28.0	50.4, 70.6	27.2, 47.4	16.9, 35.2	10.9, 27.4	6.2, 20.6	6.7, 21.0
Grade 1	13 (13.5)	25 (25.8)	26 (27.4)	20 (21.1)	15 (16.0)	9 (9.9)	9 (9.5)
Grade 2	3 (3.1)	27 (27.8)	8 (8.4)	2 (2.1)	1 (1.1)	0	0
Grade 3	2 (2.1)	7 (7.2)	1 (1.1)	2 (2.1)	1 (1.1)	2 (2.2)	1 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	96	97	94	95	94	91	95
Any	0	5 (5.2)	0	0	0	0	0
Grade 1	0	4 (4.1)	0	0	0	0	0
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	96	97	95	95	94	91	95
Any	12 (12.5)	38 (39.2)	14 (14.7)	12 (12.6)	7 (7.4)	7 (7.7)	4 (4.2)
Grade 1	10 (10.4)	27 (27.8)	12 (12.6)	10 (10.5)	6 (6.4)	6 (6.6)	4 (4.2)
Grade 2	1 (1.0)	8 (8.2)	2 (2.1)	1 (1.1)	1 (1.1)	0	0
Grade 3	1 (1.0)	3 (3.1)	0	1 (1.1)	0	1 (1.1)	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	96	97	95	95	94	91	95
Any	17 (17.7)	52 (53.6)	26 (27.4)	13 (13.7)	10 (10.6)	6 (6.6)	6 (6.3)
Grade 1	13 (13.5)	25 (25.8)	17 (17.9)	10 (10.5)	8 (8.5)	4 (4.4)	5 (5.3)
Grade 2	2 (2.1)	22 (22.7)	8 (8.4)	2 (2.1)	1 (1.1)	1 (1.1)	0
Grade 3	2 (2.1)	5 (5.2)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)	1 (1.1)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	96	97	95	95	94	91	95
Any	6 (6.3)	37 (38.1)	16 (16.8)	9 (9.5)	5 (5.3)	4 (4.4)	3 (3.2)
Grade 1	2 (2.1)	16 (16.5)	12 (12.6)	7 (7.4)	4 (4.3)	3 (3.3)	3 (3.2)
Grade 2	3 (3.1)	18 (18.6)	3 (3.2)	2 (2.1)	1 (1.1)	1 (1.1)	0
Grade 3	1 (1.0)	3 (3.1)	1 (1.1)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	96	97	95	95	94	91	95
Any	5 (5.2)	35 (36.1)	15 (15.8)	6 (6.3)	5 (5.3)	3 (3.3)	3 (3.2)
Grade 1	2 (2.1)	15 (15.5)	12 (12.6)	6 (6.3)	4 (4.3)	3 (3.3)	3 (3.2)
Grade 2	3 (3.1)	18 (18.6)	3 (3.2)	0	1 (1.1)	0	0
Grade 3	0	2 (2.1)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	96	97	95	95	94	91	95
Any	1 (1.0)	4 (4.1)	2 (2.1)	2 (2.1)	0	1 (1.1)	0
Grade 1	1 (1.0)	3 (3.1)	1 (1.1)	1 (1.1)	0	0	0
Grade 2	0	1 (1.0)	1 (1.1)	1 (1.1)	0	1 (1.1)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=98)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	96	97	95	95	94	91	95
Any	4 (4.2)	18 (18.6)	7 (7.4)	2 (2.1)	2 (2.1)	1 (1.1)	0
Grade 1	1 (1.0)	11 (11.3)	6 (6.3)	1 (1.1)	1 (1.1)	1 (1.1)	0
Grade 2	3 (3.1)	6 (6.2)	1 (1.1)	1 (1.1)	1 (1.1)	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	96	97	95	95	94	91	95
Any	1 (1.0)	1 (1.0)	1 (1.1)	0	0	0	2 (2.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	98	99	99	96	96	96	97
Any Solicited Adverse Reactions	50 (51.0)	82 (82.8)	56 (56.6)	29 (30.2)	24 (25.0)	17 (17.7)	10 (10.3)
95% CI	40.7, 61.3	73.9, 89.7	46.2, 66.5	21.3, 40.4	16.7, 34.9	10.7, 26.8	5.1, 18.1
Grade 1	46 (46.9)	40 (40.4)	41 (41.4)	21 (21.9)	21 (21.9)	14 (14.6)	7 (7.2)
Grade 2	2 (2.0)	34 (34.3)	12 (12.1)	4 (4.2)	2 (2.1)	1 (1.0)	2 (2.1)
Grade 3	2 (2.0)	8 (8.1)	3 (3.0)	4 (4.2)	1 (1.0)	2 (2.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	98	99	99	96	95	96	97
Any Solicited Local Adverse Reactions	42 (42.9)	76 (76.8)	50 (50.5)	25 (26.0)	14 (14.7)	6 (6.3)	4 (4.1)
95% CI	32.9, 53.3	67.2, 84.7	40.3, 60.7	17.6, 36.0	8.3, 23.5	2.3, 13.1	1.1, 10.2
Grade 1	42 (42.9)	67 (67.7)	45 (45.5)	20 (20.8)	14 (14.7)	6 (6.3)	4 (4.1)
Grade 2	0	8 (8.1)	4 (4.0)	2 (2.1)	0	0	0
Grade 3	0	1 (1.0)	1 (1.0)	3 (3.1)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	98	99	99	96	95	96	97
Any	42 (42.9)	76 (76.8)	45 (45.5)	22 (22.9)	12 (12.6)	5 (5.2)	4 (4.1)
Grade 1	42 (42.9)	71 (71.7)	44 (44.4)	21 (21.9)	12 (12.6)	5 (5.2)	4 (4.1)
Grade 2	0	5 (5.1)	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	98	99	99	96	95	96	97
Any	0	2 (2.0)	4 (4.0)	7 (7.3)	3 (3.2)	0	0
Grade 1	0	2 (2.0)	2 (2.0)	3 (3.1)	3 (3.2)	0	0
Grade 2	0	0	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	1 (1.0)	3 (3.1)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	98	99	99	96	95	96	97
Any	3 (3.1)	8 (8.1)	6 (6.1)	5 (5.2)	3 (3.2)	2 (2.1)	1 (1.0)
Grade 1	3 (3.1)	4 (4.0)	3 (3.0)	5 (5.2)	3 (3.2)	2 (2.1)	1 (1.0)
Grade 2	0	3 (3.0)	3 (3.0)	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	98	99	99	96	95	96	97
Any	2 (2.0)	2 (2.0)	6 (6.1)	5 (5.2)	0	0	0
Grade 1	2 (2.0)	2 (2.0)	6 (6.1)	5 (5.2)	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	98	99	99	96	96	96	97
Any Solicited Systemic Adverse Reactions	24 (24.5)	66 (66.7)	29 (29.3)	13 (13.5)	12 (12.5)	12 (12.5)	6 (6.2)
95% CI	16.4, 34.2	56.5, 75.8	20.6, 39.3	7.4, 22.0	6.6, 20.8	6.6, 20.8	2.3, 13.0
Grade 1	20 (20.4)	29 (29.3)	17 (17.2)	9 (9.4)	9 (9.4)	9 (9.4)	3 (3.1)
Grade 2	2 (2.0)	30 (30.3)	10 (10.1)	3 (3.1)	2 (2.1)	1 (1.0)	2 (2.1)
Grade 3	2 (2.0)	7 (7.1)	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	98	99	97	96	95	96	97
Any	1 (1.0)	7 (7.1)	3 (3.1)	0	0	0	0
Grade 1	1 (1.0)	5 (5.1)	3 (3.1)	0	0	0	0
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	98	99	97	96	95	96	97
Any	12 (12.2)	43 (43.4)	18 (18.6)	5 (5.2)	8 (8.4)	8 (8.3)	4 (4.1)
Grade 1	11 (11.2)	29 (29.3)	13 (13.4)	3 (3.1)	6 (6.3)	6 (6.3)	2 (2.1)
Grade 2	0	10 (10.1)	3 (3.1)	1 (1.0)	1 (1.1)	0	1 (1.0)
Grade 3	1 (1.0)	4 (4.0)	2 (2.1)	1 (1.0)	1 (1.1)	2 (2.1)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	98	99	98	96	95	96	97
Any	15 (15.3)	52 (52.5)	22 (22.4)	7 (7.3)	3 (3.2)	4 (4.2)	2 (2.1)
Grade 1	12 (12.2)	21 (21.2)	13 (13.3)	4 (4.2)	2 (2.1)	2 (2.1)	0
Grade 2	2 (2.0)	25 (25.3)	8 (8.2)	3 (3.1)	1 (1.1)	2 (2.1)	2 (2.1)
Grade 3	1 (1.0)	6 (6.1)	1 (1.0)	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	98	99	98	96	95	96	97
Any	8 (8.2)	46 (46.5)	15 (15.3)	3 (3.1)	1 (1.1)	0	2 (2.1)
Grade 1	6 (6.1)	19 (19.2)	5 (5.1)	2 (2.1)	0	0	2 (2.1)
Grade 2	1 (1.0)	23 (23.2)	8 (8.2)	1 (1.0)	1 (1.1)	0	0
Grade 3	1 (1.0)	4 (4.0)	2 (2.0)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	98	99	97	96	95	96	97
Any	4 (4.1)	35 (35.4)	9 (9.3)	5 (5.2)	4 (4.2)	3 (3.1)	2 (2.1)
Grade 1	3 (3.1)	19 (19.2)	4 (4.1)	4 (4.2)	3 (3.2)	3 (3.1)	2 (2.1)
Grade 2	0	14 (14.1)	4 (4.1)	1 (1.0)	1 (1.1)	0	0
Grade 3	1 (1.0)	2 (2.0)	1 (1.0)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	98	99	97	96	95	96	97
Any	2 (2.0)	10 (10.1)	3 (3.1)	2 (2.1)	1 (1.1)	1 (1.0)	1 (1.0)
Grade 1	2 (2.0)	7 (7.1)	2 (2.1)	2 (2.1)	1 (1.1)	0	0
Grade 2	0	3 (3.0)	1 (1.0)	0	0	1 (1.0)	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=99)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	98	99	97	96	95	96	97
Any	4 (4.1)	27 (27.3)	7 (7.2)	1 (1.0)	1 (1.1)	0	1 (1.0)
Grade 1	3 (3.1)	11 (11.1)	4 (4.1)	0	1 (1.1)	0	0
Grade 2	1 (1.0)	16 (16.2)	3 (3.1)	1 (1.0)	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	98	99	97	96	95	96	97
Any	0	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.1)	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	194	196	194	191	190	187	192
Any Solicited Adverse Reactions	92 (47.4)	160 (81.6)	120 (61.9)	66 (34.6)	49 (25.8)	32 (17.1)	23 (12.0)
95% CI	40.2, 54.7	75.5, 86.8	54.6, 68.7	27.8, 41.8	19.7, 32.6	12.0, 23.3	7.7, 17.4
Grade 1	81 (41.8)	83 (42.3)	93 (47.9)	51 (26.7)	42 (22.1)	26 (13.9)	16 (8.3)
Grade 2	7 (3.6)	62 (31.6)	23 (11.9)	9 (4.7)	5 (2.6)	2 (1.1)	3 (1.6)
Grade 3	4 (2.1)	15 (7.7)	4 (2.1)	6 (3.1)	2 (1.1)	4 (2.1)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	194	196	194	191	189	187	192
Any Solicited Local Adverse Reactions	81 (41.8)	145 (74.0)	103 (53.1)	50 (26.2)	28 (14.8)	13 (7.0)	6 (3.1)
95% CI	34.7, 49.0	67.2, 80.0	45.8, 60.3	20.1, 33.0	10.1, 20.7	3.8, 11.6	1.2, 6.7
Grade 1	77 (39.7)	125 (63.8)	92 (47.4)	42 (22.0)	26 (13.8)	12 (6.4)	5 (2.6)
Grade 2	4 (2.1)	19 (9.7)	10 (5.2)	5 (2.6)	2 (1.1)	1 (0.5)	1 (0.5)
Grade 3	0	1 (0.5)	1 (0.5)	3 (1.6)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	194	196	194	191	189	187	192
Any	79 (40.7)	145 (74.0)	97 (50.0)	46 (24.1)	25 (13.2)	9 (4.8)	6 (3.1)
Grade 1	75 (38.7)	130 (66.3)	93 (47.9)	44 (23.0)	24 (12.7)	8 (4.3)	5 (2.6)
Grade 2	4 (2.1)	15 (7.7)	4 (2.1)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	194	196	194	191	189	187	192
Any	0	5 (2.6)	8 (4.1)	10 (5.2)	4 (2.1)	0	0
Grade 1	0	4 (2.0)	3 (1.5)	4 (2.1)	3 (1.6)	0	0
Grade 2	0	1 (0.5)	4 (2.1)	3 (1.6)	1 (0.5)	0	0
Grade 3	0	0	1 (0.5)	3 (1.6)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	194	196	194	191	189	187	192
Any	3 (1.5)	12 (6.1)	11 (5.7)	10 (5.2)	7 (3.7)	4 (2.1)	1 (0.5)
Grade 1	3 (1.5)	7 (3.6)	6 (3.1)	8 (4.2)	6 (3.2)	4 (2.1)	1 (0.5)
Grade 2	0	4 (2.0)	5 (2.6)	2 (1.0)	1 (0.5)	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	194	196	194	191	189	187	192
Any	5 (2.6)	10 (5.1)	11 (5.7)	8 (4.2)	3 (1.6)	4 (2.1)	1 (0.5)
Grade 1	5 (2.6)	7 (3.6)	10 (5.2)	8 (4.2)	3 (1.6)	4 (2.1)	1 (0.5)
Grade 2	0	3 (1.5)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	194	196	194	191	190	187	192
Any Solicited Systemic Adverse Reactions	42 (21.6)	125 (63.8)	64 (33.0)	37 (19.4)	29 (15.3)	23 (12.3)	18 (9.4)
95% CI	16.1, 28.1	56.6, 70.5	26.4, 40.1	14.0, 25.7	10.5, 21.2	8.0, 17.9	5.7, 14.4
Grade 1	33 (17.0)	54 (27.6)	43 (22.2)	29 (15.2)	24 (12.6)	18 (9.6)	12 (6.3)
Grade 2	5 (2.6)	57 (29.1)	18 (9.3)	5 (2.6)	3 (1.6)	1 (0.5)	2 (1.0)
Grade 3	4 (2.1)	14 (7.1)	3 (1.5)	3 (1.6)	2 (1.1)	4 (2.1)	2 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	194	196	191	191	189	187	192
Any	1 (0.5)	12 (6.1)	3 (1.6)	0	0	0	0
Grade 1	1 (0.5)	9 (4.6)	3 (1.6)	0	0	0	0
Grade 2	0	2 (1.0)	0	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	194	196	192	191	189	187	192
Any	24 (12.4)	81 (41.3)	32 (16.7)	17 (8.9)	15 (7.9)	15 (8.0)	8 (4.2)
Grade 1	21 (10.8)	56 (28.6)	25 (13.0)	13 (6.8)	12 (6.3)	12 (6.4)	6 (3.1)
Grade 2	1 (0.5)	18 (9.2)	5 (2.6)	2 (1.0)	2 (1.1)	0	1 (0.5)
Grade 3	2 (1.0)	7 (3.6)	2 (1.0)	2 (1.0)	1 (0.5)	3 (1.6)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	194	196	193	191	189	187	192
Any	32 (16.5)	104 (53.1)	48 (24.9)	20 (10.5)	13 (6.9)	10 (5.3)	8 (4.2)
Grade 1	25 (12.9)	46 (23.5)	30 (15.5)	14 (7.3)	10 (5.3)	6 (3.2)	5 (2.6)
Grade 2	4 (2.1)	47 (24.0)	16 (8.3)	5 (2.6)	2 (1.1)	3 (1.6)	2 (1.0)
Grade 3	3 (1.5)	11 (5.6)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Myalgia - N1	194	196	193	191	189	187	192
Any	14 (7.2)	83 (42.3)	31 (16.1)	12 (6.3)	6 (3.2)	4 (2.1)	5 (2.6)
Grade 1	8 (4.1)	35 (17.9)	17 (8.8)	9 (4.7)	4 (2.1)	3 (1.6)	5 (2.6)
Grade 2	4 (2.1)	41 (20.9)	11 (5.7)	3 (1.6)	2 (1.1)	1 (0.5)	0
Grade 3	2 (1.0)	7 (3.6)	3 (1.6)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	194	196	192	191	189	187	192
Any	9 (4.6)	70 (35.7)	24 (12.5)	11 (5.8)	9 (4.8)	6 (3.2)	5 (2.6)
Grade 1	5 (2.6)	34 (17.3)	16 (8.3)	10 (5.2)	7 (3.7)	6 (3.2)	5 (2.6)
Grade 2	3 (1.5)	32 (16.3)	7 (3.6)	1 (0.5)	2 (1.1)	0	0
Grade 3	1 (0.5)	4 (2.0)	1 (0.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	194	196	192	191	189	187	192
Any	3 (1.5)	14 (7.1)	5 (2.6)	4 (2.1)	1 (0.5)	2 (1.1)	1 (0.5)
Grade 1	3 (1.5)	10 (5.1)	3 (1.6)	3 (1.6)	1 (0.5)	0	0
Grade 2	0	4 (2.0)	2 (1.0)	1 (0.5)	0	2 (1.1)	1 (0.5)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Grade and Day of Reporting
Second Injection Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=197)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	194	196	192	191	189	187	192
Any	8 (4.1)	45 (23.0)	14 (7.3)	3 (1.6)	3 (1.6)	1 (0.5)	1 (0.5)
Grade 1	4 (2.1)	22 (11.2)	10 (5.2)	1 (0.5)	2 (1.1)	1 (0.5)	0
Grade 2	4 (2.1)	22 (11.2)	4 (2.1)	2 (1.0)	1 (0.5)	0	1 (0.5)
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	194	196	192	191	189	187	192
Any	1 (0.5)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	0	2 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	200	197	198	197	199	199
Any Solicited Adverse Reactions	47 (23.5)	48 (24.0)	40 (20.3)	27 (13.6)	32 (16.2)	31 (15.6)	29 (14.6)
95% CI	17.8, 30.0	18.3, 30.5	14.9, 26.6	9.2, 19.2	11.4, 22.2	10.8, 21.4	10.0, 20.3
Grade 1	40 (20.0)	37 (18.5)	31 (15.7)	21 (10.6)	27 (13.7)	24 (12.1)	23 (11.6)
Grade 2	6 (3.0)	8 (4.0)	5 (2.5)	3 (1.5)	3 (1.5)	3 (1.5)	2 (1.0)
Grade 3	1 (0.5)	1 (0.5)	3 (1.5)	1 (0.5)	1 (0.5)	3 (1.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	197	198	197	199	199
Any Solicited Local Adverse Reactions	24 (12.0)	12 (6.0)	5 (2.5)	6 (3.0)	7 (3.6)	6 (3.0)	6 (3.0)
95% CI	7.8, 17.3	3.1, 10.2	0.8, 5.8	1.1, 6.5	1.4, 7.2	1.1, 6.4	1.1, 6.4
Grade 1	24 (12.0)	12 (6.0)	5 (2.5)	6 (3.0)	7 (3.6)	5 (2.5)	6 (3.0)
Grade 2	0	0	0	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	200	197	198	197	199	199
Any	21 (10.5)	9 (4.5)	4 (2.0)	3 (1.5)	5 (2.5)	4 (2.0)	3 (1.5)
Grade 1	21 (10.5)	9 (4.5)	4 (2.0)	3 (1.5)	5 (2.5)	4 (2.0)	3 (1.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	200	197	198	197	199	199
Any	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 1	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	200	197	198	197	199	199
Any	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 1	1 (0.5)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lymphadenopathy - N1 [1]	200	200	197	198	197	199	199
Any	2 (1.0)	1 (0.5)	0	2 (1.0)	1 (0.5)	2 (1.0)	2 (1.0)
Grade 1	2 (1.0)	1 (0.5)	0	2 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 2	0	0	0	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	197	198	197	199	199
Any Solicited Systemic Adverse Reactions	34 (17.0)	41 (20.5)	37 (18.8)	24 (12.1)	28 (14.2)	28 (14.1)	24 (12.1)
95% CI	12.1, 22.9	15.1, 26.8	13.6, 24.9	7.9, 17.5	9.7, 19.9	9.6, 19.7	7.9, 17.4
Grade 1	27 (13.5)	30 (15.0)	28 (14.2)	18 (9.1)	23 (11.7)	21 (10.6)	18 (9.0)
Grade 2	6 (3.0)	8 (4.0)	5 (2.5)	3 (1.5)	3 (1.5)	3 (1.5)	2 (1.0)
Grade 3	1 (0.5)	1 (0.5)	3 (1.5)	1 (0.5)	1 (0.5)	3 (1.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	200	197	197	197	197	197
Any	0	0	0	0	1 (0.5)	0	0
Grade 1	0	0	0	0	1 (0.5)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	199	197	198	197	199	199
Any	18 (9.0)	22 (11.1)	14 (7.1)	9 (4.5)	16 (8.1)	12 (6.0)	10 (5.0)
Grade 1	18 (9.0)	22 (11.1)	12 (6.1)	8 (4.0)	15 (7.6)	10 (5.0)	8 (4.0)
Grade 2	0	0	0	1 (0.5)	1 (0.5)	0	1 (0.5)
Grade 3	0	0	2 (1.0)	0	0	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	199	197	198	197	199	199
Any	24 (12.0)	26 (13.1)	23 (11.7)	15 (7.6)	16 (8.1)	12 (6.0)	14 (7.0)
Grade 1	18 (9.0)	18 (9.0)	21 (10.7)	12 (6.1)	14 (7.1)	9 (4.5)	11 (5.5)
Grade 2	5 (2.5)	7 (3.5)	1 (0.5)	2 (1.0)	1 (0.5)	2 (1.0)	1 (0.5)
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	199	197	198	197	199	199
Any	5 (2.5)	7 (3.5)	9 (4.6)	8 (4.0)	3 (1.5)	8 (4.0)	8 (4.0)
Grade 1	5 (2.5)	6 (3.0)	7 (3.6)	6 (3.0)	3 (1.5)	7 (3.5)	8 (4.0)
Grade 2	0	1 (0.5)	2 (1.0)	2 (1.0)	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	199	197	198	197	199	199
Any	2 (1.0)	8 (4.0)	7 (3.6)	4 (2.0)	6 (3.0)	7 (3.5)	8 (4.0)
Grade 1	2 (1.0)	7 (3.5)	4 (2.0)	4 (2.0)	6 (3.0)	6 (3.0)	8 (4.0)
Grade 2	0	1 (0.5)	3 (1.5)	0	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	199	197	198	197	199	199
Any	2 (1.0)	3 (1.5)	2 (1.0)	0	2 (1.0)	3 (1.5)	3 (1.5)
Grade 1	1 (0.5)	3 (1.5)	1 (0.5)	0	2 (1.0)	2 (1.0)	1 (0.5)
Grade 2	1 (0.5)	0	1 (0.5)	0	0	1 (0.5)	2 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	199	197	198	197	199	199
Any	2 (1.0)	3 (1.5)	3 (1.5)	1 (0.5)	3 (1.5)	1 (0.5)	0
Grade 1	2 (1.0)	2 (1.0)	3 (1.5)	1 (0.5)	2 (1.0)	0	0
Grade 2	0	1 (0.5)	0	0	1 (0.5)	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	199	197	198	197	199	199
Any	0	2 (1.0)	1 (0.5)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	200	200	199	200	197	198
Any Solicited Adverse Reactions	121 (60.5)	170 (85.0)	127 (63.5)	79 (39.7)	57 (28.5)	48 (24.4)	44 (22.2)
95% CI	53.4, 67.3	79.3, 89.6	56.4, 70.2	32.8, 46.9	22.4, 35.3	18.5, 31.0	16.6, 28.7
Grade 1	96 (48.0)	96 (48.0)	99 (49.5)	58 (29.1)	43 (21.5)	31 (15.7)	30 (15.2)
Grade 2	16 (8.0)	57 (28.5)	21 (10.5)	13 (6.5)	8 (4.0)	8 (4.1)	5 (2.5)
Grade 3	8 (4.0)	17 (8.5)	7 (3.5)	6 (3.0)	5 (2.5)	6 (3.0)	6 (3.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	200	199	200	197	198
Any Solicited Local Adverse Reactions	111 (55.5)	158 (79.0)	111 (55.5)	50 (25.1)	26 (13.0)	12 (6.1)	4 (2.0)
95% CI	48.3, 62.5	72.7, 84.4	48.3, 62.5	19.3, 31.7	8.7, 18.5	3.2, 10.4	0.6, 5.1
Grade 1	98 (49.0)	131 (65.5)	101 (50.5)	46 (23.1)	23 (11.5)	10 (5.1)	2 (1.0)
Grade 2	11 (5.5)	25 (12.5)	9 (4.5)	3 (1.5)	2 (1.0)	1 (0.5)	1 (0.5)
Grade 3	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	200	200	199	200	197	198
Any	108 (54.0)	158 (79.0)	110 (55.0)	47 (23.6)	22 (11.0)	8 (4.1)	4 (2.0)
Grade 1	97 (48.5)	134 (67.0)	105 (52.5)	45 (22.6)	20 (10.0)	6 (3.0)	2 (1.0)
Grade 2	9 (4.5)	22 (11.0)	4 (2.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 3	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	200	200	199	200	197	198
Any	2 (1.0)	9 (4.5)	8 (4.0)	5 (2.5)	1 (0.5)	0	0
Grade 1	1 (0.5)	7 (3.5)	3 (1.5)	3 (1.5)	0	0	0
Grade 2	1 (0.5)	2 (1.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	200	200	199	200	197	198
Any	2 (1.0)	15 (7.5)	9 (4.5)	8 (4.0)	6 (3.0)	2 (1.0)	0
Grade 1	1 (0.5)	12 (6.0)	6 (3.0)	6 (3.0)	5 (2.5)	2 (1.0)	0
Grade 2	1 (0.5)	3 (1.5)	3 (1.5)	2 (1.0)	1 (0.5)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	200	200	200	199	200	197	198
Any	7 (3.5)	17 (8.5)	10 (5.0)	4 (2.0)	4 (2.0)	5 (2.5)	1 (0.5)
Grade 1	7 (3.5)	11 (5.5)	8 (4.0)	4 (2.0)	4 (2.0)	5 (2.5)	1 (0.5)
Grade 2	0	6 (3.0)	2 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	200	199	200	197	198
Any Solicited Systemic Adverse Reactions	60 (30.0)	121 (60.5)	73 (36.5)	59 (29.6)	45 (22.5)	43 (21.8)	42 (21.2)
95% CI	23.7, 36.9	53.4, 67.3	29.8, 43.6	23.4, 36.5	16.9, 28.9	16.3, 28.3	15.7, 27.6
Grade 1	38 (19.0)	51 (25.5)	49 (24.5)	40 (20.1)	34 (17.0)	28 (14.2)	30 (15.2)
Grade 2	12 (6.0)	54 (27.0)	17 (8.5)	11 (5.5)	6 (3.0)	7 (3.6)	4 (2.0)
Grade 3	7 (3.5)	16 (8.0)	7 (3.5)	6 (3.0)	4 (2.0)	5 (2.5)	5 (2.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	200	200	198	197	196	198
Any	2 (1.0)	12 (6.0)	0	0	0	0	0
Grade 1	1 (0.5)	7 (3.5)	0	0	0	0	0
Grade 2	0	3 (1.5)	0	0	0	0	0
Grade 3	1 (0.5)	2 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	200	200	199	200	197	198
Any	37 (18.5)	81 (40.5)	45 (22.5)	35 (17.6)	24 (12.0)	26 (13.2)	27 (13.6)
Grade 1	30 (15.0)	53 (26.5)	35 (17.5)	26 (13.1)	21 (10.5)	20 (10.2)	23 (11.6)
Grade 2	4 (2.0)	23 (11.5)	9 (4.5)	7 (3.5)	3 (1.5)	4 (2.0)	2 (1.0)
Grade 3	3 (1.5)	5 (2.5)	1 (0.5)	2 (1.0)	0	2 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	200	200	199	200	197	198
Any	33 (16.5)	97 (48.5)	48 (24.0)	34 (17.1)	22 (11.0)	22 (11.2)	17 (8.6)
Grade 1	21 (10.5)	44 (22.0)	29 (14.5)	23 (11.6)	15 (7.5)	13 (6.6)	12 (6.1)
Grade 2	8 (4.0)	44 (22.0)	15 (7.5)	9 (4.5)	4 (2.0)	7 (3.6)	3 (1.5)
Grade 3	4 (2.0)	9 (4.5)	4 (2.0)	2 (1.0)	3 (1.5)	2 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	200	200	199	200	197	198
Any	19 (9.5)	76 (38.0)	33 (16.5)	21 (10.6)	13 (6.5)	9 (4.6)	8 (4.0)
Grade 1	9 (4.5)	32 (16.0)	21 (10.5)	15 (7.5)	10 (5.0)	7 (3.6)	6 (3.0)
Grade 2	5 (2.5)	34 (17.0)	6 (3.0)	4 (2.0)	2 (1.0)	1 (0.5)	1 (0.5)
Grade 3	5 (2.5)	10 (5.0)	6 (3.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	200	200	199	200	197	198
Any	14 (7.0)	62 (31.0)	33 (16.5)	16 (8.0)	13 (6.5)	9 (4.6)	7 (3.5)
Grade 1	6 (3.0)	29 (14.5)	23 (11.5)	12 (6.0)	9 (4.5)	6 (3.0)	5 (2.5)
Grade 2	5 (2.5)	26 (13.0)	5 (2.5)	1 (0.5)	2 (1.0)	1 (0.5)	0
Grade 3	3 (1.5)	7 (3.5)	5 (2.5)	3 (1.5)	2 (1.0)	2 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	200	200	199	200	197	198
Any	5 (2.5)	19 (9.5)	9 (4.5)	5 (2.5)	3 (1.5)	3 (1.5)	1 (0.5)
Grade 1	4 (2.0)	14 (7.0)	8 (4.0)	4 (2.0)	3 (1.5)	2 (1.0)	1 (0.5)
Grade 2	1 (0.5)	5 (2.5)	1 (0.5)	1 (0.5)	0	1 (0.5)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	200	200	199	200	197	198
Any	15 (7.5)	46 (23.0)	14 (7.0)	6 (3.0)	3 (1.5)	1 (0.5)	0
Grade 1	7 (3.5)	20 (10.0)	12 (6.0)	5 (2.5)	2 (1.0)	1 (0.5)	0
Grade 2	7 (3.5)	24 (12.0)	1 (0.5)	1 (0.5)	1 (0.5)	0	0
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	200	200	199	200	197	198
Any	4 (2.0)	3 (1.5)	3 (1.5)	3 (1.5)	5 (2.5)	6 (3.0)	6 (3.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010203.sas 19NOV2020 02:15 Database Lock Date: 05NOV2020

Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	200	198	200	197	198	200
Any Solicited Adverse Reactions	138 (69.0)	184 (92.0)	142 (71.7)	85 (42.5)	58 (29.4)	47 (23.7)	38 (19.0)
95% CI	62.1, 75.3	87.3, 95.4	64.9, 77.9	35.6, 49.7	23.2, 36.3	18.0, 30.3	13.8, 25.1
Grade 1	115 (57.5)	79 (39.5)	99 (50.0)	58 (29.0)	45 (22.8)	38 (19.2)	29 (14.5)
Grade 2	17 (8.5)	79 (39.5)	28 (14.1)	11 (5.5)	6 (3.0)	3 (1.5)	5 (2.5)
Grade 3	6 (3.0)	25 (12.5)	15 (7.6)	14 (7.0)	6 (3.0)	5 (2.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	198	200	197	198	200
Any Solicited Local Adverse Reactions	126 (63.0)	176 (88.0)	127 (64.1)	66 (33.0)	25 (12.7)	19 (9.6)	11 (5.5)
95% CI	55.9, 69.7	82.7, 92.2	57.0, 70.8	26.5, 40.0	8.4, 18.2	5.9, 14.6	2.8, 9.6
Grade 1	121 (60.5)	139 (69.5)	113 (57.1)	57 (28.5)	25 (12.7)	19 (9.6)	11 (5.5)
Grade 2	5 (2.5)	34 (17.0)	12 (6.1)	4 (2.0)	0	0	0
Grade 3	0	3 (1.5)	2 (1.0)	5 (2.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	200	198	200	197	198	200
Any	126 (63.0)	175 (87.5)	124 (62.6)	59 (29.5)	22 (11.2)	12 (6.1)	8 (4.0)
Grade 1	121 (60.5)	142 (71.0)	116 (58.6)	55 (27.5)	22 (11.2)	12 (6.1)	8 (4.0)
Grade 2	5 (2.5)	31 (15.5)	7 (3.5)	3 (1.5)	0	0	0
Grade 3	0	2 (1.0)	1 (0.5)	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	200	198	200	197	198	200
Any	1 (0.5)	7 (3.5)	13 (6.6)	11 (5.5)	3 (1.5)	0	0
Grade 1	1 (0.5)	7 (3.5)	9 (4.5)	6 (3.0)	3 (1.5)	0	0
Grade 2	0	0	3 (1.5)	1 (0.5)	0	0	0
Grade 3	0	0	1 (0.5)	4 (2.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	200	198	200	197	198	200
Any	7 (3.5)	16 (8.0)	16 (8.1)	12 (6.0)	6 (3.0)	5 (2.5)	4 (2.0)
Grade 1	6 (3.0)	12 (6.0)	13 (6.6)	12 (6.0)	6 (3.0)	5 (2.5)	4 (2.0)
Grade 2	1 (0.5)	3 (1.5)	3 (1.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	200	200	198	200	197	198	200
Any	10 (5.0)	14 (7.0)	14 (7.1)	10 (5.0)	1 (0.5)	5 (2.5)	3 (1.5)
Grade 1	7 (3.5)	11 (5.5)	13 (6.6)	10 (5.0)	1 (0.5)	5 (2.5)	3 (1.5)
Grade 2	3 (1.5)	3 (1.5)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	198	200	197	198	200
Any Solicited Systemic Adverse Reactions	69 (34.5)	148 (74.0)	79 (39.9)	49 (24.5)	41 (20.8)	37 (18.7)	31 (15.5)
95% CI	27.9, 41.5	67.3, 79.9	33.0, 47.1	18.7, 31.1	15.4, 27.2	13.5, 24.8	10.8, 21.3
Grade 1	46 (23.0)	54 (27.0)	45 (22.7)	28 (14.0)	28 (14.2)	28 (14.1)	22 (11.0)
Grade 2	16 (8.0)	70 (35.0)	20 (10.1)	9 (4.5)	6 (3.0)	3 (1.5)	5 (2.5)
Grade 3	6 (3.0)	23 (11.5)	13 (6.6)	9 (4.5)	6 (3.0)	5 (2.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	200	198	199	196	198	198
Any	3 (1.5)	21 (10.5)	7 (3.5)	2 (1.0)	1 (0.5)	1 (0.5)	0
Grade 1	2 (1.0)	15 (7.5)	3 (1.5)	1 (0.5)	1 (0.5)	0	0
Grade 2	0	2 (1.0)	2 (1.0)	0	0	1 (0.5)	0
Grade 3	1 (0.5)	4 (2.0)	2 (1.0)	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	200	197	200	196	198	200
Any	37 (18.5)	99 (49.5)	38 (19.3)	22 (11.0)	20 (10.2)	22 (11.1)	18 (9.0)
Grade 1	31 (15.5)	54 (27.0)	24 (12.2)	15 (7.5)	14 (7.1)	18 (9.1)	13 (6.5)
Grade 2	4 (2.0)	37 (18.5)	10 (5.1)	4 (2.0)	3 (1.5)	1 (0.5)	3 (1.5)
Grade 3	2 (1.0)	8 (4.0)	4 (2.0)	3 (1.5)	3 (1.5)	3 (1.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	200	197	200	196	198	200
Any	46 (23.0)	117 (58.5)	61 (31.0)	29 (14.5)	25 (12.8)	18 (9.1)	15 (7.5)
Grade 1	29 (14.5)	40 (20.0)	38 (19.3)	19 (9.5)	20 (10.2)	13 (6.6)	10 (5.0)
Grade 2	15 (7.5)	61 (30.5)	14 (7.1)	7 (3.5)	3 (1.5)	4 (2.0)	4 (2.0)
Grade 3	2 (1.0)	16 (8.0)	9 (4.6)	3 (1.5)	2 (1.0)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	200	197	200	196	198	200
Any	32 (16.0)	103 (51.5)	37 (18.8)	13 (6.5)	11 (5.6)	8 (4.0)	10 (5.0)
Grade 1	21 (10.5)	37 (18.5)	18 (9.1)	7 (3.5)	6 (3.1)	4 (2.0)	8 (4.0)
Grade 2	8 (4.0)	50 (25.0)	10 (5.1)	2 (1.0)	2 (1.0)	2 (1.0)	1 (0.5)
Grade 3	3 (1.5)	16 (8.0)	9 (4.6)	4 (2.0)	3 (1.5)	2 (1.0)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	200	197	200	196	198	200
Any	18 (9.0)	74 (37.0)	27 (13.7)	11 (5.5)	10 (5.1)	9 (4.5)	4 (2.0)
Grade 1	10 (5.0)	30 (15.0)	15 (7.6)	6 (3.0)	5 (2.6)	6 (3.0)	4 (2.0)
Grade 2	6 (3.0)	35 (17.5)	6 (3.0)	2 (1.0)	3 (1.5)	2 (1.0)	0
Grade 3	2 (1.0)	9 (4.5)	6 (3.0)	3 (1.5)	2 (1.0)	1 (0.5)	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	200	197	200	196	198	200
Any	8 (4.0)	31 (15.5)	11 (5.6)	3 (1.5)	4 (2.0)	2 (1.0)	5 (2.5)
Grade 1	5 (2.5)	22 (11.0)	7 (3.6)	2 (1.0)	4 (2.0)	1 (0.5)	4 (2.0)
Grade 2	3 (1.5)	9 (4.5)	4 (2.0)	0	0	1 (0.5)	1 (0.5)
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	200	197	200	196	198	200
Any	17 (8.5)	73 (36.5)	17 (8.6)	5 (2.5)	3 (1.5)	1 (0.5)	3 (1.5)
Grade 1	13 (6.5)	30 (15.0)	7 (3.6)	2 (1.0)	3 (1.5)	1 (0.5)	1 (0.5)
Grade 2	4 (2.0)	42 (21.0)	10 (5.1)	2 (1.0)	0	0	2 (1.0)
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	200	197	200	196	198	200
Any	2 (1.0)	6 (3.0)	2 (1.0)	4 (2.0)	2 (1.0)	1 (0.5)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	400	400	398	399	397	395	398
Any Solicited Adverse Reactions	259 (64.8)	354 (88.5)	269 (67.6)	164 (41.1)	115 (29.0)	95 (24.1)	82 (20.6)
95% CI	59.8, 69.4	85.0, 91.5	62.7, 72.2	36.2, 46.1	24.6, 33.7	19.9, 28.6	16.7, 24.9
Grade 1	211 (52.8)	175 (43.8)	198 (49.7)	116 (29.1)	88 (22.2)	69 (17.5)	59 (14.8)
Grade 2	33 (8.3)	136 (34.0)	49 (12.3)	24 (6.0)	14 (3.5)	11 (2.8)	10 (2.5)
Grade 3	14 (3.5)	42 (10.5)	22 (5.5)	20 (5.0)	11 (2.8)	11 (2.8)	9 (2.3)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	400	400	398	399	397	395	398
Any Solicited Local Adverse Reactions	237 (59.3)	334 (83.5)	238 (59.8)	116 (29.1)	51 (12.8)	31 (7.8)	15 (3.8)
95% CI	54.3, 64.1	79.5, 87.0	54.8, 64.7	24.7, 33.8	9.7, 16.5	5.4, 11.0	2.1, 6.1
Grade 1	219 (54.8)	270 (67.5)	214 (53.8)	103 (25.8)	48 (12.1)	29 (7.3)	13 (3.3)
Grade 2	16 (4.0)	59 (14.8)	21 (5.3)	7 (1.8)	2 (0.5)	1 (0.3)	1 (0.3)
Grade 3	2 (0.5)	5 (1.3)	3 (0.8)	6 (1.5)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	400	400	398	399	397	395	398
Any	234 (58.5)	333 (83.3)	234 (58.8)	106 (26.6)	44 (11.1)	20 (5.1)	12 (3.0)
Grade 1	218 (54.5)	276 (69.0)	221 (55.5)	100 (25.1)	42 (10.6)	18 (4.6)	10 (2.5)
Grade 2	14 (3.5)	53 (13.3)	11 (2.8)	4 (1.0)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 3	2 (0.5)	4 (1.0)	2 (0.5)	2 (0.5)	1 (0.3)	1 (0.3)	1 (0.3)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	400	400	398	399	397	395	398
Any	3 (0.8)	16 (4.0)	21 (5.3)	16 (4.0)	4 (1.0)	0	0
Grade 1	2 (0.5)	14 (3.5)	12 (3.0)	9 (2.3)	3 (0.8)	0	0
Grade 2	1 (0.3)	2 (0.5)	8 (2.0)	3 (0.8)	1 (0.3)	0	0
Grade 3	0	0	1 (0.3)	4 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	400	400	398	399	397	395	398
Any	9 (2.3)	31 (7.8)	25 (6.3)	20 (5.0)	12 (3.0)	7 (1.8)	4 (1.0)
Grade 1	7 (1.8)	24 (6.0)	19 (4.8)	18 (4.5)	11 (2.8)	7 (1.8)	4 (1.0)
Grade 2	2 (0.5)	6 (1.5)	6 (1.5)	2 (0.5)	1 (0.3)	0	0
Grade 3	0	1 (0.3)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lymphadenopathy - N1 [1]	400	400	398	399	397	395	398
Any	17 (4.3)	31 (7.8)	24 (6.0)	14 (3.5)	5 (1.3)	10 (2.5)	4 (1.0)
Grade 1	14 (3.5)	22 (5.5)	21 (5.3)	14 (3.5)	5 (1.3)	10 (2.5)	4 (1.0)
Grade 2	3 (0.8)	9 (2.3)	3 (0.8)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	400	400	398	399	397	395	398
Any Solicited Systemic Adverse Reactions	129 (32.3)	269 (67.3)	152 (38.2)	108 (27.1)	86 (21.7)	80 (20.3)	73 (18.3)
95% CI	27.7, 37.1	62.4, 71.8	33.4, 43.2	22.8, 31.7	17.7, 26.0	16.4, 24.6	14.7, 22.5
Grade 1	84 (21.0)	105 (26.3)	94 (23.6)	68 (17.0)	62 (15.6)	56 (14.2)	52 (13.1)
Grade 2	28 (7.0)	124 (31.0)	37 (9.3)	20 (5.0)	12 (3.0)	10 (2.5)	9 (2.3)
Grade 3	13 (3.3)	39 (9.8)	20 (5.0)	15 (3.8)	10 (2.5)	10 (2.5)	8 (2.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	400	400	398	397	393	394	396
Any	5 (1.3)	33 (8.3)	7 (1.8)	2 (0.5)	1 (0.3)	1 (0.3)	0
Grade 1	3 (0.8)	22 (5.5)	3 (0.8)	1 (0.3)	1 (0.3)	0	0
Grade 2	0	5 (1.3)	2 (0.5)	0	0	1 (0.3)	0
Grade 3	2 (0.5)	6 (1.5)	2 (0.5)	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	400	400	397	399	396	395	398
Any	74 (18.5)	180 (45.0)	83 (20.9)	57 (14.3)	44 (11.1)	48 (12.2)	45 (11.3)
Grade 1	61 (15.3)	107 (26.8)	59 (14.9)	41 (10.3)	35 (8.8)	38 (9.6)	36 (9.0)
Grade 2	8 (2.0)	60 (15.0)	19 (4.8)	11 (2.8)	6 (1.5)	5 (1.3)	5 (1.3)
Grade 3	5 (1.3)	13 (3.3)	5 (1.3)	5 (1.3)	3 (0.8)	5 (1.3)	4 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	400	400	397	399	396	395	398
Any	79 (19.8)	214 (53.5)	109 (27.5)	63 (15.8)	47 (11.9)	40 (10.1)	32 (8.0)
Grade 1	50 (12.5)	84 (21.0)	67 (16.9)	42 (10.5)	35 (8.8)	26 (6.6)	22 (5.5)
Grade 2	23 (5.8)	105 (26.3)	29 (7.3)	16 (4.0)	7 (1.8)	11 (2.8)	7 (1.8)
Grade 3	6 (1.5)	25 (6.3)	13 (3.3)	5 (1.3)	5 (1.3)	3 (0.8)	3 (0.8)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	400	400	397	399	396	395	398
Any	51 (12.8)	179 (44.8)	70 (17.6)	34 (8.5)	24 (6.1)	17 (4.3)	18 (4.5)
Grade 1	30 (7.5)	69 (17.3)	39 (9.8)	22 (5.5)	16 (4.0)	11 (2.8)	14 (3.5)
Grade 2	13 (3.3)	84 (21.0)	16 (4.0)	6 (1.5)	4 (1.0)	3 (0.8)	2 (0.5)
Grade 3	8 (2.0)	26 (6.5)	15 (3.8)	6 (1.5)	4 (1.0)	3 (0.8)	2 (0.5)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	400	400	397	399	396	395	398
Any	32 (8.0)	136 (34.0)	60 (15.1)	27 (6.8)	23 (5.8)	18 (4.6)	11 (2.8)
Grade 1	16 (4.0)	59 (14.8)	38 (9.6)	18 (4.5)	14 (3.5)	12 (3.0)	9 (2.3)
Grade 2	11 (2.8)	61 (15.3)	11 (2.8)	3 (0.8)	5 (1.3)	3 (0.8)	0
Grade 3	5 (1.3)	16 (4.0)	11 (2.8)	6 (1.5)	4 (1.0)	3 (0.8)	2 (0.5)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	400	400	397	399	396	395	398
Any	13 (3.3)	50 (12.5)	20 (5.0)	8 (2.0)	7 (1.8)	5 (1.3)	6 (1.5)
Grade 1	9 (2.3)	36 (9.0)	15 (3.8)	6 (1.5)	7 (1.8)	3 (0.8)	5 (1.3)
Grade 2	4 (1.0)	14 (3.5)	5 (1.3)	1 (0.3)	0	2 (0.5)	1 (0.3)
Grade 3	0	0	0	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	400	400	397	399	396	395	398
Any	32 (8.0)	119 (29.8)	31 (7.8)	11 (2.8)	6 (1.5)	2 (0.5)	3 (0.8)
Grade 1	20 (5.0)	50 (12.5)	19 (4.8)	7 (1.8)	5 (1.3)	2 (0.5)	1 (0.3)
Grade 2	11 (2.8)	66 (16.5)	11 (2.8)	3 (0.8)	1 (0.3)	0	2 (0.5)
Grade 3	1 (0.3)	3 (0.8)	1 (0.3)	1 (0.3)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	400	400	397	399	396	395	398
Any	6 (1.5)	9 (2.3)	5 (1.3)	7 (1.8)	7 (1.8)	7 (1.8)	7 (1.8)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	99	98	97	100	99
Any Solicited Adverse Reactions	24 (24.0)	23 (23.0)	17 (17.2)	14 (14.3)	18 (18.6)	15 (15.0)	16 (16.2)
95% CI	16.0, 33.6	15.2, 32.5	10.3, 26.1	8.0, 22.8	11.4, 27.7	8.6, 23.5	9.5, 24.9
Grade 1	23 (23.0)	17 (17.0)	11 (11.1)	10 (10.2)	15 (15.5)	9 (9.0)	11 (11.1)
Grade 2	0	3 (3.0)	4 (4.0)	2 (2.0)	2 (2.1)	3 (3.0)	1 (1.0)
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	3 (3.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	99	98	97	100	99
Any Solicited Local Adverse Reactions	16 (16.0)	7 (7.0)	3 (3.0)	4 (4.1)	4 (4.1)	3 (3.0)	4 (4.0)
95% CI	9.4, 24.7	2.9, 13.9	0.6, 8.6	1.1, 10.1	1.1, 10.2	0.6, 8.5	1.1, 10.0
Grade 1	16 (16.0)	7 (7.0)	3 (3.0)	4 (4.1)	4 (4.1)	2 (2.0)	4 (4.0)
Grade 2	0	0	0	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	99	98	97	100	99
Any	14 (14.0)	6 (6.0)	3 (3.0)	3 (3.1)	4 (4.1)	3 (3.0)	2 (2.0)
Grade 1	14 (14.0)	6 (6.0)	3 (3.0)	3 (3.1)	4 (4.1)	3 (3.0)	2 (2.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	99	98	97	100	99
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	99	98	97	100	99
Any	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	99	98	97	100	99
Any	2 (2.0)	1 (1.0)	0	1 (1.0)	0	1 (1.0)	2 (2.0)
Grade 1	2 (2.0)	1 (1.0)	0	1 (1.0)	0	0	2 (2.0)
Grade 2	0	0	0	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	99	98	97	100	99
Any Solicited Systemic Adverse Reactions	15 (15.0)	20 (20.0)	16 (16.2)	12 (12.2)	17 (17.5)	14 (14.0)	13 (13.1)
95% CI	8.6, 23.5	12.7, 29.2	9.5, 24.9	6.5, 20.4	10.6, 26.6	7.9, 22.4	7.2, 21.4
Grade 1	14 (14.0)	14 (14.0)	10 (10.1)	8 (8.2)	14 (14.4)	8 (8.0)	8 (8.1)
Grade 2	0	3 (3.0)	4 (4.0)	2 (2.0)	2 (2.1)	3 (3.0)	1 (1.0)
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	3 (3.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	99	98	97	100	98
Any	0	0	0	0	1 (1.0)	0	0
Grade 1	0	0	0	0	1 (1.0)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	99	99	98	97	100	99
Any	8 (8.0)	10 (10.1)	4 (4.0)	5 (5.1)	12 (12.4)	6 (6.0)	8 (8.1)
Grade 1	8 (8.0)	10 (10.1)	4 (4.0)	4 (4.1)	11 (11.3)	5 (5.0)	7 (7.1)
Grade 2	0	0	0	1 (1.0)	1 (1.0)	0	0
Grade 3	0	0	0	0	0	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	99	99	98	97	100	99
Any	10 (10.0)	12 (12.1)	10 (10.1)	8 (8.2)	10 (10.3)	8 (8.0)	7 (7.1)
Grade 1	9 (9.0)	8 (8.1)	9 (9.1)	5 (5.1)	9 (9.3)	5 (5.0)	5 (5.1)
Grade 2	0	3 (3.0)	0	2 (2.0)	0	2 (2.0)	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Myalgia - N1	100	99	99	98	97	100	99
Any	1 (1.0)	1 (1.0)	3 (3.0)	3 (3.1)	1 (1.0)	4 (4.0)	3 (3.0)
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (3.0)	3 (3.0)
Grade 2	0	0	2 (2.0)	1 (1.0)	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	99	99	98	97	100	99
Any	0	2 (2.0)	3 (3.0)	1 (1.0)	2 (2.1)	3 (3.0)	3 (3.0)
Grade 1	0	2 (2.0)	0	1 (1.0)	2 (2.1)	2 (2.0)	3 (3.0)
Grade 2	0	0	3 (3.0)	0	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	99	99	98	97	100	99
Any	0	3 (3.0)	1 (1.0)	0	2 (2.1)	2 (2.0)	1 (1.0)
Grade 1	0	3 (3.0)	0	0	2 (2.1)	1 (1.0)	0
Grade 2	0	0	1 (1.0)	0	0	1 (1.0)	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	99	99	98	97	100	99
Any	1 (1.0)	2 (2.0)	2 (2.0)	0	1 (1.0)	1 (1.0)	0
Grade 1	1 (1.0)	1 (1.0)	2 (2.0)	0	0	0	0
Grade 2	0	1 (1.0)	0	0	1 (1.0)	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	99	99	98	97	100	99
Any	0	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	100	99	100	98	99
Any Solicited Adverse Reactions	68 (68.0)	85 (85.0)	60 (60.0)	36 (36.4)	25 (25.0)	21 (21.4)	25 (25.3)
95% CI	57.9, 77.0	76.5, 91.4	49.7, 69.7	26.9, 46.6	16.9, 34.7	13.8, 30.9	17.1, 35.0
Grade 1	51 (51.0)	47 (47.0)	46 (46.0)	27 (27.3)	17 (17.0)	10 (10.2)	15 (15.2)
Grade 2	11 (11.0)	28 (28.0)	8 (8.0)	4 (4.0)	4 (4.0)	5 (5.1)	4 (4.0)
Grade 3	5 (5.0)	10 (10.0)	6 (6.0)	3 (3.0)	3 (3.0)	3 (3.1)	4 (4.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	99	100	98	99
Any Solicited Local Adverse Reactions	64 (64.0)	81 (81.0)	55 (55.0)	23 (23.2)	9 (9.0)	3 (3.1)	2 (2.0)
95% CI	53.8, 73.4	71.9, 88.2	44.7, 65.0	15.3, 32.8	4.2, 16.4	0.6, 8.7	0.2, 7.1
Grade 1	56 (56.0)	65 (65.0)	51 (51.0)	22 (22.2)	8 (8.0)	2 (2.0)	1 (1.0)
Grade 2	7 (7.0)	14 (14.0)	3 (3.0)	0	0	0	0
Grade 3	1 (1.0)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	100	99	100	98	99
Any	64 (64.0)	81 (81.0)	55 (55.0)	21 (21.2)	7 (7.0)	2 (2.0)	2 (2.0)
Grade 1	58 (58.0)	67 (67.0)	53 (53.0)	20 (20.2)	6 (6.0)	1 (1.0)	1 (1.0)
Grade 2	5 (5.0)	12 (12.0)	1 (1.0)	0	0	0	0
Grade 3	1 (1.0)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	99	100	98	99
Any	1 (1.0)	5 (5.0)	4 (4.0)	2 (2.0)	0	0	0
Grade 1	0	4 (4.0)	2 (2.0)	2 (2.0)	0	0	0
Grade 2	1 (1.0)	1 (1.0)	2 (2.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	100	99	100	98	99
Any	2 (2.0)	8 (8.0)	4 (4.0)	3 (3.0)	2 (2.0)	0	0
Grade 1	1 (1.0)	6 (6.0)	3 (3.0)	3 (3.0)	2 (2.0)	0	0
Grade 2	1 (1.0)	2 (2.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	100	99	100	98	99
Any	4 (4.0)	7 (7.0)	5 (5.0)	1 (1.0)	0	1 (1.0)	0
Grade 1	4 (4.0)	4 (4.0)	4 (4.0)	1 (1.0)	0	1 (1.0)	0
Grade 2	0	3 (3.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	100	99	100	98	99
Any Solicited Systemic Adverse Reactions	36 (36.0)	59 (59.0)	33 (33.0)	27 (27.3)	20 (20.0)	20 (20.4)	24 (24.2)
95% CI	26.6, 46.2	48.7, 68.7	23.9, 43.1	18.8, 37.1	12.7, 29.2	12.9, 29.7	16.2, 33.9
Grade 1	20 (20.0)	24 (24.0)	20 (20.0)	18 (18.2)	13 (13.0)	10 (10.2)	15 (15.2)
Grade 2	8 (8.0)	26 (26.0)	7 (7.0)	4 (4.0)	4 (4.0)	5 (5.1)	4 (4.0)
Grade 3	5 (5.0)	9 (9.0)	6 (6.0)	3 (3.0)	2 (2.0)	2 (2.0)	3 (3.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	100	99	98	97	99
Any	2 (2.0)	7 (7.0)	0	0	0	0	0
Grade 1	1 (1.0)	3 (3.0)	0	0	0	0	0
Grade 2	0	2 (2.0)	0	0	0	0	0
Grade 3	1 (1.0)	2 (2.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	100	100	99	100	98	99
Any	20 (20.0)	40 (40.0)	27 (27.0)	19 (19.2)	13 (13.0)	10 (10.2)	17 (17.2)
Grade 1	15 (15.0)	24 (24.0)	19 (19.0)	15 (15.2)	11 (11.0)	7 (7.1)	14 (14.1)
Grade 2	3 (3.0)	14 (14.0)	7 (7.0)	4 (4.0)	2 (2.0)	3 (3.1)	2 (2.0)
Grade 3	2 (2.0)	2 (2.0)	1 (1.0)	0	0	0	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	100	100	99	100	98	99
Any	14 (14.0)	43 (43.0)	18 (18.0)	16 (16.2)	8 (8.0)	10 (10.2)	8 (8.1)
Grade 1	7 (7.0)	18 (18.0)	10 (10.0)	11 (11.1)	5 (5.0)	5 (5.1)	4 (4.0)
Grade 2	5 (5.0)	21 (21.0)	5 (5.0)	4 (4.0)	2 (2.0)	4 (4.1)	3 (3.0)
Grade 3	2 (2.0)	4 (4.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	100	99	100	98	99
Any	12 (12.0)	38 (38.0)	15 (15.0)	10 (10.1)	7 (7.0)	5 (5.1)	5 (5.1)
Grade 1	6 (6.0)	15 (15.0)	8 (8.0)	7 (7.1)	5 (5.0)	4 (4.1)	3 (3.0)
Grade 2	2 (2.0)	16 (16.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	1 (1.0)
Grade 3	4 (4.0)	7 (7.0)	5 (5.0)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	100	100	99	100	98	99
Any	8 (8.0)	24 (24.0)	15 (15.0)	7 (7.1)	7 (7.0)	5 (5.1)	3 (3.0)
Grade 1	3 (3.0)	11 (11.0)	9 (9.0)	3 (3.0)	4 (4.0)	2 (2.0)	1 (1.0)
Grade 2	2 (2.0)	8 (8.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 3	3 (3.0)	5 (5.0)	5 (5.0)	3 (3.0)	2 (2.0)	2 (2.0)	2 (2.0)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	100	99	100	98	99
Any	4 (4.0)	14 (14.0)	5 (5.0)	2 (2.0)	2 (2.0)	2 (2.0)	1 (1.0)
Grade 1	3 (3.0)	10 (10.0)	5 (5.0)	2 (2.0)	2 (2.0)	2 (2.0)	1 (1.0)
Grade 2	1 (1.0)	4 (4.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	100	100	99	100	98	99
Any	9 (9.0)	28 (28.0)	6 (6.0)	3 (3.0)	0	0	0
Grade 1	4 (4.0)	9 (9.0)	5 (5.0)	3 (3.0)	0	0	0
Grade 2	4 (4.0)	18 (18.0)	0	0	0	0	0
Grade 3	1 (1.0)	1 (1.0)	1 (1.0)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	100	100	99	100	98	99
Any	3 (3.0)	2 (2.0)	2 (2.0)	2 (2.0)	3 (3.0)	4 (4.1)	2 (2.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	98	100	98	98	100
Any Solicited Adverse Reactions	71 (71.0)	94 (94.0)	73 (74.5)	43 (43.0)	26 (26.5)	23 (23.5)	21 (21.0)
95% CI	61.1, 79.6	87.4, 97.8	64.7, 82.8	33.1, 53.3	18.1, 36.4	15.5, 33.1	13.5, 30.3
Grade 1	56 (56.0)	33 (33.0)	49 (50.0)	28 (28.0)	17 (17.3)	18 (18.4)	16 (16.0)
Grade 2	12 (12.0)	44 (44.0)	13 (13.3)	4 (4.0)	4 (4.1)	1 (1.0)	3 (3.0)
Grade 3	3 (3.0)	16 (16.0)	11 (11.2)	9 (9.0)	4 (4.1)	3 (3.1)	2 (2.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	98	100	98	98	100
Any Solicited Local Adverse Reactions	68 (68.0)	90 (90.0)	65 (66.3)	32 (32.0)	10 (10.2)	13 (13.3)	7 (7.0)
95% CI	57.9, 77.0	82.4, 95.1	56.1, 75.6	23.0, 42.1	5.0, 18.0	7.3, 21.6	2.9, 13.9
Grade 1	64 (64.0)	62 (62.0)	56 (57.1)	28 (28.0)	10 (10.2)	13 (13.3)	7 (7.0)
Grade 2	4 (4.0)	26 (26.0)	8 (8.2)	2 (2.0)	0	0	0
Grade 3	0	2 (2.0)	1 (1.0)	2 (2.0)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	98	100	98	98	100
Any	68 (68.0)	90 (90.0)	65 (66.3)	28 (28.0)	9 (9.2)	7 (7.1)	4 (4.0)
Grade 1	64 (64.0)	62 (62.0)	58 (59.2)	25 (25.0)	9 (9.2)	7 (7.1)	4 (4.0)
Grade 2	4 (4.0)	26 (26.0)	6 (6.1)	2 (2.0)	0	0	0
Grade 3	0	2 (2.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	98	100	98	98	100
Any	1 (1.0)	5 (5.0)	7 (7.1)	3 (3.0)	0	0	0
Grade 1	1 (1.0)	5 (5.0)	5 (5.1)	2 (2.0)	0	0	0
Grade 2	0	0	2 (2.0)	0	0	0	0
Grade 3	0	0	0	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	98	100	98	98	100
Any	4 (4.0)	7 (7.0)	8 (8.2)	5 (5.0)	3 (3.1)	3 (3.1)	3 (3.0)
Grade 1	3 (3.0)	7 (7.0)	8 (8.2)	5 (5.0)	3 (3.1)	3 (3.1)	3 (3.0)
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	98	100	98	98	100
Any	7 (7.0)	11 (11.0)	7 (7.1)	5 (5.0)	1 (1.0)	5 (5.1)	3 (3.0)
Grade 1	5 (5.0)	8 (8.0)	6 (6.1)	5 (5.0)	1 (1.0)	5 (5.1)	3 (3.0)
Grade 2	2 (2.0)	3 (3.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	98	100	98	98	100
Any Solicited Systemic Adverse Reactions	37 (37.0)	79 (79.0)	43 (43.9)	29 (29.0)	21 (21.4)	18 (18.4)	18 (18.0)
95% CI	27.6, 47.2	69.7, 86.5	33.9, 54.3	20.4, 38.9	13.8, 30.9	11.3, 27.5	11.0, 26.9
Grade 1	22 (22.0)	24 (24.0)	25 (25.5)	16 (16.0)	12 (12.2)	13 (13.3)	13 (13.0)
Grade 2	11 (11.0)	39 (39.0)	7 (7.1)	3 (3.0)	4 (4.1)	1 (1.0)	3 (3.0)
Grade 3	3 (3.0)	15 (15.0)	10 (10.2)	7 (7.0)	4 (4.1)	3 (3.1)	2 (2.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	98	99	97	98	99
Any	2 (2.0)	14 (14.0)	3 (3.1)	2 (2.0)	1 (1.0)	1 (1.0)	0
Grade 1	1 (1.0)	10 (10.0)	0	1 (1.0)	1 (1.0)	0	0
Grade 2	0	1 (1.0)	1 (1.0)	0	0	1 (1.0)	0
Grade 3	1 (1.0)	3 (3.0)	2 (2.0)	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	100	98	100	98	98	100
Any	19 (19.0)	53 (53.0)	18 (18.4)	13 (13.0)	10 (10.2)	11 (11.2)	13 (13.0)
Grade 1	15 (15.0)	22 (22.0)	10 (10.2)	9 (9.0)	6 (6.1)	9 (9.2)	10 (10.0)
Grade 2	3 (3.0)	27 (27.0)	6 (6.1)	2 (2.0)	2 (2.0)	1 (1.0)	2 (2.0)
Grade 3	1 (1.0)	4 (4.0)	2 (2.0)	2 (2.0)	2 (2.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	100	98	100	98	98	100
Any	24 (24.0)	62 (62.0)	33 (33.7)	16 (16.0)	16 (16.3)	9 (9.2)	9 (9.0)
Grade 1	13 (13.0)	18 (18.0)	21 (21.4)	12 (12.0)	13 (13.3)	7 (7.1)	6 (6.0)
Grade 2	11 (11.0)	35 (35.0)	5 (5.1)	2 (2.0)	2 (2.0)	1 (1.0)	2 (2.0)
Grade 3	0	9 (9.0)	7 (7.1)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	98	100	98	98	100
Any	22 (22.0)	55 (55.0)	17 (17.3)	7 (7.0)	7 (7.1)	6 (6.1)	6 (6.0)
Grade 1	14 (14.0)	18 (18.0)	9 (9.2)	4 (4.0)	4 (4.1)	3 (3.1)	4 (4.0)
Grade 2	7 (7.0)	26 (26.0)	2 (2.0)	0	1 (1.0)	1 (1.0)	1 (1.0)
Grade 3	1 (1.0)	11 (11.0)	6 (6.1)	3 (3.0)	2 (2.0)	2 (2.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	100	98	100	98	98	100
Any	13 (13.0)	37 (37.0)	15 (15.3)	5 (5.0)	4 (4.1)	5 (5.1)	2 (2.0)
Grade 1	7 (7.0)	11 (11.0)	9 (9.2)	2 (2.0)	1 (1.0)	3 (3.1)	2 (2.0)
Grade 2	6 (6.0)	20 (20.0)	2 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	0
Grade 3	0	6 (6.0)	4 (4.1)	2 (2.0)	1 (1.0)	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	98	100	98	98	100
Any	6 (6.0)	20 (20.0)	7 (7.1)	0	2 (2.0)	1 (1.0)	3 (3.0)
Grade 1	3 (3.0)	14 (14.0)	5 (5.1)	0	2 (2.0)	1 (1.0)	3 (3.0)
Grade 2	3 (3.0)	6 (6.0)	2 (2.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	100	98	100	98	98	100
Any	11 (11.0)	44 (44.0)	7 (7.1)	3 (3.0)	1 (1.0)	1 (1.0)	2 (2.0)
Grade 1	9 (9.0)	18 (18.0)	2 (2.0)	2 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 2	2 (2.0)	25 (25.0)	5 (5.1)	1 (1.0)	0	0	1 (1.0)
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	100	98	100	98	98	100
Any	2 (2.0)	5 (5.0)	1 (1.0)	3 (3.0)	1 (1.0)	1 (1.0)	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	200	198	199	198	196	199
Any Solicited Adverse Reactions	139 (69.5)	179 (89.5)	133 (67.2)	79 (39.7)	51 (25.8)	44 (22.4)	46 (23.1)
95% CI	62.6, 75.8	84.4, 93.4	60.2, 73.7	32.8, 46.9	19.8, 32.4	16.8, 28.9	17.4, 29.6
Grade 1	107 (53.5)	80 (40.0)	95 (48.0)	55 (27.6)	34 (17.2)	28 (14.3)	31 (15.6)
Grade 2	23 (11.5)	72 (36.0)	21 (10.6)	8 (4.0)	8 (4.0)	6 (3.1)	7 (3.5)
Grade 3	8 (4.0)	26 (13.0)	17 (8.6)	12 (6.0)	7 (3.5)	6 (3.1)	6 (3.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	198	199	198	196	199
Any Solicited Local Adverse Reactions	132 (66.0)	171 (85.5)	120 (60.6)	55 (27.6)	19 (9.6)	16 (8.2)	9 (4.5)
95% CI	59.0, 72.5	79.8, 90.1	53.4, 67.5	21.5, 34.4	5.9, 14.6	4.7, 12.9	2.1, 8.4
Grade 1	120 (60.0)	127 (63.5)	107 (54.0)	50 (25.1)	18 (9.1)	15 (7.7)	8 (4.0)
Grade 2	11 (5.5)	40 (20.0)	11 (5.6)	2 (1.0)	0	0	0
Grade 3	1 (0.5)	4 (2.0)	2 (1.0)	3 (1.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	200	198	199	198	196	199
Any	132 (66.0)	171 (85.5)	120 (60.6)	49 (24.6)	16 (8.1)	9 (4.6)	6 (3.0)
Grade 1	122 (61.0)	129 (64.5)	111 (56.1)	45 (22.6)	15 (7.6)	8 (4.1)	5 (2.5)
Grade 2	9 (4.5)	38 (19.0)	7 (3.5)	2 (1.0)	0	0	0
Grade 3	1 (0.5)	4 (2.0)	2 (1.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	200	198	199	198	196	199
Any	2 (1.0)	10 (5.0)	11 (5.6)	5 (2.5)	0	0	0
Grade 1	1 (0.5)	9 (4.5)	7 (3.5)	4 (2.0)	0	0	0
Grade 2	1 (0.5)	1 (0.5)	4 (2.0)	0	0	0	0
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	200	198	199	198	196	199
Any	6 (3.0)	15 (7.5)	12 (6.1)	8 (4.0)	5 (2.5)	3 (1.5)	3 (1.5)
Grade 1	4 (2.0)	13 (6.5)	11 (5.6)	8 (4.0)	5 (2.5)	3 (1.5)	3 (1.5)
Grade 2	2 (1.0)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Lymphadenopathy - N1 [1]	200	200	198	199	198	196	199
Any	11 (5.5)	18 (9.0)	12 (6.1)	6 (3.0)	1 (0.5)	6 (3.1)	3 (1.5)
Grade 1	9 (4.5)	12 (6.0)	10 (5.1)	6 (3.0)	1 (0.5)	6 (3.1)	3 (1.5)
Grade 2	2 (1.0)	6 (3.0)	2 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	198	199	198	196	199
Any Solicited Systemic Adverse Reactions	73 (36.5)	138 (69.0)	76 (38.4)	56 (28.1)	41 (20.7)	38 (19.4)	42 (21.1)
95% CI	29.8, 43.6	62.1, 75.3	31.6, 45.5	22.0, 34.9	15.3, 27.0	14.1, 25.6	15.7, 27.4
Grade 1	42 (21.0)	48 (24.0)	45 (22.7)	34 (17.1)	25 (12.6)	23 (11.7)	28 (14.1)
Grade 2	19 (9.5)	65 (32.5)	14 (7.1)	7 (3.5)	8 (4.0)	6 (3.1)	7 (3.5)
Grade 3	8 (4.0)	24 (12.0)	16 (8.1)	10 (5.0)	6 (3.0)	5 (2.6)	5 (2.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	200	198	198	195	195	198
Any	4 (2.0)	21 (10.5)	3 (1.5)	2 (1.0)	1 (0.5)	1 (0.5)	0
Grade 1	2 (1.0)	13 (6.5)	0	1 (0.5)	1 (0.5)	0	0
Grade 2	0	3 (1.5)	1 (0.5)	0	0	1 (0.5)	0
Grade 3	2 (1.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	200	198	199	198	196	199
Any	39 (19.5)	93 (46.5)	45 (22.7)	32 (16.1)	23 (11.6)	21 (10.7)	30 (15.1)
Grade 1	30 (15.0)	46 (23.0)	29 (14.6)	24 (12.1)	17 (8.6)	16 (8.2)	24 (12.1)
Grade 2	6 (3.0)	41 (20.5)	13 (6.6)	6 (3.0)	4 (2.0)	4 (2.0)	4 (2.0)
Grade 3	3 (1.5)	6 (3.0)	3 (1.5)	2 (1.0)	2 (1.0)	1 (0.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	200	198	199	198	196	199
Any	38 (19.0)	105 (52.5)	51 (25.8)	32 (16.1)	24 (12.1)	19 (9.7)	17 (8.5)
Grade 1	20 (10.0)	36 (18.0)	31 (15.7)	23 (11.6)	18 (9.1)	12 (6.1)	10 (5.0)
Grade 2	16 (8.0)	56 (28.0)	10 (5.1)	6 (3.0)	4 (2.0)	5 (2.6)	5 (2.5)
Grade 3	2 (1.0)	13 (6.5)	10 (5.1)	3 (1.5)	2 (1.0)	2 (1.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	200	198	199	198	196	199
Any	34 (17.0)	93 (46.5)	32 (16.2)	17 (8.5)	14 (7.1)	11 (5.6)	11 (5.5)
Grade 1	20 (10.0)	33 (16.5)	17 (8.6)	11 (5.5)	9 (4.5)	7 (3.6)	7 (3.5)
Grade 2	9 (4.5)	42 (21.0)	4 (2.0)	1 (0.5)	2 (1.0)	1 (0.5)	2 (1.0)
Grade 3	5 (2.5)	18 (9.0)	11 (5.6)	5 (2.5)	3 (1.5)	3 (1.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	200	198	199	198	196	199
Any	21 (10.5)	61 (30.5)	30 (15.2)	12 (6.0)	11 (5.6)	10 (5.1)	5 (2.5)
Grade 1	10 (5.0)	22 (11.0)	18 (9.1)	5 (2.5)	5 (2.5)	5 (2.6)	3 (1.5)
Grade 2	8 (4.0)	28 (14.0)	3 (1.5)	2 (1.0)	3 (1.5)	2 (1.0)	0
Grade 3	3 (1.5)	11 (5.5)	9 (4.5)	5 (2.5)	3 (1.5)	3 (1.5)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	200	198	199	198	196	199
Any	10 (5.0)	34 (17.0)	12 (6.1)	2 (1.0)	4 (2.0)	3 (1.5)	4 (2.0)
Grade 1	6 (3.0)	24 (12.0)	10 (5.1)	2 (1.0)	4 (2.0)	3 (1.5)	4 (2.0)
Grade 2	4 (2.0)	10 (5.0)	2 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	200	198	199	198	196	199
Any	20 (10.0)	72 (36.0)	13 (6.6)	6 (3.0)	1 (0.5)	1 (0.5)	2 (1.0)
Grade 1	13 (6.5)	27 (13.5)	7 (3.5)	5 (2.5)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 2	6 (3.0)	43 (21.5)	5 (2.5)	1 (0.5)	0	0	1 (0.5)
Grade 3	1 (0.5)	2 (1.0)	1 (0.5)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	200	198	199	198	196	199
Any	5 (2.5)	7 (3.5)	3 (1.5)	5 (2.5)	4 (2.0)	5 (2.6)	2 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	98	100	100	99	100
Any Solicited Adverse Reactions	23 (23.0)	25 (25.0)	23 (23.5)	13 (13.0)	14 (14.0)	16 (16.2)	13 (13.0)
95% CI	15.2, 32.5	16.9, 34.7	15.5, 33.1	7.1, 21.2	7.9, 22.4	9.5, 24.9	7.1, 21.2
Grade 1	17 (17.0)	20 (20.0)	20 (20.4)	11 (11.0)	12 (12.0)	15 (15.2)	12 (12.0)
Grade 2	6 (6.0)	5 (5.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)
Grade 3	0	0	2 (2.0)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	98	100	100	99	100
Any Solicited Local Adverse Reactions	8 (8.0)	5 (5.0)	2 (2.0)	2 (2.0)	3 (3.0)	3 (3.0)	2 (2.0)
95% CI	3.5, 15.2	1.6, 11.3	0.2, 7.2	0.2, 7.0	0.6, 8.5	0.6, 8.6	0.2, 7.0
Grade 1	8 (8.0)	5 (5.0)	2 (2.0)	2 (2.0)	3 (3.0)	3 (3.0)	2 (2.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	98	100	100	99	100
Any	7 (7.0)	3 (3.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	1 (1.0)
Grade 1	7 (7.0)	3 (3.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	98	100	100	99	100
Any	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	98	100	100	99	100
Any	0	1 (1.0)	0	0	0	0	0
Grade 1	0	1 (1.0)	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	98	100	100	99	100
Any	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 1	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	98	100	100	99	100
Any Solicited Systemic Adverse Reactions	19 (19.0)	21 (21.0)	21 (21.4)	12 (12.0)	11 (11.0)	14 (14.1)	11 (11.0)
95% CI	11.8, 28.1	13.5, 30.3	13.8, 30.9	6.4, 20.0	5.6, 18.8	8.0, 22.6	5.6, 18.8
Grade 1	13 (13.0)	16 (16.0)	18 (18.4)	10 (10.0)	9 (9.0)	13 (13.1)	10 (10.0)
Grade 2	6 (6.0)	5 (5.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)
Grade 3	0	0	2 (2.0)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	98	99	100	97	99
Any	0	0	0	0	0	0	0
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	100	98	100	100	99	100
Any	10 (10.0)	12 (12.0)	10 (10.2)	4 (4.0)	4 (4.0)	6 (6.1)	2 (2.0)
Grade 1	10 (10.0)	12 (12.0)	8 (8.2)	4 (4.0)	4 (4.0)	5 (5.1)	1 (1.0)
Grade 2	0	0	0	0	0	0	1 (1.0)
Grade 3	0	0	2 (2.0)	0	0	1 (1.0)	0
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	100	98	100	100	99	100
Any	14 (14.0)	14 (14.0)	13 (13.3)	7 (7.0)	6 (6.0)	4 (4.0)	7 (7.0)
Grade 1	9 (9.0)	10 (10.0)	12 (12.2)	7 (7.0)	5 (5.0)	4 (4.0)	6 (6.0)
Grade 2	5 (5.0)	4 (4.0)	1 (1.0)	0	1 (1.0)	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	98	100	100	99	100
Any	4 (4.0)	6 (6.0)	6 (6.1)	5 (5.0)	2 (2.0)	4 (4.0)	5 (5.0)
Grade 1	4 (4.0)	5 (5.0)	6 (6.1)	4 (4.0)	2 (2.0)	4 (4.0)	5 (5.0)
Grade 2	0	1 (1.0)	0	1 (1.0)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	100	98	100	100	99	100
Any	2 (2.0)	6 (6.0)	4 (4.1)	3 (3.0)	4 (4.0)	4 (4.0)	5 (5.0)
Grade 1	2 (2.0)	5 (5.0)	4 (4.1)	3 (3.0)	4 (4.0)	4 (4.0)	5 (5.0)
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	98	100	100	99	100
Any	2 (2.0)	0	1 (1.0)	0	0	1 (1.0)	2 (2.0)
Grade 1	1 (1.0)	0	1 (1.0)	0	0	1 (1.0)	1 (1.0)
Grade 2	1 (1.0)	0	0	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	100	98	100	100	99	100
Any	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	0	0
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	100	98	100	100	99	100
Any	0	0	0	1 (1.0)	1 (1.0)	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	100	100	100	99	99
Any Solicited Adverse Reactions	53 (53.0)	85 (85.0)	67 (67.0)	43 (43.0)	32 (32.0)	27 (27.3)	19 (19.2)
95% CI	42.8, 63.1	76.5, 91.4	56.9, 76.1	33.1, 53.3	23.0, 42.1	18.8, 37.1	12.0, 28.3
Grade 1	45 (45.0)	49 (49.0)	53 (53.0)	31 (31.0)	26 (26.0)	21 (21.2)	15 (15.2)
Grade 2	5 (5.0)	29 (29.0)	13 (13.0)	9 (9.0)	4 (4.0)	3 (3.0)	1 (1.0)
Grade 3	3 (3.0)	7 (7.0)	1 (1.0)	3 (3.0)	2 (2.0)	3 (3.0)	2 (2.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	100	100	99	99
Any Solicited Local Adverse Reactions	47 (47.0)	77 (77.0)	56 (56.0)	27 (27.0)	17 (17.0)	9 (9.1)	2 (2.0)
95% CI	36.9, 57.2	67.5, 84.8	45.7, 65.9	18.6, 36.8	10.2, 25.8	4.2, 16.6	0.2, 7.1
Grade 1	42 (42.0)	66 (66.0)	50 (50.0)	24 (24.0)	15 (15.0)	8 (8.1)	1 (1.0)
Grade 2	4 (4.0)	11 (11.0)	6 (6.0)	3 (3.0)	2 (2.0)	1 (1.0)	1 (1.0)
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	100	100	100	99	99
Any	44 (44.0)	77 (77.0)	55 (55.0)	26 (26.0)	15 (15.0)	6 (6.1)	2 (2.0)
Grade 1	39 (39.0)	67 (67.0)	52 (52.0)	25 (25.0)	14 (14.0)	5 (5.1)	1 (1.0)
Grade 2	4 (4.0)	10 (10.0)	3 (3.0)	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)
Grade 3	1 (1.0)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	100	100	99	99
Any	1 (1.0)	4 (4.0)	4 (4.0)	3 (3.0)	1 (1.0)	0	0
Grade 1	1 (1.0)	3 (3.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 2	0	1 (1.0)	3 (3.0)	2 (2.0)	1 (1.0)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	100	100	100	99	99
Any	0	7 (7.0)	5 (5.0)	5 (5.0)	4 (4.0)	2 (2.0)	0
Grade 1	0	6 (6.0)	3 (3.0)	3 (3.0)	3 (3.0)	2 (2.0)	0
Grade 2	0	1 (1.0)	2 (2.0)	2 (2.0)	1 (1.0)	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	100	100	100	99	99
Any	3 (3.0)	10 (10.0)	5 (5.0)	3 (3.0)	4 (4.0)	4 (4.0)	1 (1.0)
Grade 1	3 (3.0)	7 (7.0)	4 (4.0)	3 (3.0)	4 (4.0)	4 (4.0)	1 (1.0)
Grade 2	0	3 (3.0)	1 (1.0)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	100	100	100	99	99
Any Solicited Systemic Adverse Reactions	24 (24.0)	62 (62.0)	40 (40.0)	32 (32.0)	25 (25.0)	23 (23.2)	18 (18.2)
95% CI	16.0, 33.6	51.7, 71.5	30.3, 50.3	23.0, 42.1	16.9, 34.7	15.3, 32.8	11.1, 27.2
Grade 1	18 (18.0)	27 (27.0)	29 (29.0)	22 (22.0)	21 (21.0)	18 (18.2)	15 (15.2)
Grade 2	4 (4.0)	28 (28.0)	10 (10.0)	7 (7.0)	2 (2.0)	2 (2.0)	0
Grade 3	2 (2.0)	7 (7.0)	1 (1.0)	3 (3.0)	2 (2.0)	3 (3.0)	2 (2.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	100	99	99	99	99
Any	0	5 (5.0)	0	0	0	0	0
Grade 1	0	4 (4.0)	0	0	0	0	0
Grade 2	0	1 (1.0)	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	100	100	100	100	99	99
Any	17 (17.0)	41 (41.0)	18 (18.0)	16 (16.0)	11 (11.0)	16 (16.2)	10 (10.1)
Grade 1	15 (15.0)	29 (29.0)	16 (16.0)	11 (11.0)	10 (10.0)	13 (13.1)	9 (9.1)
Grade 2	1 (1.0)	9 (9.0)	2 (2.0)	3 (3.0)	1 (1.0)	1 (1.0)	0
Grade 3	1 (1.0)	3 (3.0)	0	2 (2.0)	0	2 (2.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	100	100	100	100	99	99
Any	19 (19.0)	54 (54.0)	30 (30.0)	18 (18.0)	14 (14.0)	12 (12.1)	9 (9.1)
Grade 1	14 (14.0)	26 (26.0)	19 (19.0)	12 (12.0)	10 (10.0)	8 (8.1)	8 (8.1)
Grade 2	3 (3.0)	23 (23.0)	10 (10.0)	5 (5.0)	2 (2.0)	3 (3.0)	0
Grade 3	2 (2.0)	5 (5.0)	1 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	100	100	100	99	99
Any	7 (7.0)	38 (38.0)	18 (18.0)	11 (11.0)	6 (6.0)	4 (4.0)	3 (3.0)
Grade 1	3 (3.0)	17 (17.0)	13 (13.0)	8 (8.0)	5 (5.0)	3 (3.0)	3 (3.0)
Grade 2	3 (3.0)	18 (18.0)	4 (4.0)	3 (3.0)	1 (1.0)	1 (1.0)	0
Grade 3	1 (1.0)	3 (3.0)	1 (1.0)	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	100	100	100	100	99	99
Any	6 (6.0)	38 (38.0)	18 (18.0)	9 (9.0)	6 (6.0)	4 (4.0)	4 (4.0)
Grade 1	3 (3.0)	18 (18.0)	14 (14.0)	9 (9.0)	5 (5.0)	4 (4.0)	4 (4.0)
Grade 2	3 (3.0)	18 (18.0)	4 (4.0)	0	1 (1.0)	0	0
Grade 3	0	2 (2.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	100	100	100	99	99
Any	1 (1.0)	5 (5.0)	4 (4.0)	3 (3.0)	1 (1.0)	1 (1.0)	0
Grade 1	1 (1.0)	4 (4.0)	3 (3.0)	2 (2.0)	1 (1.0)	0	0
Grade 2	0	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	100	100	100	100	99	99
Any	6 (6.0)	18 (18.0)	8 (8.0)	3 (3.0)	3 (3.0)	1 (1.0)	0
Grade 1	3 (3.0)	11 (11.0)	7 (7.0)	2 (2.0)	2 (2.0)	1 (1.0)	0
Grade 2	3 (3.0)	6 (6.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	100	100	100	100	99	99
Any	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	2 (2.0)	4 (4.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	100	100	100	100	99	100	100
Any Solicited Adverse Reactions	67 (67.0)	90 (90.0)	69 (69.0)	42 (42.0)	32 (32.3)	24 (24.0)	17 (17.0)
95% CI	56.9, 76.1	82.4, 95.1	59.0, 77.9	32.2, 52.3	23.3, 42.5	16.0, 33.6	10.2, 25.8
Grade 1	59 (59.0)	46 (46.0)	50 (50.0)	30 (30.0)	28 (28.3)	20 (20.0)	13 (13.0)
Grade 2	5 (5.0)	35 (35.0)	15 (15.0)	7 (7.0)	2 (2.0)	2 (2.0)	2 (2.0)
Grade 3	3 (3.0)	9 (9.0)	4 (4.0)	5 (5.0)	2 (2.0)	2 (2.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	100	99	100	100
Any Solicited Local Adverse Reactions	58 (58.0)	86 (86.0)	62 (62.0)	34 (34.0)	15 (15.2)	6 (6.0)	4 (4.0)
95% CI	47.7, 67.8	77.6, 92.1	51.7, 71.5	24.8, 44.2	8.7, 23.8	2.2, 12.6	1.1, 9.9
Grade 1	57 (57.0)	77 (77.0)	57 (57.0)	29 (29.0)	15 (15.2)	6 (6.0)	4 (4.0)
Grade 2	1 (1.0)	8 (8.0)	4 (4.0)	2 (2.0)	0	0	0
Grade 3	0	1 (1.0)	1 (1.0)	3 (3.0)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	100	100	99	100	100
Any	58 (58.0)	85 (85.0)	59 (59.0)	31 (31.0)	13 (13.1)	5 (5.0)	4 (4.0)
Grade 1	57 (57.0)	80 (80.0)	58 (58.0)	30 (30.0)	13 (13.1)	5 (5.0)	4 (4.0)
Grade 2	1 (1.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	100	99	100	100
Any	0	2 (2.0)	6 (6.0)	8 (8.0)	3 (3.0)	0	0
Grade 1	0	2 (2.0)	4 (4.0)	4 (4.0)	3 (3.0)	0	0
Grade 2	0	0	1 (1.0)	1 (1.0)	0	0	0
Grade 3	0	0	1 (1.0)	3 (3.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	100	100	100	100	99	100	100
Any	3 (3.0)	9 (9.0)	8 (8.0)	7 (7.0)	3 (3.0)	2 (2.0)	1 (1.0)
Grade 1	3 (3.0)	5 (5.0)	5 (5.0)	7 (7.0)	3 (3.0)	2 (2.0)	1 (1.0)
Grade 2	0	3 (3.0)	3 (3.0)	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	100	100	100	100	99	100	100
Any	3 (3.0)	3 (3.0)	7 (7.0)	5 (5.0)	0	0	0
Grade 1	2 (2.0)	3 (3.0)	7 (7.0)	5 (5.0)	0	0	0
Grade 2	1 (1.0)	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	100	100	99	100	100
Any Solicited Systemic Adverse Reactions	32 (32.0)	69 (69.0)	36 (36.0)	20 (20.0)	20 (20.2)	19 (19.0)	13 (13.0)
95% CI	23.0, 42.1	59.0, 77.9	26.6, 46.2	12.7, 29.2	12.8, 29.5	11.8, 28.1	7.1, 21.2
Grade 1	24 (24.0)	30 (30.0)	20 (20.0)	12 (12.0)	16 (16.2)	15 (15.0)	9 (9.0)
Grade 2	5 (5.0)	31 (31.0)	13 (13.0)	6 (6.0)	2 (2.0)	2 (2.0)	2 (2.0)
Grade 3	3 (3.0)	8 (8.0)	3 (3.0)	2 (2.0)	2 (2.0)	2 (2.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	100	100	100	100	99	100	99
Any	1 (1.0)	7 (7.0)	4 (4.0)	0	0	0	0
Grade 1	1 (1.0)	5 (5.0)	3 (3.0)	0	0	0	0
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	0
Grade 3	0	1 (1.0)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	100	100	99	100	98	100	100
Any	18 (18.0)	46 (46.0)	20 (20.2)	9 (9.0)	10 (10.2)	11 (11.0)	5 (5.0)
Grade 1	16 (16.0)	32 (32.0)	14 (14.1)	6 (6.0)	8 (8.2)	9 (9.0)	3 (3.0)
Grade 2	1 (1.0)	10 (10.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	1 (1.0)
Grade 3	1 (1.0)	4 (4.0)	2 (2.0)	1 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	100	100	99	100	98	100	100
Any	22 (22.0)	55 (55.0)	28 (28.3)	13 (13.0)	9 (9.2)	9 (9.0)	6 (6.0)
Grade 1	16 (16.0)	22 (22.0)	17 (17.2)	7 (7.0)	7 (7.1)	6 (6.0)	4 (4.0)
Grade 2	4 (4.0)	26 (26.0)	9 (9.1)	5 (5.0)	1 (1.0)	3 (3.0)	2 (2.0)
Grade 3	2 (2.0)	7 (7.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Category	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Grade							
Myalgia - N1	100	100	99	100	98	100	100
Any	10 (10.0)	48 (48.0)	20 (20.2)	6 (6.0)	4 (4.1)	2 (2.0)	4 (4.0)
Grade 1	7 (7.0)	19 (19.0)	9 (9.1)	3 (3.0)	2 (2.0)	1 (1.0)	4 (4.0)
Grade 2	1 (1.0)	24 (24.0)	8 (8.1)	2 (2.0)	1 (1.0)	1 (1.0)	0
Grade 3	2 (2.0)	5 (5.0)	3 (3.0)	1 (1.0)	1 (1.0)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	100	100	99	100	98	100	100
Any	5 (5.0)	37 (37.0)	12 (12.1)	6 (6.0)	6 (6.1)	4 (4.0)	2 (2.0)
Grade 1	3 (3.0)	19 (19.0)	6 (6.1)	4 (4.0)	4 (4.1)	3 (3.0)	2 (2.0)
Grade 2	0	15 (15.0)	4 (4.0)	1 (1.0)	1 (1.0)	1 (1.0)	0
Grade 3	2 (2.0)	3 (3.0)	2 (2.0)	1 (1.0)	1 (1.0)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	100	100	99	100	98	100	100
Any	2 (2.0)	11 (11.0)	4 (4.0)	3 (3.0)	2 (2.0)	1 (1.0)	2 (2.0)
Grade 1	2 (2.0)	8 (8.0)	2 (2.0)	2 (2.0)	2 (2.0)	0	1 (1.0)
Grade 2	0	3 (3.0)	2 (2.0)	0	0	1 (1.0)	1 (1.0)
Grade 3	0	0	0	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	100	100	99	100	98	100	100
Any	6 (6.0)	29 (29.0)	10 (10.1)	2 (2.0)	2 (2.0)	0	1 (1.0)
Grade 1	4 (4.0)	12 (12.0)	5 (5.1)	0	2 (2.0)	0	0
Grade 2	2 (2.0)	17 (17.0)	5 (5.1)	1 (1.0)	0	0	1 (1.0)
Grade 3	0	0	0	1 (1.0)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	100	100	99	100	98	100	100
Any	0	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Solicited Adverse Reactions - N1	200	200	200	200	199	199	199
Any Solicited Adverse Reactions	120 (60.0)	175 (87.5)	136 (68.0)	85 (42.5)	64 (32.2)	51 (25.6)	36 (18.1)
95% CI	52.9, 66.8	82.1, 91.7	61.1, 74.4	35.6, 49.7	25.7, 39.1	19.7, 32.3	13.0, 24.2
Grade 1	104 (52.0)	95 (47.5)	103 (51.5)	61 (30.5)	54 (27.1)	41 (20.6)	28 (14.1)
Grade 2	10 (5.0)	64 (32.0)	28 (14.0)	16 (8.0)	6 (3.0)	5 (2.5)	3 (1.5)
Grade 3	6 (3.0)	16 (8.0)	5 (2.5)	8 (4.0)	4 (2.0)	5 (2.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	200	200	200	200	199	199	199
Any Solicited Local Adverse Reactions	105 (52.5)	163 (81.5)	118 (59.0)	61 (30.5)	32 (16.1)	15 (7.5)	6 (3.0)
95% CI	45.3, 59.6	75.4, 86.6	51.8, 65.9	24.2, 37.4	11.3, 21.9	4.3, 12.1	1.1, 6.4
Grade 1	99 (49.5)	143 (71.5)	107 (53.5)	53 (26.5)	30 (15.1)	14 (7.0)	5 (2.5)
Grade 2	5 (2.5)	19 (9.5)	10 (5.0)	5 (2.5)	2 (1.0)	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	1 (0.5)	1 (0.5)	3 (1.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	200	200	200	200	199	199	199
Any	102 (51.0)	162 (81.0)	114 (57.0)	57 (28.5)	28 (14.1)	11 (5.5)	6 (3.0)
Grade 1	96 (48.0)	147 (73.5)	110 (55.0)	55 (27.5)	27 (13.6)	10 (5.0)	5 (2.5)
Grade 2	5 (2.5)	15 (7.5)	4 (2.0)	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)
Grade 3	1 (0.5)	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Erythema (Redness) - N1	200	200	200	200	199	199	199
Any	1 (0.5)	6 (3.0)	10 (5.0)	11 (5.5)	4 (2.0)	0	0
Grade 1	1 (0.5)	5 (2.5)	5 (2.5)	5 (2.5)	3 (1.5)	0	0
Grade 2	0	1 (0.5)	4 (2.0)	3 (1.5)	1 (0.5)	0	0
Grade 3	0	0	1 (0.5)	3 (1.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Swelling (Hardness) - N1	200	200	200	200	199	199	199
Any	3 (1.5)	16 (8.0)	13 (6.5)	12 (6.0)	7 (3.5)	4 (2.0)	1 (0.5)
Grade 1	3 (1.5)	11 (5.5)	8 (4.0)	10 (5.0)	6 (3.0)	4 (2.0)	1 (0.5)
Grade 2	0	4 (2.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Lymphadenopathy - N1 [1]	200	200	200	200	199	199	199
Any	6 (3.0)	13 (6.5)	12 (6.0)	8 (4.0)	4 (2.0)	4 (2.0)	1 (0.5)
Grade 1	5 (2.5)	10 (5.0)	11 (5.5)	8 (4.0)	4 (2.0)	4 (2.0)	1 (0.5)
Grade 2	1 (0.5)	3 (1.5)	1 (0.5)	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	200	200	199	199	199
Any Solicited Systemic Adverse Reactions	56 (28.0)	131 (65.5)	76 (38.0)	52 (26.0)	45 (22.6)	42 (21.1)	31 (15.6)
95% CI	21.9, 34.8	58.5, 72.1	31.2, 45.1	20.1, 32.7	17.0, 29.1	15.7, 27.4	10.8, 21.4
Grade 1	42 (21.0)	57 (28.5)	49 (24.5)	34 (17.0)	37 (18.6)	33 (16.6)	24 (12.1)
Grade 2	9 (4.5)	59 (29.5)	23 (11.5)	13 (6.5)	4 (2.0)	4 (2.0)	2 (1.0)
Grade 3	5 (2.5)	15 (7.5)	4 (2.0)	5 (2.5)	4 (2.0)	5 (2.5)	3 (1.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fever - N1	200	200	200	199	198	199	198
Any	1 (0.5)	12 (6.0)	4 (2.0)	0	0	0	0
Grade 1	1 (0.5)	9 (4.5)	3 (1.5)	0	0	0	0
Grade 2	0	2 (1.0)	1 (0.5)	0	0	0	0
Grade 3	0	1 (0.5)	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Headache - N1	200	200	199	200	198	199	199
Any	35 (17.5)	87 (43.5)	38 (19.1)	25 (12.5)	21 (10.6)	27 (13.6)	15 (7.5)
Grade 1	31 (15.5)	61 (30.5)	30 (15.1)	17 (8.5)	18 (9.1)	22 (11.1)	12 (6.0)
Grade 2	2 (1.0)	19 (9.5)	6 (3.0)	5 (2.5)	2 (1.0)	1 (0.5)	1 (0.5)
Grade 3	2 (1.0)	7 (3.5)	2 (1.0)	3 (1.5)	1 (0.5)	4 (2.0)	2 (1.0)
Grade 4	0	0	0	0	0	0	0
Fatigue - N1	200	200	199	200	198	199	199
Any	41 (20.5)	109 (54.5)	58 (29.1)	31 (15.5)	23 (11.6)	21 (10.6)	15 (7.5)
Grade 1	30 (15.0)	48 (24.0)	36 (18.1)	19 (9.5)	17 (8.6)	14 (7.0)	12 (6.0)
Grade 2	7 (3.5)	49 (24.5)	19 (9.5)	10 (5.0)	3 (1.5)	6 (3.0)	2 (1.0)
Grade 3	4 (2.0)	12 (6.0)	3 (1.5)	2 (1.0)	3 (1.5)	1 (0.5)	1 (0.5)
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	200	200	199	200	198	199	199
Any	17 (8.5)	86 (43.0)	38 (19.1)	17 (8.5)	10 (5.1)	6 (3.0)	7 (3.5)
Grade 1	10 (5.0)	36 (18.0)	22 (11.1)	11 (5.5)	7 (3.5)	4 (2.0)	7 (3.5)
Grade 2	4 (2.0)	42 (21.0)	12 (6.0)	5 (2.5)	2 (1.0)	2 (1.0)	0
Grade 3	3 (1.5)	8 (4.0)	4 (2.0)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Arthralgia - N1	200	200	199	200	198	199	199
Any	11 (5.5)	75 (37.5)	30 (15.1)	15 (7.5)	12 (6.1)	8 (4.0)	6 (3.0)
Grade 1	6 (3.0)	37 (18.5)	20 (10.1)	13 (6.5)	9 (4.5)	7 (3.5)	6 (3.0)
Grade 2	3 (1.5)	33 (16.5)	8 (4.0)	1 (0.5)	2 (1.0)	1 (0.5)	0
Grade 3	2 (1.0)	5 (2.5)	2 (1.0)	1 (0.5)	1 (0.5)	0	0
Grade 4	0	0	0	0	0	0	0
Nausea/Vomiting - N1	200	200	199	200	198	199	199
Any	3 (1.5)	16 (8.0)	8 (4.0)	6 (3.0)	3 (1.5)	2 (1.0)	2 (1.0)
Grade 1	3 (1.5)	12 (6.0)	5 (2.5)	4 (2.0)	3 (1.5)	0	1 (0.5)
Grade 2	0	4 (2.0)	3 (1.5)	1 (0.5)	0	2 (1.0)	1 (0.5)
Grade 3	0	0	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.2.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Grade and Day of Reporting
Solicited Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)

Solicited Adverse Reaction Category Grade	Day 1 n (%)	Day 2 n (%)	Day 3 n (%)	Day 4 n (%)	Day 5 n (%)	Day 6 n (%)	Day 7 n (%)
Chills - N1	200	200	199	200	198	199	199
Any	12 (6.0)	47 (23.5)	18 (9.0)	5 (2.5)	5 (2.5)	1 (0.5)	1 (0.5)
Grade 1	7 (3.5)	23 (11.5)	12 (6.0)	2 (1.0)	4 (2.0)	1 (0.5)	0
Grade 2	5 (2.5)	23 (11.5)	6 (3.0)	2 (1.0)	1 (0.5)	0	1 (0.5)
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0	0
Grade 4	0	0	0	0	0	0	0
Rash - N1	200	200	199	200	198	199	199
Any	1 (0.5)	2 (1.0)	2 (1.0)	2 (1.0)	3 (1.5)	2 (1.0)	5 (2.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

95% CI is calculated using the Clopper-Pearson method.

In eDiary, rash is not reported by grade.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Adverse Reactions - N1	199	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	12 (6.0)	23 (11.5)	12 (6.0)	35 (8.8)
Day 1, after Vaccination (at Home)	19 (9.5)	59 (29.5)	87 (43.5)	146 (36.5)
Day 2	18 (9.0)	48 (24.0)	66 (33.0)	114 (28.5)
Day 3	11 (5.5)	8 (4.0)	6 (3.0)	14 (3.5)
Day 4	7 (3.5)	1 (0.5)	4 (2.0)	5 (1.3)
Day 5	4 (2.0)	2 (1.0)	0	2 (0.5)
Day 6	4 (2.0)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	2 (1.0)	0	0	0
Solicited Local Adverse Reactions - N1	199	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	8 (4.0)	13 (6.5)	9 (4.5)	22 (5.5)
Day 1, after Vaccination (at Home)	6 (3.0)	58 (29.0)	83 (41.5)	141 (35.3)
Day 2	7 (3.5)	54 (27.0)	69 (34.5)	123 (30.8)
Day 3	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Day 4	1 (0.5)	0	1 (0.5)	1 (0.3)
Day 5	2 (1.0)	0	0	0
Day 6	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Pain - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	7 (3.5)	13 (6.5)	9 (4.5)	22 (5.5)
Day 1, after Vaccination (at Home)	4 (2.0)	57 (28.5)	83 (41.7)	140 (35.1)
Day 2	6 (3.0)	55 (27.5)	68 (34.2)	123 (30.8)
Day 3	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Day 4	0	0	1 (0.5)	1 (0.3)
Day 5	2 (1.0)	0	0	0
Day 6	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 7	0	0	0	0
Erythema (Redness) - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 2	0	3 (1.5)	2 (1.0)	5 (1.3)
Day 3	0	1 (0.5)	3 (1.5)	4 (1.0)
Day 4	0	0	0	0
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Swelling (Hardness) - N1	199	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (1.0)	0	2 (0.5)
Day 2	1 (0.5)	6 (3.0)	4 (2.0)	10 (2.5)
Day 3	0	0	3 (1.5)	3 (0.8)
Day 4	0	0	0	0
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	1 (0.5)	1 (0.3)
Lymphadenopathy - N1 [1]	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	0	0	0
Day 1, after Vaccination (at Home)	1 (0.5)	3 (1.5)	6 (3.0)	9 (2.3)
Day 2	0	5 (2.5)	4 (2.0)	9 (2.3)
Day 3	0	1 (0.5)	3 (1.5)	4 (1.0)
Day 4	1 (0.5)	0	1 (0.5)	1 (0.3)
Day 5	0	1 (0.5)	0	1 (0.3)
Day 6	1 (0.5)	0	4 (2.0)	4 (1.0)
Day 7	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	5 (2.5)	13 (6.5)	4 (2.0)	17 (4.3)
Day 1, after Vaccination (at Home)	16 (8.0)	20 (10.0)	34 (17.1)	54 (13.5)
Day 2	15 (7.5)	23 (11.5)	32 (16.1)	55 (13.8)
Day 3	10 (5.0)	11 (5.5)	7 (3.5)	18 (4.5)
Day 4	6 (3.0)	1 (0.5)	8 (4.0)	9 (2.3)
Day 5	4 (2.0)	6 (3.0)	1 (0.5)	7 (1.8)
Day 6	6 (3.0)	5 (2.5)	1 (0.5)	6 (1.5)
Day 7	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Fever - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	0	0
Day 2	0	0	0	0
Day 3	0	0	1 (0.5)	1 (0.3)
Day 4	0	0	0	0
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Headache - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	6 (3.0)	3 (1.5)	9 (2.3)
Day 1, after Vaccination (at Home)	8 (4.0)	11 (5.5)	11 (5.5)	22 (5.5)
Day 2	8 (4.0)	12 (6.0)	20 (10.1)	32 (8.0)
Day 3	6 (3.0)	8 (4.0)	1 (0.5)	9 (2.3)
Day 4	2 (1.0)	2 (1.0)	4 (2.0)	6 (1.5)
Day 5	5 (2.5)	4 (2.0)	0	4 (1.0)
Day 6	3 (1.5)	9 (4.5)	2 (1.0)	11 (2.8)
Day 7	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Fatigue - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	3 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)
Day 1, after Vaccination (at Home)	13 (6.5)	11 (5.5)	20 (10.1)	31 (7.8)
Day 2	6 (3.0)	17 (8.5)	18 (9.0)	35 (8.8)
Day 3	3 (1.5)	12 (6.0)	6 (3.0)	18 (4.5)
Day 4	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
Day 5	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Day 6	4 (2.0)	1 (0.5)	0	1 (0.3)
Day 7	2 (1.0)	1 (0.5)	0	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Myalgia - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Day 1, after Vaccination (at Home)	0	3 (1.5)	8 (4.0)	11 (2.8)
Day 2	3 (1.5)	9 (4.5)	13 (6.5)	22 (5.5)
Day 3	3 (1.5)	4 (2.0)	2 (1.0)	6 (1.5)
Day 4	3 (1.5)	1 (0.5)	3 (1.5)	4 (1.0)
Day 5	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 6	1 (0.5)	0	1 (0.5)	1 (0.3)
Day 7	0	0	0	0
Arthralgia - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
Day 1, after Vaccination (at Home)	0	3 (1.5)	2 (1.0)	5 (1.3)
Day 2	3 (1.5)	6 (3.0)	11 (5.5)	17 (4.3)
Day 3	2 (1.0)	3 (1.5)	0	3 (0.8)
Day 4	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Day 5	2 (1.0)	1 (0.5)	0	1 (0.3)
Day 6	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Nausea/Vomiting - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (1.0)	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	3 (1.5)	0	3 (0.8)
Day 2	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Day 3	2 (1.0)	3 (1.5)	2 (1.0)	5 (1.3)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	0	1 (0.5)	0	1 (0.3)
Day 6	3 (1.5)	0	0	0
Day 7	1 (0.5)	0	2 (1.0)	2 (0.5)
Chills - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	4 (2.0)	0	4 (1.0)
Day 1, after Vaccination (at Home)	1 (0.5)	4 (2.0)	4 (2.0)	8 (2.0)
Day 2	2 (1.0)	3 (1.5)	4 (2.0)	7 (1.8)
Day 3	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	1 (0.5)	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	199	200	199	399
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	0	1 (0.5)	1 (0.3)
Day 2	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Day 3	0	0	0	0
Day 4	2 (1.0)	0	1 (0.5)	1 (0.3)
Day 5	1 (0.5)	2 (1.0)	0	2 (0.5)
Day 6	0	1 (0.5)	0	1 (0.3)
Day 7	0	0	1 (0.5)	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=99) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Solicited Adverse Reactions - N1	100	100	100	200	99	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	7 (7.0)	14 (14.0)	9 (9.0)	23 (11.5)	5 (5.1)	9 (9.0)	3 (3.0)	12 (6.0)
Day 1, after Vaccination (at Home)	9 (9.0)	37 (37.0)	48 (48.0)	85 (42.5)	10 (10.1)	22 (22.0)	39 (39.0)	61 (30.5)
Day 2	9 (9.0)	22 (22.0)	30 (30.0)	52 (26.0)	9 (9.1)	26 (26.0)	36 (36.0)	62 (31.0)
Day 3	4 (4.0)	4 (4.0)	2 (2.0)	6 (3.0)	7 (7.1)	4 (4.0)	4 (4.0)	8 (4.0)
Day 4	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	4 (4.0)	0	3 (3.0)	3 (1.5)
Day 5	2 (2.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Day 6	1 (1.0)	0	1 (1.0)	1 (0.5)	3 (3.0)	1 (1.0)	0	1 (0.5)
Day 7	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	200	99	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	6 (6.0)	8 (8.0)	6 (6.0)	14 (7.0)	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)
Day 1, after Vaccination (at Home)	5 (5.0)	38 (38.0)	47 (47.0)	85 (42.5)	1 (1.0)	20 (20.0)	36 (36.0)	56 (28.0)
Day 2	3 (3.0)	24 (24.0)	32 (32.0)	56 (28.0)	4 (4.0)	30 (30.0)	37 (37.0)	67 (33.5)
Day 3	0	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	4 (4.0)	6 (3.0)
Day 4	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Day 5	2 (2.0)	0	0	0	0	0	0	0
Day 6	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 7	1 (1.0)	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	5 (5.0)	8 (8.0)	6 (6.0)	14 (7.0)	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)
Day 1, after Vaccination (at Home)	4 (4.0)	38 (38.0)	47 (47.0)	85 (42.5)	0	19 (19.0)	36 (36.4)	55 (27.6)
Day 2	3 (3.0)	24 (24.0)	32 (32.0)	56 (28.0)	3 (3.0)	31 (31.0)	36 (36.4)	67 (33.7)
Day 3	0	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	4 (4.0)	6 (3.0)
Day 4	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Day 5	2 (2.0)	0	0	0	0	0	0	0
Day 6	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 7	0	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 2	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Day 3	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	100	100	100	200	99	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Day 2	0	3 (3.0)	3 (3.0)	6 (3.0)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
Day 3	0	0	1 (1.0)	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Day 4	0	0	0	0	0	0	0	0
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Lymphadenopathy - N1 [1]	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.0)	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	1 (1.0)	3 (3.0)	5 (5.0)	8 (4.0)	0	0	1 (1.0)	1 (0.5)
Day 2	0	3 (3.0)	3 (3.0)	6 (3.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
Day 3	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Day 4	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Day 5	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 6	1 (1.0)	0	4 (4.0)	4 (2.0)	0	0	0	0
Day 7	1 (1.0)	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (2.0)	8 (8.0)	4 (4.0)	12 (6.0)	3 (3.0)	5 (5.0)	0	5 (2.5)
Day 1, after Vaccination (at Home)	7 (7.0)	13 (13.0)	20 (20.0)	33 (16.5)	9 (9.1)	7 (7.0)	14 (14.1)	21 (10.6)
Day 2	9 (9.0)	11 (11.0)	17 (17.0)	28 (14.0)	6 (6.1)	12 (12.0)	15 (15.2)	27 (13.6)
Day 3	4 (4.0)	5 (5.0)	5 (5.0)	10 (5.0)	6 (6.1)	6 (6.0)	2 (2.0)	8 (4.0)
Day 4	3 (3.0)	1 (1.0)	4 (4.0)	5 (2.5)	3 (3.0)	0	4 (4.0)	4 (2.0)
Day 5	2 (2.0)	4 (4.0)	1 (1.0)	5 (2.5)	2 (2.0)	2 (2.0)	0	2 (1.0)
Day 6	2 (2.0)	2 (2.0)	0	2 (1.0)	4 (4.0)	3 (3.0)	1 (1.0)	4 (2.0)
Day 7	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Fever - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	0	0	0	0	0	0
Day 2	0	0	0	0	0	0	0	0
Day 3	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=100)	mRNA-1273				Placebo (N=99)	mRNA-1273			
		50 µg (N=100)	100 µg (N=100)	Total (N=200)			50 µg (N=100)	100 µg (N=100)	Total (N=200)	
	n (%)	n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	
Headache - N1	100	100	100	200		99	100	99	199	
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	3 (3.0)	3 (3.0)	6 (3.0)		1 (1.0)	3 (3.0)	0	3 (1.5)	
Day 1, after Vaccination (at Home)	4 (4.0)	6 (6.0)	4 (4.0)	10 (5.0)		4 (4.0)	5 (5.0)	7 (7.1)	12 (6.0)	
Day 2	4 (4.0)	6 (6.0)	14 (14.0)	20 (10.0)		4 (4.0)	6 (6.0)	6 (6.1)	12 (6.0)	
Day 3	2 (2.0)	5 (5.0)	0	5 (2.5)		4 (4.0)	3 (3.0)	1 (1.0)	4 (2.0)	
Day 4	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)		1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	
Day 5	4 (4.0)	2 (2.0)	0	2 (1.0)		1 (1.0)	2 (2.0)	0	2 (1.0)	
Day 6	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)		2 (2.0)	7 (7.0)	1 (1.0)	8 (4.0)	
Day 7	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)		1 (1.0)	2 (2.0)	0	2 (1.0)	
Fatigue - N1	100	100	100	200		99	100	99	199	
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)		2 (2.0)	0	0	0	
Day 1, after Vaccination (at Home)	5 (5.0)	6 (6.0)	12 (12.0)	18 (9.0)		8 (8.1)	5 (5.0)	8 (8.1)	13 (6.5)	
Day 2	4 (4.0)	6 (6.0)	9 (9.0)	15 (7.5)		2 (2.0)	11 (11.0)	9 (9.1)	20 (10.1)	
Day 3	2 (2.0)	6 (6.0)	5 (5.0)	11 (5.5)		1 (1.0)	6 (6.0)	1 (1.0)	7 (3.5)	
Day 4	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)		1 (1.0)	0	2 (2.0)	2 (1.0)	
Day 5	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)		1 (1.0)	1 (1.0)	0	1 (0.5)	
Day 6	2 (2.0)	0	0	0		2 (2.0)	1 (1.0)	0	1 (0.5)	
Day 7	1 (1.0)	1 (1.0)	0	1 (0.5)		1 (1.0)	0	0	0	

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=99)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	2 (2.0)	6 (6.0)	8 (4.0)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 2	0	5 (5.0)	7 (7.0)	12 (6.0)	3 (3.0)	4 (4.0)	6 (6.1)	10 (5.0)
Day 3	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Day 4	3 (3.0)	0	1 (1.0)	1 (0.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 5	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Day 6	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Day 7	0	0	0	0	0	0	0	0
Arthralgia - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Day 2	2 (2.0)	1 (1.0)	5 (5.0)	6 (3.0)	1 (1.0)	5 (5.0)	6 (6.1)	11 (5.5)
Day 3	0	1 (1.0)	0	1 (0.5)	2 (2.0)	2 (2.0)	0	2 (1.0)
Day 4	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Day 5	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Day 6	1 (1.0)	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Day 2	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Day 3	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Day 4	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 5	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 6	2 (2.0)	0	0	0	1 (1.0)	0	0	0
Day 7	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Chills - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	3 (3.0)	0	3 (1.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 2	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 3	1 (1.0)	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Day 4	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	1 (1.0)	1 (0.5)	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.1
Summary of Solicited Adverse Reactions within 7 Days After First Injection by Onset Day
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg	100 µg	Total		50 µg	100 µg	Total
		(N=100)	(N=100)	(N=200)		(N=100)	(N=100)	(N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Rash - N1	100	100	100	200	99	100	99	199
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Day 2	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Day 3	0	0	0	0	0	0	0	0
Day 4	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Day 5	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Day 6	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 7	0	0	0	0	0	0	1 (1.0)	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Adverse Reactions - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	8 (4.1)	22 (11.3)	10 (5.1)	32 (8.1)
Day 1, after Vaccination (at Home)	16 (8.2)	75 (38.5)	100 (50.5)	175 (44.5)
Day 2	15 (7.7)	66 (33.8)	65 (32.8)	131 (33.3)
Day 3	10 (5.2)	5 (2.6)	2 (1.0)	7 (1.8)
Day 4	3 (1.5)	1 (0.5)	0	1 (0.3)
Day 5	8 (4.1)	1 (0.5)	1 (0.5)	2 (0.5)
Day 6	4 (2.1)	1 (0.5)	0	1 (0.3)
Day 7	2 (1.0)	0	0	0
Solicited Local Adverse Reactions - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	7 (3.6)	17 (8.7)	9 (4.5)	26 (6.6)
Day 1, after Vaccination (at Home)	4 (2.1)	73 (37.4)	93 (47.0)	166 (42.2)
Day 2	3 (1.5)	61 (31.3)	64 (32.3)	125 (31.8)
Day 3	1 (0.5)	4 (2.1)	4 (2.0)	8 (2.0)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Pain - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	7 (3.6)	14 (7.2)	9 (4.5)	23 (5.9)
Day 1, after Vaccination (at Home)	4 (2.1)	74 (37.9)	92 (46.5)	166 (42.2)
Day 2	2 (1.0)	62 (31.8)	65 (32.8)	127 (32.3)
Day 3	1 (0.5)	4 (2.1)	3 (1.5)	7 (1.8)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	1 (0.5)	0	0	0
Erythema (Redness) - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	0	1 (0.5)	1 (0.3)
Day 2	0	6 (3.1)	6 (3.0)	12 (3.1)
Day 3	0	3 (1.5)	4 (2.0)	7 (1.8)
Day 4	0	0	4 (2.0)	4 (1.0)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194)	mRNA-1273		
		50 µg (N=195)	100 µg (N=198)	Total (N=393)
	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	1 (0.5)	0	7 (3.5)	7 (1.8)
Day 2	0	9 (4.6)	8 (4.0)	17 (4.3)
Day 3	0	3 (1.5)	4 (2.0)	7 (1.8)
Day 4	0	0	2 (1.0)	2 (0.5)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0
Lymphadenopathy - N1 [1]	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	3 (1.5)	1 (0.5)	4 (1.0)
Day 1, after Vaccination (at Home)	0	2 (1.0)	5 (2.5)	7 (1.8)
Day 2	1 (0.5)	10 (5.1)	7 (3.5)	17 (4.3)
Day 3	0	3 (1.5)	6 (3.0)	9 (2.3)
Day 4	0	0	1 (0.5)	1 (0.3)
Day 5	0	1 (0.5)	0	1 (0.3)
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Systemic Adverse Reactions - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	3 (1.5)	10 (5.1)	2 (1.0)	12 (3.1)
Day 1, after Vaccination (at Home)	15 (7.7)	30 (15.4)	48 (24.2)	78 (19.8)
Day 2	14 (7.2)	79 (40.5)	94 (47.5)	173 (44.0)
Day 3	10 (5.2)	10 (5.1)	4 (2.0)	14 (3.6)
Day 4	3 (1.5)	2 (1.0)	0	2 (0.5)
Day 5	8 (4.1)	1 (0.5)	2 (1.0)	3 (0.8)
Day 6	4 (2.1)	1 (0.5)	2 (1.0)	3 (0.8)
Day 7	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Fever - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (1.0)	3 (1.5)	5 (1.3)
Day 2	0	10 (5.1)	20 (10.1)	30 (7.6)
Day 3	0	0	3 (1.5)	3 (0.8)
Day 4	0	0	0	0
Day 5	1 (0.5)	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Headache - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	8 (4.1)	2 (1.0)	10 (2.5)
Day 1, after Vaccination (at Home)	9 (4.6)	18 (9.2)	26 (13.1)	44 (11.2)
Day 2	9 (4.6)	56 (28.7)	67 (33.8)	123 (31.3)
Day 3	4 (2.1)	5 (2.6)	3 (1.5)	8 (2.0)
Day 4	2 (1.0)	3 (1.5)	0	3 (0.8)
Day 5	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)
Day 6	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	3 (1.5)	3 (1.5)	0	3 (0.8)
Fatigue - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	2 (1.0)	0	2 (0.5)
Day 1, after Vaccination (at Home)	10 (5.2)	25 (12.8)	33 (16.7)	58 (14.8)
Day 2	11 (5.7)	65 (33.3)	86 (43.4)	151 (38.4)
Day 3	7 (3.6)	6 (3.1)	6 (3.0)	12 (3.1)
Day 4	4 (2.1)	1 (0.5)	1 (0.5)	2 (0.5)
Day 5	5 (2.6)	2 (1.0)	0	2 (0.5)
Day 6	0	2 (1.0)	2 (1.0)	4 (1.0)
Day 7	3 (1.5)	1 (0.5)	0	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Myalgia - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	2 (1.0)	0	2 (0.5)
Day 1, after Vaccination (at Home)	1 (0.5)	15 (7.7)	25 (12.6)	40 (10.2)
Day 2	5 (2.6)	57 (29.2)	75 (37.9)	132 (33.6)
Day 3	3 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)
Day 4	2 (1.0)	3 (1.5)	0	3 (0.8)
Day 5	0	0	0	0
Day 6	3 (1.5)	1 (0.5)	0	1 (0.3)
Day 7	0	1 (0.5)	1 (0.5)	2 (0.5)
Arthralgia - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	11 (5.6)	15 (7.6)	26 (6.6)
Day 2	4 (2.1)	49 (25.1)	58 (29.3)	107 (27.2)
Day 3	3 (1.5)	5 (2.6)	1 (0.5)	6 (1.5)
Day 4	0	0	0	0
Day 5	2 (1.0)	0	2 (1.0)	2 (0.5)
Day 6	3 (1.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	0	1 (0.5)	0	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Nausea/Vomiting - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	3 (1.5)	8 (4.0)	11 (2.8)
Day 2	1 (0.5)	17 (8.7)	26 (13.1)	43 (10.9)
Day 3	0	2 (1.0)	3 (1.5)	5 (1.3)
Day 4	0	0	0	0
Day 5	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Day 6	0	2 (1.0)	1 (0.5)	3 (0.8)
Day 7	0	0	1 (0.5)	1 (0.3)
Chills - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	9 (4.6)	14 (7.1)	23 (5.9)
Day 2	1 (0.5)	37 (19.0)	60 (30.3)	97 (24.7)
Day 3	1 (0.5)	3 (1.5)	4 (2.0)	7 (1.8)
Day 4	0	0	0	0
Day 5	3 (1.5)	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Rash - N1	194	195	198	393
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	2 (1.0)	1 (0.5)	3 (0.8)
Day 2	0	1 (0.5)	3 (1.5)	4 (1.0)
Day 3	0	1 (0.5)	2 (1.0)	3 (0.8)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 6	0	1 (0.5)	0	1 (0.3)
Day 7	0	2 (1.0)	0	2 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	5 (5.3)	16 (16.5)	6 (6.1)	22 (11.2)	3 (3.0)	6 (6.1)	4 (4.0)	10 (5.1)
Day 1, after Vaccination (at Home)	6 (6.4)	39 (40.2)	54 (54.5)	93 (47.4)	10 (10.0)	36 (36.7)	46 (46.5)	82 (41.6)
Day 2	7 (7.4)	27 (27.8)	31 (31.3)	58 (29.6)	8 (8.0)	39 (39.8)	34 (34.3)	73 (37.1)
Day 3	3 (3.2)	1 (1.0)	1 (1.0)	2 (1.0)	7 (7.0)	4 (4.1)	1 (1.0)	5 (2.5)
Day 4	1 (1.1)	1 (1.0)	0	1 (0.5)	2 (2.0)	0	0	0
Day 5	4 (4.3)	1 (1.0)	0	1 (0.5)	4 (4.0)	0	1 (1.0)	1 (0.5)
Day 6	1 (1.1)	1 (1.0)	0	1 (0.5)	3 (3.0)	0	0	0
Day 7	1 (1.1)	0	0	0	1 (1.0)	0	0	0
Solicited Local Adverse Reactions - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	4 (4.3)	11 (11.3)	5 (5.1)	16 (8.2)	3 (3.0)	6 (6.1)	4 (4.0)	10 (5.1)
Day 1, after Vaccination (at Home)	2 (2.1)	40 (41.2)	55 (55.6)	95 (48.5)	2 (2.0)	33 (33.7)	38 (38.4)	71 (36.0)
Day 2	3 (3.2)	27 (27.8)	27 (27.3)	54 (27.6)	0	34 (34.7)	37 (37.4)	71 (36.0)
Day 3	1 (1.1)	0	2 (2.0)	2 (1.0)	0	4 (4.1)	2 (2.0)	6 (3.0)
Day 4	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	1 (1.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	4 (4.3)	9 (9.3)	5 (5.1)	14 (7.1)	3 (3.0)	5 (5.1)	4 (4.0)	9 (4.6)
Day 1, after Vaccination (at Home)	2 (2.1)	42 (43.3)	54 (54.5)	96 (49.0)	2 (2.0)	32 (32.7)	38 (38.4)	70 (35.5)
Day 2	2 (2.1)	27 (27.8)	28 (28.3)	55 (28.1)	0	35 (35.7)	37 (37.4)	72 (36.5)
Day 3	1 (1.1)	0	2 (2.0)	2 (1.0)	0	4 (4.1)	1 (1.0)	5 (2.5)
Day 4	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	1 (1.0)	0	0	0
Erythema (Redness) - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Day 2	0	3 (3.1)	4 (4.0)	7 (3.6)	0	3 (3.1)	2 (2.0)	5 (2.5)
Day 3	0	1 (1.0)	2 (2.0)	3 (1.5)	0	2 (2.0)	2 (2.0)	4 (2.0)
Day 4	0	0	1 (1.0)	1 (0.5)	0	0	3 (3.0)	3 (1.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	1 (1.1)	0	4 (4.0)	4 (2.0)	0	0	3 (3.0)	3 (1.5)
Day 2	0	5 (5.2)	3 (3.0)	8 (4.1)	0	4 (4.1)	5 (5.1)	9 (4.6)
Day 3	0	1 (1.0)	3 (3.0)	4 (2.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
Day 4	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0
Lymphadenopathy - N1 [1]	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	1 (1.0)	2 (1.0)	0	2 (2.0)	0	2 (1.0)
Day 1, after Vaccination (at Home)	0	1 (1.0)	3 (3.0)	4 (2.0)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 2	1 (1.1)	3 (3.1)	5 (5.1)	8 (4.1)	0	7 (7.1)	2 (2.0)	9 (4.6)
Day 3	0	2 (2.1)	1 (1.0)	3 (1.5)	0	1 (1.0)	5 (5.1)	6 (3.0)
Day 4	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Day 5	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.1)	8 (8.2)	1 (1.0)	9 (4.6)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
Day 1, after Vaccination (at Home)	6 (6.4)	14 (14.4)	25 (25.3)	39 (19.9)	9 (9.0)	16 (16.3)	23 (23.2)	39 (19.8)
Day 2	6 (6.4)	36 (37.1)	48 (48.5)	84 (42.9)	8 (8.0)	43 (43.9)	46 (46.5)	89 (45.2)
Day 3	3 (3.2)	6 (6.2)	3 (3.0)	9 (4.6)	7 (7.0)	4 (4.1)	1 (1.0)	5 (2.5)
Day 4	1 (1.1)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Day 5	4 (4.3)	1 (1.0)	0	1 (0.5)	4 (4.0)	0	2 (2.0)	2 (1.0)
Day 6	1 (1.1)	1 (1.0)	0	1 (0.5)	3 (3.0)	0	2 (2.0)	2 (1.0)
Day 7	1 (1.1)	2 (2.1)	1 (1.0)	3 (1.5)	0	0	0	0
Fever - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (2.1)	2 (2.0)	4 (2.0)	0	0	1 (1.0)	1 (0.5)
Day 2	0	5 (5.2)	13 (13.1)	18 (9.2)	0	5 (5.1)	7 (7.1)	12 (6.1)
Day 3	0	0	0	0	0	0	3 (3.0)	3 (1.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.1)	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
	Placebo (N=94)	mRNA-1273				Placebo (N=100)	mRNA-1273			
		50 µg (N=97)	100 µg (N=99)	Total (N=196)			50 µg (N=98)	100 µg (N=99)	Total (N=197)	
	n (%)	n (%)	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	
Headache - N1	94	97	99	196		100	98	99	197	
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	7 (7.2)	1 (1.0)	8 (4.1)		1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	
Day 1, after Vaccination (at Home)	4 (4.3)	7 (7.2)	15 (15.2)	22 (11.2)		5 (5.0)	11 (11.2)	11 (11.1)	22 (11.2)	
Day 2	2 (2.1)	25 (25.8)	35 (35.4)	60 (30.6)		7 (7.0)	31 (31.6)	32 (32.3)	63 (32.0)	
Day 3	0	4 (4.1)	2 (2.0)	6 (3.1)		4 (4.0)	1 (1.0)	1 (1.0)	2 (1.0)	
Day 4	2 (2.1)	1 (1.0)	0	1 (0.5)		0	2 (2.0)	0	2 (1.0)	
Day 5	2 (2.1)	2 (2.1)	2 (2.0)	4 (2.0)		1 (1.0)	0	3 (3.0)	3 (1.5)	
Day 6	1 (1.1)	1 (1.0)	0	1 (0.5)		1 (1.0)	0	1 (1.0)	1 (0.5)	
Day 7	3 (3.2)	2 (2.1)	0	2 (1.0)		0	1 (1.0)	0	1 (0.5)	
Fatigue - N1	94	97	99	196		100	98	99	197	
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.1)	2 (2.1)	0	2 (1.0)		0	0	0	0	
Day 1, after Vaccination (at Home)	4 (4.3)	8 (8.2)	18 (18.2)	26 (13.3)		6 (6.0)	17 (17.3)	15 (15.2)	32 (16.2)	
Day 2	5 (5.3)	28 (28.9)	44 (44.4)	72 (36.7)		6 (6.0)	37 (37.8)	42 (42.4)	79 (40.1)	
Day 3	2 (2.1)	1 (1.0)	3 (3.0)	4 (2.0)		5 (5.0)	5 (5.1)	3 (3.0)	8 (4.1)	
Day 4	2 (2.1)	1 (1.0)	0	1 (0.5)		2 (2.0)	0	1 (1.0)	1 (0.5)	
Day 5	4 (4.3)	1 (1.0)	0	1 (0.5)		1 (1.0)	1 (1.0)	0	1 (0.5)	
Day 6	0	2 (2.1)	0	2 (1.0)		0	0	2 (2.0)	2 (1.0)	
Day 7	1 (1.1)	1 (1.0)	0	1 (0.5)		2 (2.0)	0	0	0	

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	10 (10.3)	17 (17.2)	27 (13.8)	1 (1.0)	5 (5.1)	8 (8.1)	13 (6.6)
Day 2	1 (1.1)	26 (26.8)	37 (37.4)	63 (32.1)	4 (4.0)	31 (31.6)	38 (38.4)	69 (35.0)
Day 3	2 (2.1)	2 (2.1)	2 (2.0)	4 (2.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Day 4	0	1 (1.0)	0	1 (0.5)	2 (2.0)	2 (2.0)	0	2 (1.0)
Day 5	0	0	0	0	0	0	0	0
Day 6	1 (1.1)	1 (1.0)	0	1 (0.5)	2 (2.0)	0	0	0
Day 7	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Arthralgia - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	7 (7.2)	11 (11.1)	18 (9.2)	0	4 (4.1)	4 (4.0)	8 (4.1)
Day 2	0	18 (18.6)	26 (26.3)	44 (22.4)	4 (4.0)	31 (31.6)	32 (32.3)	63 (32.0)
Day 3	2 (2.1)	4 (4.1)	1 (1.0)	5 (2.6)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	0	0	0	0	2 (2.0)	0	2 (2.0)	2 (1.0)
Day 6	1 (1.1)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	0	0	0
Day 7	0	0	0	0	0	1 (1.0)	0	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (2.1)	6 (6.1)	8 (4.1)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 2	1 (1.1)	13 (13.4)	17 (17.2)	30 (15.3)	0	4 (4.1)	9 (9.1)	13 (6.6)
Day 3	0	2 (2.1)	2 (2.0)	4 (2.0)	0	0	1 (1.0)	1 (0.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Day 6	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Day 7	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Chills - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	5 (5.2)	10 (10.1)	15 (7.7)	0	4 (4.1)	4 (4.0)	8 (4.1)
Day 2	0	22 (22.7)	35 (35.4)	57 (29.1)	1 (1.0)	15 (15.3)	25 (25.3)	40 (20.3)
Day 3	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	0	2 (2.0)	2 (2.0)	4 (2.0)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.1)	0	0	0	2 (2.0)	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.2
Summary of Solicited Adverse Reactions within 7 Days After Second Injection by Onset Day
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Rash - N1	94	97	99	196	100	98	99	197
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 1, after Vaccination (at Home)	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Day 2	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Day 3	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Day 4	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 5	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Day 6	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 7	0	0	0	0	0	2 (2.0)	0	2 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Solicited Adverse Reactions - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	20 (10.0)	39 (19.5)	21 (10.5)	60 (15.0)
Day 1, after Vaccination (at Home)	27 (13.5)	82 (41.0)	117 (58.5)	199 (49.8)
Day 2	24 (12.0)	53 (26.5)	51 (25.5)	104 (26.0)
Day 3	13 (6.5)	7 (3.5)	2 (1.0)	9 (2.3)
Day 4	8 (4.0)	0	0	0
Day 5	5 (2.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 6	5 (2.5)	0	0	0
Day 7	1 (0.5)	0	0	0
Solicited Local Adverse Reactions - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	15 (7.5)	28 (14.0)	18 (9.0)	46 (11.5)
Day 1, after Vaccination (at Home)	9 (4.5)	83 (41.5)	108 (54.0)	191 (47.8)
Day 2	8 (4.0)	54 (27.0)	56 (28.0)	110 (27.5)
Day 3	2 (1.0)	6 (3.0)	3 (1.5)	9 (2.3)
Day 4	1 (0.5)	0	0	0
Day 5	1 (0.5)	0	0	0
Day 6	1 (0.5)	0	0	0
Day 7	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Pain - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	14 (7.0)	25 (12.5)	18 (9.0)	43 (10.8)
Day 1, after Vaccination (at Home)	7 (3.5)	83 (41.5)	108 (54.0)	191 (47.8)
Day 2	7 (3.5)	56 (28.0)	55 (27.5)	111 (27.8)
Day 3	2 (1.0)	6 (3.0)	2 (1.0)	8 (2.0)
Day 4	0	0	0	0
Day 5	1 (0.5)	0	0	0
Day 6	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 7	0	0	0	0
Erythema (Redness) - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 2	0	8 (4.0)	7 (3.5)	15 (3.8)
Day 3	0	2 (1.0)	7 (3.5)	9 (2.3)
Day 4	0	0	4 (2.0)	4 (1.0)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Swelling (Hardness) - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	1 (0.5)	2 (1.0)	7 (3.5)	9 (2.3)
Day 2	1 (0.5)	13 (6.5)	11 (5.5)	24 (6.0)
Day 3	0	1 (0.5)	5 (2.5)	6 (1.5)
Day 4	0	0	2 (1.0)	2 (0.5)
Day 5	0	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0
Lymphadenopathy - N1 [1]	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Day 1, after Vaccination (at Home)	1 (0.5)	4 (2.0)	9 (4.5)	13 (3.3)
Day 2	1 (0.5)	13 (6.5)	8 (4.0)	21 (5.3)
Day 3	0	3 (1.5)	9 (4.5)	12 (3.0)
Day 4	1 (0.5)	0	2 (1.0)	2 (0.5)
Day 5	0	1 (0.5)	0	1 (0.3)
Day 6	0	0	3 (1.5)	3 (0.8)
Day 7	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	8 (4.0)	19 (9.5)	5 (2.5)	24 (6.0)
Day 1, after Vaccination (at Home)	26 (13.0)	41 (20.5)	64 (32.0)	105 (26.3)
Day 2	22 (11.0)	72 (36.0)	85 (42.5)	157 (39.3)
Day 3	15 (7.5)	9 (4.5)	5 (2.5)	14 (3.5)
Day 4	8 (4.0)	2 (1.0)	2 (1.0)	4 (1.0)
Day 5	5 (2.5)	2 (1.0)	3 (1.5)	5 (1.3)
Day 6	6 (3.0)	2 (1.0)	2 (1.0)	4 (1.0)
Day 7	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Fever - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (1.0)	3 (1.5)	5 (1.3)
Day 2	0	10 (5.0)	20 (10.0)	30 (7.5)
Day 3	0	0	3 (1.5)	3 (0.8)
Day 4	0	0	0	0
Day 5	1 (0.5)	0	0	0
Day 6	0	0	0	0
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Headache - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (1.0)	12 (6.0)	4 (2.0)	16 (4.0)
Day 1, after Vaccination (at Home)	16 (8.0)	25 (12.5)	33 (16.5)	58 (14.5)
Day 2	14 (7.0)	56 (28.0)	66 (33.0)	122 (30.5)
Day 3	9 (4.5)	6 (3.0)	2 (1.0)	8 (2.0)
Day 4	4 (2.0)	3 (1.5)	2 (1.0)	5 (1.3)
Day 5	6 (3.0)	4 (2.0)	5 (2.5)	9 (2.3)
Day 6	4 (2.0)	3 (1.5)	2 (1.0)	5 (1.3)
Day 7	4 (2.0)	2 (1.0)	1 (0.5)	3 (0.8)
Fatigue - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	4 (2.0)	3 (1.5)	1 (0.5)	4 (1.0)
Day 1, after Vaccination (at Home)	20 (10.0)	30 (15.0)	45 (22.5)	75 (18.8)
Day 2	13 (6.5)	67 (33.5)	80 (40.0)	147 (36.8)
Day 3	8 (4.0)	7 (3.5)	7 (3.5)	14 (3.5)
Day 4	5 (2.5)	1 (0.5)	2 (1.0)	3 (0.8)
Day 5	6 (3.0)	1 (0.5)	1 (0.5)	2 (0.5)
Day 6	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)
Day 7	2 (1.0)	2 (1.0)	0	2 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Myalgia - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	4 (2.0)	4 (2.0)	1 (0.5)	5 (1.3)
Day 1, after Vaccination (at Home)	1 (0.5)	15 (7.5)	31 (15.5)	46 (11.5)
Day 2	6 (3.0)	60 (30.0)	73 (36.5)	133 (33.3)
Day 3	6 (3.0)	2 (1.0)	4 (2.0)	6 (1.5)
Day 4	5 (2.5)	4 (2.0)	2 (1.0)	6 (1.5)
Day 5	1 (0.5)	0	0	0
Day 6	3 (1.5)	1 (0.5)	0	1 (0.3)
Day 7	0	1 (0.5)	0	1 (0.3)
Arthralgia - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (1.0)	3 (1.5)	2 (1.0)	5 (1.3)
Day 1, after Vaccination (at Home)	0	11 (5.5)	16 (8.0)	27 (6.8)
Day 2	7 (3.5)	51 (25.5)	57 (28.5)	108 (27.0)
Day 3	5 (2.5)	7 (3.5)	1 (0.5)	8 (2.0)
Day 4	1 (0.5)	1 (0.5)	0	1 (0.3)
Day 5	3 (1.5)	0	2 (1.0)	2 (0.5)
Day 6	3 (1.5)	1 (0.5)	1 (0.5)	2 (0.5)
Day 7	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nausea/Vomiting - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (1.0)	1 (0.5)	0	1 (0.3)
Day 1, after Vaccination (at Home)	0	4 (2.0)	8 (4.0)	12 (3.0)
Day 2	3 (1.5)	17 (8.5)	27 (13.5)	44 (11.0)
Day 3	2 (1.0)	4 (2.0)	3 (1.5)	7 (1.8)
Day 4	0	1 (0.5)	0	1 (0.3)
Day 5	0	2 (1.0)	2 (1.0)	4 (1.0)
Day 6	3 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)
Day 7	1 (0.5)	0	2 (1.0)	2 (0.5)
Chills - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (0.5)	4 (2.0)	0	4 (1.0)
Day 1, after Vaccination (at Home)	1 (0.5)	11 (5.5)	17 (8.5)	28 (7.0)
Day 2	3 (1.5)	34 (17.0)	60 (30.0)	94 (23.5)
Day 3	3 (1.5)	3 (1.5)	5 (2.5)	8 (2.0)
Day 4	0	0	0	0
Day 5	3 (1.5)	0	0	0
Day 6	0	0	0	0
Day 7	0	0	1 (0.5)	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	200	200	200	400
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	2 (1.0)	0	2 (0.5)
Day 1, after Vaccination (at Home)	0	2 (1.0)	2 (1.0)	4 (1.0)
Day 2	2 (1.0)	2 (1.0)	5 (2.5)	7 (1.8)
Day 3	0	0	2 (1.0)	2 (0.5)
Day 4	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Day 5	2 (1.0)	3 (1.5)	0	3 (0.8)
Day 6	0	2 (1.0)	0	2 (0.5)
Day 7	0	2 (1.0)	1 (0.5)	3 (0.8)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	12 (12.0)	26 (26.0)	14 (14.0)	40 (20.0)	8 (8.0)	13 (13.0)	7 (7.0)	20 (10.0)
Day 1, after Vaccination (at Home)	12 (12.0)	42 (42.0)	57 (57.0)	99 (49.5)	15 (15.0)	40 (40.0)	60 (60.0)	100 (50.0)
Day 2	11 (11.0)	20 (20.0)	24 (24.0)	44 (22.0)	13 (13.0)	33 (33.0)	27 (27.0)	60 (30.0)
Day 3	5 (5.0)	3 (3.0)	0	3 (1.5)	8 (8.0)	4 (4.0)	2 (2.0)	6 (3.0)
Day 4	3 (3.0)	0	0	0	5 (5.0)	0	0	0
Day 5	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
Day 6	1 (1.0)	0	0	0	4 (4.0)	0	0	0
Day 7	1 (1.0)	0	0	0	0	0	0	0
Solicited Local Adverse Reactions - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	10 (10.0)	18 (18.0)	11 (11.0)	29 (14.5)	5 (5.0)	10 (10.0)	7 (7.0)	17 (8.5)
Day 1, after Vaccination (at Home)	6 (6.0)	46 (46.0)	57 (57.0)	103 (51.5)	3 (3.0)	37 (37.0)	51 (51.0)	88 (44.0)
Day 2	4 (4.0)	21 (21.0)	24 (24.0)	45 (22.5)	4 (4.0)	33 (33.0)	32 (32.0)	65 (32.5)
Day 3	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	5 (5.0)	2 (2.0)	7 (3.5)
Day 4	0	0	0	0	1 (1.0)	0	0	0
Day 5	1 (1.0)	0	0	0	0	0	0	0
Day 6	0	0	0	0	1 (1.0)	0	0	0
Day 7	1 (1.0)	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pain - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	9 (9.0)	16 (16.0)	11 (11.0)	27 (13.5)	5 (5.0)	9 (9.0)	7 (7.0)	16 (8.0)
Day 1, after Vaccination (at Home)	5 (5.0)	48 (48.0)	57 (57.0)	105 (52.5)	2 (2.0)	35 (35.0)	51 (51.0)	86 (43.0)
Day 2	4 (4.0)	21 (21.0)	24 (24.0)	45 (22.5)	3 (3.0)	35 (35.0)	31 (31.0)	66 (33.0)
Day 3	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	5 (5.0)	1 (1.0)	6 (3.0)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.0)	0	0	0	0	0	0	0
Day 6	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 7	0	0	0	0	0	0	0	0
Erythema (Redness) - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Day 1, after Vaccination (at Home)	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 2	0	4 (4.0)	5 (5.0)	9 (4.5)	0	4 (4.0)	2 (2.0)	6 (3.0)
Day 3	0	0	3 (3.0)	3 (1.5)	0	2 (2.0)	4 (4.0)	6 (3.0)
Day 4	0	0	1 (1.0)	1 (0.5)	0	0	3 (3.0)	3 (1.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	1 (1.0)	2 (2.0)	4 (4.0)	6 (3.0)	0	0	3 (3.0)	3 (1.5)
Day 2	0	6 (6.0)	5 (5.0)	11 (5.5)	1 (1.0)	7 (7.0)	6 (6.0)	13 (6.5)
Day 3	0	0	3 (3.0)	3 (1.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 4	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Day 5	0	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0
Lymphadenopathy - N1 [1]	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	2 (2.0)	0	2 (1.0)
Day 1, after Vaccination (at Home)	1 (1.0)	3 (3.0)	6 (6.0)	9 (4.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
Day 2	1 (1.0)	4 (4.0)	5 (5.0)	9 (4.5)	0	9 (9.0)	3 (3.0)	12 (6.0)
Day 3	0	3 (3.0)	3 (3.0)	6 (3.0)	0	0	6 (6.0)	6 (3.0)
Day 4	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Day 5	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 6	0	0	3 (3.0)	3 (1.5)	0	0	0	0
Day 7	1 (1.0)	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	3 (3.0)	14 (14.0)	4 (4.0)	18 (9.0)	5 (5.0)	5 (5.0)	1 (1.0)	6 (3.0)
Day 1, after Vaccination (at Home)	12 (12.0)	22 (22.0)	33 (33.0)	55 (27.5)	14 (14.0)	19 (19.0)	31 (31.0)	50 (25.0)
Day 2	11 (11.0)	30 (30.0)	43 (43.0)	73 (36.5)	11 (11.0)	42 (42.0)	42 (42.0)	84 (42.0)
Day 3	5 (5.0)	6 (6.0)	3 (3.0)	9 (4.5)	10 (10.0)	3 (3.0)	2 (2.0)	5 (2.5)
Day 4	3 (3.0)	1 (1.0)	0	1 (0.5)	5 (5.0)	1 (1.0)	2 (2.0)	3 (1.5)
Day 5	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	0	2 (2.0)	2 (1.0)
Day 6	2 (2.0)	0	0	0	4 (4.0)	2 (2.0)	2 (2.0)	4 (2.0)
Day 7	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Fever - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	0	0	0	0	0	0	0
Day 1, after Vaccination (at Home)	0	2 (2.0)	2 (2.0)	4 (2.0)	0	0	1 (1.0)	1 (0.5)
Day 2	0	5 (5.0)	13 (13.0)	18 (9.0)	0	5 (5.0)	7 (7.0)	12 (6.0)
Day 3	0	0	0	0	0	0	3 (3.0)	3 (1.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.0)	0	0	0	0	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Headache - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	8 (8.0)	3 (3.0)	11 (5.5)	2 (2.0)	4 (4.0)	1 (1.0)	5 (2.5)
Day 1, after Vaccination (at Home)	8 (8.0)	12 (12.0)	16 (16.0)	28 (14.0)	8 (8.0)	13 (13.0)	17 (17.0)	30 (15.0)
Day 2	5 (5.0)	25 (25.0)	36 (36.0)	61 (30.5)	9 (9.0)	31 (31.0)	30 (30.0)	61 (30.5)
Day 3	2 (2.0)	6 (6.0)	1 (1.0)	7 (3.5)	7 (7.0)	0	1 (1.0)	1 (0.5)
Day 4	3 (3.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)
Day 5	5 (5.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)
Day 6	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
Day 7	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)	1 (1.0)	0	0	0
Fatigue - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	2 (2.0)	0	0	0
Day 1, after Vaccination (at Home)	8 (8.0)	11 (11.0)	23 (23.0)	34 (17.0)	12 (12.0)	19 (19.0)	22 (22.0)	41 (20.5)
Day 2	8 (8.0)	30 (30.0)	41 (41.0)	71 (35.5)	5 (5.0)	37 (37.0)	39 (39.0)	76 (38.0)
Day 3	2 (2.0)	2 (2.0)	4 (4.0)	6 (3.0)	6 (6.0)	5 (5.0)	3 (3.0)	8 (4.0)
Day 4	2 (2.0)	1 (1.0)	0	1 (0.5)	3 (3.0)	0	2 (2.0)	2 (1.0)
Day 5	5 (5.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 6	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)
Day 7	0	2 (2.0)	0	2 (1.0)	2 (2.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Myalgia - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	3 (3.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	9 (9.0)	21 (21.0)	30 (15.0)	1 (1.0)	6 (6.0)	10 (10.0)	16 (8.0)
Day 2	1 (1.0)	29 (29.0)	35 (35.0)	64 (32.0)	5 (5.0)	31 (31.0)	38 (38.0)	69 (34.5)
Day 3	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	0	2 (2.0)	2 (1.0)
Day 4	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)
Day 5	0	0	0	0	1 (1.0)	0	0	0
Day 6	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Day 7	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Arthralgia - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	0	6 (6.0)	11 (11.0)	17 (8.5)	0	5 (5.0)	5 (5.0)	10 (5.0)
Day 2	2 (2.0)	18 (18.0)	24 (24.0)	42 (21.0)	5 (5.0)	33 (33.0)	33 (33.0)	66 (33.0)
Day 3	2 (2.0)	5 (5.0)	1 (1.0)	6 (3.0)	3 (3.0)	2 (2.0)	0	2 (1.0)
Day 4	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 5	1 (1.0)	0	0	0	2 (2.0)	0	2 (2.0)	2 (1.0)
Day 6	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Day 7	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	0	0
Day 1, after Vaccination (at Home)	0	3 (3.0)	6 (6.0)	9 (4.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
Day 2	3 (3.0)	12 (12.0)	17 (17.0)	29 (14.5)	0	5 (5.0)	10 (10.0)	15 (7.5)
Day 3	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Day 4	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Day 5	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Day 6	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Day 7	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Chills - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	3 (3.0)	0	3 (1.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 1, after Vaccination (at Home)	1 (1.0)	6 (6.0)	11 (11.0)	17 (8.5)	0	5 (5.0)	6 (6.0)	11 (5.5)
Day 2	2 (2.0)	20 (20.0)	34 (34.0)	54 (27.0)	1 (1.0)	14 (14.0)	26 (26.0)	40 (20.0)
Day 3	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)
Day 4	0	0	0	0	0	0	0	0
Day 5	1 (1.0)	0	0	0	2 (2.0)	0	0	0
Day 6	0	0	0	0	0	0	0	0
Day 7	0	0	1 (1.0)	1 (0.5)	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.3.3
Summary of Solicited Adverse Reactions within 7 Days After Any Injection by Onset Day
Solicited Safety Set

Solicited Adverse Reaction Category Onset Day	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Rash - N1	100	100	100	200	100	100	100	200
Day 1, 1 Hour after Vaccination (at Study Clinic)	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Day 1, after Vaccination (at Home)	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Day 2	2 (2.0)	2 (2.0)	4 (4.0)	6 (3.0)	0	0	1 (1.0)	1 (0.5)
Day 3	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Day 4	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	0	0
Day 5	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Day 6	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Day 7	0	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Adverse Reactions				
n	77	142	176	318
Mean (SD)	2.2 (1.96)	3.1 (2.99)	2.8 (2.29)	2.9 (2.63)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 10	1, 24	1, 20	1, 24
Solicited Local Adverse Reactions				
n	27	131	168	299
Mean (SD)	1.6 (1.82)	2.0 (0.93)	2.4 (1.84)	2.2 (1.52)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 10	1, 5	1, 20	1, 20
Pain				
n	21	131	166	297
Mean (SD)	1.1 (0.36)	2.0 (0.91)	2.2 (1.10)	2.1 (1.02)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 2	1, 4	1, 7	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Erythema (Redness)				
n	1	5	5	10
Mean (SD)	10.0 (NA)	1.4 (0.89)	1.6 (0.89)	1.5 (0.85)
Median	10.0	1.0	1.0	1.0
Min, Max	10, 10	1, 3	1, 3	1, 3
Swelling (Hardness)				
n	1	8	8	16
Mean (SD)	1.0 (NA)	1.5 (0.76)	4.4 (5.85)	2.9 (4.30)
Median	1.0	1.0	2.0	1.5
Min, Max	1, 1	1, 3	1, 18	1, 18
Lymphadenopathy [1]				
n	5	10	18	28
Mean (SD)	2.0 (1.00)	1.3 (0.48)	1.9 (1.64)	1.7 (1.36)
Median	2.0	1.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 6	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions				
n	64	83	89	172
Mean (SD)	2.1 (1.78)	3.1 (3.72)	2.2 (2.17)	2.6 (3.04)
Median	1.5	2.0	1.0	2.0
Min, Max	1, 9	1, 24	1, 14	1, 24
Fever				
n	0	0	1	1
Mean (SD)			1.0 (NA)	1.0 (NA)
Median			1.0	1.0
Min, Max			1, 1	1, 1
Headache				
n	36	58	43	101
Mean (SD)	1.6 (0.87)	2.0 (1.75)	1.8 (1.20)	1.9 (1.53)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 4	1, 10	1, 6	1, 10

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Fatigue				
n	35	48	50	98
Mean (SD)	2.1 (1.89)	2.8 (3.42)	2.5 (2.65)	2.7 (3.04)
Median	2.0	1.0	1.0	1.0
Min, Max	1, 9	1, 13	1, 14	1, 14
Myalgia				
n	14	21	28	49
Mean (SD)	2.0 (1.66)	2.0 (2.04)	1.8 (1.06)	1.9 (1.54)
Median	1.0	1.0	1.5	1.0
Min, Max	1, 7	1, 9	1, 5	1, 9
Arthralgia				
n	10	18	18	36
Mean (SD)	2.6 (2.59)	3.6 (5.38)	1.7 (1.14)	2.6 (3.95)
Median	1.5	2.0	1.0	2.0
Min, Max	1, 9	1, 23	1, 5	1, 23

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nausea/Vomiting				
n	10	11	6	17
Mean (SD)	1.2 (0.42)	1.2 (0.60)	1.5 (1.22)	1.3 (0.85)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 4	1, 4
Chills				
n	6	13	10	23
Mean (SD)	1.0 (0.00)	1.3 (0.63)	1.6 (1.26)	1.4 (0.95)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 3	1, 5	1, 5
Rash				
n	5	6	5	11
Mean (SD)	2.2 (2.17)	3.3 (2.42)	1.2 (0.45)	2.4 (2.06)
Median	1.0	3.0	1.0	1.0
Min, Max	1, 6	1, 7	1, 2	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions								
n	36	79	91	170	41	63	85	148
Mean (SD)	2.4 (2.26)	2.6 (1.66)	3.1 (2.73)	2.9 (2.30)	2.1 (1.69)	3.7 (4.04)	2.5 (1.67)	3.0 (2.97)
Median	2.0	2.0	2.0	2.0	2.0	3.0	2.0	2.0
Min, Max	1, 9	1, 11	1, 20	1, 20	1, 10	1, 24	1, 8	1, 24
Solicited Local Adverse Reactions								
n	17	73	87	160	10	58	81	139
Mean (SD)	1.3 (0.77)	2.2 (0.94)	2.7 (2.33)	2.4 (1.84)	2.2 (2.82)	1.8 (0.89)	2.0 (1.01)	1.9 (0.97)
Median	1.0	2.0	2.0	2.0	1.0	2.0	2.0	2.0
Min, Max	1, 4	1, 4	1, 20	1, 20	1, 10	1, 5	1, 5	1, 5
Pain								
n	14	73	86	159	7	58	80	138
Mean (SD)	1.1 (0.36)	2.1 (0.93)	2.4 (1.16)	2.3 (1.06)	1.1 (0.38)	1.8 (0.85)	2.0 (1.02)	1.9 (0.95)
Median	1.0	2.0	2.0	2.0	1.0	2.0	2.0	2.0
Min, Max	1, 2	1, 4	1, 7	1, 7	1, 2	1, 4	1, 5	1, 5

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Erythema (Redness)								
n	0	2	3	5	1	3	2	5
Mean (SD)		2.0 (1.41)	1.7 (1.15)	1.8 (1.10)	10.0 (NA)	1.0 (0.00)	1.5 (0.71)	1.2 (0.45)
Median		2.0	1.0	1.0	10.0	1.0	1.5	1.0
Min, Max		1, 3	1, 3	1, 3	10, 10	1, 1	1, 2	1, 2
Swelling (Hardness)								
n	0	5	5	10	1	3	3	6
Mean (SD)		1.8 (0.84)	5.8 (7.26)	3.8 (5.31)	1.0 (NA)	1.0 (0.00)	2.0 (1.00)	1.5 (0.84)
Median		2.0	2.0	2.0	1.0	1.0	2.0	1.0
Min, Max		1, 3	1, 18	1, 18	1, 1	1, 1	1, 3	1, 3
Lymphadenopathy [1]								
n	4	7	15	22	1	3	3	6
Mean (SD)	1.8 (0.96)	1.4 (0.53)	2.1 (1.75)	1.9 (1.49)	3.0 (NA)	1.0 (0.00)	1.0 (0.00)	1.0 (0.00)
Median	1.5	1.0	1.0	1.0	3.0	1.0	1.0	1.0
Min, Max	1, 3	1, 2	1, 6	1, 6	3, 3	1, 1	1, 1	1, 1

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions								
Reactions								
n	30	46	52	98	34	37	37	74
Mean (SD)	2.4 (2.30)	2.1 (1.80)	2.2 (2.35)	2.1 (2.10)	1.9 (1.15)	4.3 (4.97)	2.4 (1.93)	3.3 (3.87)
Median	1.0	1.5	1.0	1.0	2.0	2.0	2.0	2.0
Min, Max	1, 9	1, 11	1, 14	1, 14	1, 5	1, 24	1, 8	1, 24
Fever								
n	0	0	0	0	0	0	1	1
Mean (SD)							1.0 (NA)	1.0 (NA)
Median							1.0	1.0
Min, Max							1, 1	1, 1
Headache								
n	18	29	25	54	18	29	18	47
Mean (SD)	1.6 (0.86)	1.9 (1.83)	1.7 (0.98)	1.8 (1.48)	1.6 (0.92)	2.1 (1.69)	1.9 (1.47)	2.0 (1.59)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 4	1, 10	1, 4	1, 10	1, 4	1, 8	1, 6	1, 8

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fatigue								
n	17	24	30	54	18	24	20	44
Mean (SD)	2.5 (2.55)	2.0 (1.97)	2.4 (2.91)	2.2 (2.52)	1.8 (0.88)	3.7 (4.30)	2.6 (2.28)	3.2 (3.54)
Median	1.0	1.0	1.0	1.0	2.0	2.0	1.0	2.0
Min, Max	1, 9	1, 10	1, 14	1, 14	1, 4	1, 13	1, 8	1, 13
Myalgia								
n	6	11	16	27	8	10	12	22
Mean (SD)	2.3 (2.42)	1.6 (1.03)	1.5 (0.73)	1.6 (0.85)	1.8 (0.89)	2.5 (2.76)	2.3 (1.29)	2.4 (2.04)
Median	1.0	1.0	1.0	1.0	1.5	1.0	2.0	2.0
Min, Max	1, 7	1, 4	1, 3	1, 4	1, 3	1, 9	1, 5	1, 9
Arthralgia								
n	4	7	9	16	6	11	9	20
Mean (SD)	3.3 (3.86)	2.0 (1.00)	1.3 (0.50)	1.6 (0.81)	2.2 (1.60)	4.5 (6.77)	2.0 (1.50)	3.4 (5.17)
Median	1.5	2.0	1.0	1.5	1.5	2.0	1.0	2.0
Min, Max	1, 9	1, 4	1, 2	1, 4	1, 5	1, 23	1, 5	1, 23

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.1
Summary of Number of Days Reporting Solicited Adverse Reactions After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting								
n	5	6	3	9	5	5	3	8
Mean (SD)	1.2 (0.45)	1.3 (0.82)	1.0 (0.00)	1.2 (0.67)	1.2 (0.45)	1.0 (0.00)	2.0 (1.73)	1.4 (1.06)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 1	1, 3	1, 2	1, 1	1, 4	1, 4
Chills								
n	4	8	5	13	2	5	5	10
Mean (SD)	1.0 (0.00)	1.3 (0.46)	1.2 (0.45)	1.2 (0.44)	1.0 (0.00)	1.4 (0.89)	2.0 (1.73)	1.7 (1.34)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 2	1, 2	1, 1	1, 3	1, 5	1, 5
Rash								
n	4	4	4	8	1	2	1	3
Mean (SD)	2.5 (2.38)	2.0 (1.41)	1.3 (0.50)	1.6 (1.06)	1.0 (NA)	6.0 (1.41)	1.0 (NA)	4.3 (3.06)
Median	1.5	1.5	1.0	1.0	1.0	6.0	1.0	5.0
Min, Max	1, 6	1, 4	1, 2	1, 4	1, 1	5, 7	1, 1	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days of the first injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Adverse Reactions				
n	66	171	178	349
Mean (SD)	2.4 (2.63)	3.4 (2.56)	3.6 (3.50)	3.5 (3.07)
Median	1.0	3.0	3.0	3.0
Min, Max	1, 16	1, 19	1, 33	1, 33
Solicited Local Adverse Reactions				
n	16	156	170	326
Mean (SD)	2.4 (3.77)	2.6 (1.62)	2.7 (1.62)	2.7 (1.61)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 16	1, 13	1, 10	1, 13
Pain				
n	15	155	169	324
Mean (SD)	2.1 (2.69)	2.6 (1.56)	2.6 (1.42)	2.6 (1.49)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 11	1, 13	1, 7	1, 13

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Erythema (Redness)				
n	0	10	15	25
Mean (SD)		2.1 (1.10)	1.9 (0.92)	2.0 (0.98)
Median		2.0	2.0	2.0
Min, Max		1, 4	1, 4	1, 4
Swelling (Hardness)				
n	1	12	21	33
Mean (SD)	16.0 (NA)	2.8 (1.48)	2.8 (2.86)	2.8 (2.42)
Median	16.0	3.0	2.0	2.0
Min, Max	16, 16	1, 5	1, 10	1, 10
Lymphadenopathy [1]				
n	1	19	20	39
Mean (SD)	2.0 (NA)	2.1 (1.39)	1.6 (0.82)	1.8 (1.14)
Median	2.0	2.0	1.0	2.0
Min, Max	2, 2	1, 6	1, 4	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Solicited Systemic Adverse Reactions				
n	58	135	153	288
Mean (SD)	2.3 (2.10)	2.9 (2.68)	2.9 (3.70)	2.9 (3.26)
Median	1.5	2.0	2.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Fever				
n	1	12	26	38
Mean (SD)	1.0 (NA)	1.2 (0.39)	1.3 (0.93)	1.3 (0.79)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5
Headache				
n	33	96	104	200
Mean (SD)	1.6 (1.80)	2.4 (2.14)	2.3 (2.42)	2.3 (2.29)
Median	1.0	1.0	2.0	2.0
Min, Max	1, 10	1, 13	1, 18	1, 18

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Fatigue				
n	41	104	128	232
Mean (SD)	2.0 (1.79)	2.5 (2.63)	2.2 (3.14)	2.3 (2.92)
Median	1.0	2.0	1.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Myalgia				
n	15	81	104	185
Mean (SD)	1.8 (1.78)	2.2 (1.98)	1.8 (1.32)	2.0 (1.65)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 7	1, 11	1, 7	1, 11
Arthralgia				
n	13	68	77	145
Mean (SD)	2.1 (2.25)	2.1 (1.83)	2.1 (3.06)	2.1 (2.55)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 9	1, 9	1, 24	1, 24

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Nausea/Vomiting				
n	2	25	41	66
Mean (SD)	1.5 (0.71)	1.4 (0.76)	1.5 (1.12)	1.5 (1.00)
Median	1.5	1.0	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6
Chills				
n	5	49	78	127
Mean (SD)	1.4 (0.55)	1.5 (0.94)	1.4 (0.83)	1.4 (0.87)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 6	1, 5	1, 6
Rash				
n	1	10	6	16
Mean (SD)	1.0 (NA)	2.1 (1.91)	2.0 (1.26)	2.1 (1.65)
Median	1.0	1.0	1.5	1.0
Min, Max	1, 1	1, 7	1, 4	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions								
n	28	86	92	178	38	85	86	171
Mean (SD)	3.0 (3.50)	3.5 (2.94)	4.0 (4.31)	3.7 (3.71)	1.9 (1.65)	3.4 (2.13)	3.3 (2.32)	3.3 (2.22)
Median	2.0	3.0	3.0	3.0	1.0	3.0	3.0	3.0
Min, Max	1, 16	1, 19	1, 33	1, 33	1, 9	1, 13	1, 13	1, 13
Solicited Local Adverse Reactions								
n	10	78	89	167	6	78	81	159
Mean (SD)	3.2 (4.66)	2.5 (1.41)	2.7 (1.62)	2.6 (1.52)	1.0 (0.00)	2.8 (1.80)	2.7 (1.62)	2.7 (1.71)
Median	1.5	2.0	2.0	2.0	1.0	2.0	2.0	2.0
Min, Max	1, 16	1, 9	1, 10	1, 10	1, 1	1, 13	1, 9	1, 13
Pain								
n	9	78	89	167	6	77	80	157
Mean (SD)	2.8 (3.35)	2.4 (1.36)	2.6 (1.35)	2.5 (1.35)	1.0 (0.00)	2.7 (1.74)	2.6 (1.51)	2.6 (1.62)
Median	1.0	2.0	2.0	2.0	1.0	2.0	2.0	2.0
Min, Max	1, 11	1, 9	1, 7	1, 9	1, 1	1, 13	1, 7	1, 13

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Erythema (Redness)								
n	0	5	8	13	0	5	7	12
Mean (SD)		2.0 (1.22)	1.5 (0.53)	1.7 (0.85)		2.2 (1.10)	2.3 (1.11)	2.3 (1.06)
Median		2.0	1.5	2.0		2.0	2.0	2.0
Min, Max		1, 4	1, 2	1, 4		1, 4	1, 4	1, 4
Swelling (Hardness)								
n	1	6	11	17	0	6	10	16
Mean (SD)	16.0 (NA)	2.2 (1.47)	2.6 (3.20)	2.5 (2.67)		3.3 (1.37)	3.0 (2.58)	3.1 (2.16)
Median	16.0	1.5	1.0	1.0		3.5	2.0	3.0
Min, Max	16, 16	1, 4	1, 10	1, 10		1, 5	1, 9	1, 9
Lymphadenopathy [1]								
n	1	7	10	17	0	12	10	22
Mean (SD)	2.0 (NA)	1.7 (0.76)	1.7 (1.06)	1.7 (0.92)		2.3 (1.66)	1.5 (0.53)	1.9 (1.31)
Median	2.0	2.0	1.0	1.0		2.0	1.5	2.0
Min, Max	2, 2	1, 3	1, 4	1, 4		1, 6	1, 2	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions								
Reactions								
n	23	69	78	147	35	66	75	141
Mean (SD)	2.7 (2.59)	3.0 (3.21)	3.4 (4.67)	3.2 (4.04)	2.0 (1.70)	2.8 (2.02)	2.3 (2.22)	2.5 (2.13)
Median	2.0	2.0	2.0	2.0	1.0	2.0	2.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33	1, 9	1, 9	1, 13	1, 13
Fever								
n	1	7	15	22	0	5	11	16
Mean (SD)	1.0 (NA)	1.3 (0.49)	1.5 (1.19)	1.5 (1.01)		1.0 (0.00)	1.0 (0.00)	1.0 (0.00)
Median	1.0	1.0	1.0	1.0		1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5		1, 1	1, 1	1, 1
Headache								
n	14	49	55	104	19	47	49	96
Mean (SD)	2.1 (2.63)	2.7 (2.46)	2.4 (2.61)	2.5 (2.53)	1.3 (0.65)	2.0 (1.71)	2.2 (2.22)	2.1 (1.97)
Median	1.0	2.0	2.0	2.0	1.0	1.0	1.0	1.0
Min, Max	1, 10	1, 13	1, 18	1, 18	1, 3	1, 9	1, 12	1, 12

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fatigue								
n	19	44	65	109	22	60	63	123
Mean (SD)	2.0 (2.16)	2.7 (3.53)	2.8 (4.22)	2.7 (3.94)	1.9 (1.44)	2.3 (1.69)	1.7 (1.13)	2.0 (1.46)
Median	1.0	1.0	2.0	2.0	1.0	2.0	1.0	1.0
Min, Max	1, 10	1, 19	1, 33	1, 33	1, 7	1, 8	1, 7	1, 8
Myalgia								
n	4	42	57	99	11	39	47	86
Mean (SD)	1.3 (0.50)	2.3 (2.22)	2.0 (1.61)	2.1 (1.89)	2.0 (2.05)	2.1 (1.72)	1.6 (0.80)	1.8 (1.32)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 11	1, 7	1, 11	1, 7	1, 8	1, 4	1, 8
Arthralgia								
n	3	30	39	69	10	38	38	76
Mean (SD)	1.3 (0.58)	2.3 (2.12)	2.4 (3.82)	2.4 (3.17)	2.3 (2.54)	1.9 (1.58)	1.8 (2.03)	1.9 (1.81)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 9	1, 24	1, 24	1, 9	1, 8	1, 13	1, 13

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.2
Summary of Number of Days Reporting Solicited Adverse Reactions After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting								
n	2	19	28	47	0	6	13	19
Mean (SD)	1.5 (0.71)	1.3 (0.75)	1.4 (1.00)	1.4 (0.90)		1.7 (0.82)	1.6 (1.39)	1.6 (1.21)
Median	1.5	1.0	1.0	1.0		1.5	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6		1, 3	1, 6	1, 6
Chills								
n	2	28	47	75	3	21	31	52
Mean (SD)	1.5 (0.71)	1.4 (0.63)	1.4 (0.85)	1.4 (0.77)	1.3 (0.58)	1.6 (1.24)	1.3 (0.79)	1.4 (1.00)
Median	1.5	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 5	1, 5	1, 2	1, 6	1, 4	1, 6
Rash								
n	0	7	4	11	1	3	2	5
Mean (SD)		2.3 (2.21)	2.0 (1.41)	2.2 (1.89)	1.0 (NA)	1.7 (1.15)	2.0 (1.41)	1.8 (1.10)
Median		1.0	1.5	1.0	1.0	1.0	2.0	1.0
Min, Max		1, 7	1, 4	1, 7	1, 1	1, 3	1, 3	1, 3

n = Number of exposed subjects who reported the event on any day within 7 days of the second injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Adverse Reactions				
n	103	182	192	374
Mean (SD)	2.6 (2.61)	3.8 (3.19)	4.0 (3.65)	3.9 (3.43)
Median	2.0	3.0	3.0	3.0
Min, Max	1, 16	1, 24	1, 33	1, 33
Solicited Local Adverse Reactions				
n	38	171	185	356
Mean (SD)	2.0 (2.86)	2.7 (1.56)	3.0 (1.99)	2.9 (1.80)
Median	1.0	2.0	3.0	3.0
Min, Max	1, 16	1, 13	1, 20	1, 20
Pain				
n	32	171	183	354
Mean (SD)	1.6 (1.88)	2.6 (1.50)	2.8 (1.39)	2.7 (1.45)
Median	1.0	2.0	3.0	2.0
Min, Max	1, 11	1, 13	1, 7	1, 13

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Erythema (Redness)				
n	1	12	19	31
Mean (SD)	10.0 (NA)	2.0 (1.13)	1.8 (0.90)	1.9 (0.98)
Median	10.0	2.0	2.0	2.0
Min, Max	10, 10	1, 4	1, 4	1, 4
Swelling (Hardness)				
n	2	16	25	41
Mean (SD)	8.5 (10.61)	2.5 (1.41)	3.2 (3.87)	2.9 (3.14)
Median	8.5	2.5	2.0	2.0
Min, Max	1, 16	1, 5	1, 18	1, 18
Lymphadenopathy [1]				
n	5	24	32	56
Mean (SD)	2.0 (1.00)	1.9 (1.30)	1.8 (1.33)	1.8 (1.30)
Median	2.0	1.5	1.0	1.0
Min, Max	1, 3	1, 6	1, 6	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Solicited Systemic Adverse Reactions				
n	91	148	167	315
Mean (SD)	2.4 (2.16)	3.3 (3.51)	3.0 (3.72)	3.1 (3.62)
Median	2.0	2.0	2.0	2.0
Min, Max	1, 10	1, 24	1, 33	1, 33
Fever				
n	1	12	26	38
Mean (SD)	1.0 (NA)	1.2 (0.39)	1.3 (0.93)	1.3 (0.79)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5
Headache				
n	59	111	115	226
Mean (SD)	1.7 (1.47)	2.4 (2.09)	2.3 (2.34)	2.3 (2.22)
Median	1.0	2.0	2.0	2.0
Min, Max	1, 10	1, 13	1, 18	1, 18

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Fatigue				
n	61	113	138	251
Mean (SD)	2.1 (2.01)	2.7 (3.15)	2.4 (3.29)	2.6 (3.22)
Median	1.0	2.0	1.5	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33
Myalgia				
n	26	87	111	198
Mean (SD)	2.0 (1.78)	2.2 (2.07)	1.9 (1.34)	2.0 (1.70)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 7	1, 11	1, 7	1, 11
Arthralgia				
n	21	74	79	153
Mean (SD)	2.4 (2.44)	2.4 (3.15)	2.2 (3.04)	2.3 (3.09)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 9	1, 23	1, 24	1, 24

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nausea/Vomiting				
n	11	31	43	74
Mean (SD)	1.3 (0.47)	1.4 (0.76)	1.5 (1.16)	1.5 (1.01)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6
Chills				
n	11	52	83	135
Mean (SD)	1.2 (0.40)	1.5 (0.94)	1.4 (0.90)	1.4 (0.91)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 6	1, 5	1, 6
Rash				
n	6	14	11	25
Mean (SD)	2.0 (2.00)	2.6 (2.28)	1.6 (1.03)	2.2 (1.86)
Median	1.0	1.0	1.0	1.0
Min, Max	1, 6	1, 7	1, 4	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions								
n	48	92	95	187	55	90	97	187
Mean (SD)	3.0 (3.22)	3.6 (2.85)	4.4 (4.60)	4.0 (3.85)	2.3 (1.89)	4.0 (3.52)	3.6 (2.35)	3.8 (2.97)
Median	2.0	3.0	3.0	3.0	1.0	3.0	3.0	3.0
Min, Max	1, 16	1, 19	1, 33	1, 33	1, 10	1, 24	1, 13	1, 24
Solicited Local Adverse Reactions								
n	23	86	93	179	15	85	92	177
Mean (SD)	2.1 (3.20)	2.7 (1.32)	3.2 (2.34)	2.9 (1.93)	1.8 (2.34)	2.7 (1.77)	2.8 (1.55)	2.8 (1.65)
Median	1.0	2.0	3.0	3.0	1.0	2.0	3.0	2.0
Min, Max	1, 16	1, 9	1, 20	1, 20	1, 10	1, 13	1, 9	1, 13
Pain								
n	20	86	93	179	12	85	90	175
Mean (SD)	1.9 (2.34)	2.6 (1.28)	2.9 (1.33)	2.7 (1.31)	1.1 (0.29)	2.6 (1.71)	2.7 (1.46)	2.7 (1.58)
Median	1.0	2.0	3.0	3.0	1.0	2.0	2.0	2.0
Min, Max	1, 11	1, 9	1, 7	1, 9	1, 2	1, 13	1, 7	1, 13

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Erythema (Redness)								
n	0	5	10	15	1	7	9	16
Mean (SD)		2.2 (1.30)	1.6 (0.70)	1.8 (0.94)	10.0 (NA)	1.9 (1.07)	2.1 (1.05)	2.0 (1.03)
Median		2.0	1.5	2.0	10.0	2.0	2.0	2.0
Min, Max		1, 4	1, 3	1, 4	10, 10	1, 4	1, 4	1, 4
Swelling (Hardness)								
n	1	8	13	21	1	8	12	20
Mean (SD)	16.0 (NA)	2.3 (1.28)	3.5 (4.98)	3.0 (3.97)	1.0 (NA)	2.8 (1.58)	2.9 (2.35)	2.9 (2.03)
Median	16.0	2.0	1.0	1.0	1.0	3.0	2.0	2.5
Min, Max	16, 16	1, 4	1, 18	1, 18	1, 1	1, 5	1, 9	1, 9
Lymphadenopathy [1]								
n	4	11	19	30	1	13	13	26
Mean (SD)	1.8 (0.96)	1.5 (0.69)	2.1 (1.63)	1.9 (1.37)	3.0 (NA)	2.2 (1.63)	1.4 (0.51)	1.8 (1.24)
Median	1.5	1.0	1.0	1.0	3.0	2.0	1.0	1.0
Min, Max	1, 3	1, 3	1, 6	1, 6	3, 3	1, 6	1, 2	1, 6

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Systemic Adverse Reactions								
Reactions								
n	40	76	84	160	51	72	83	155
Mean (SD)	2.8 (2.68)	3.0 (3.07)	3.4 (4.67)	3.2 (3.98)	2.1 (1.60)	3.6 (3.91)	2.5 (2.34)	3.0 (3.20)
Median	2.0	2.0	2.0	2.0	1.0	2.5	2.0	2.0
Min, Max	1, 10	1, 19	1, 33	1, 33	1, 9	1, 24	1, 13	1, 24
Fever								
n	1	7	15	22	0	5	11	16
Mean (SD)	1.0 (NA)	1.3 (0.49)	1.5 (1.19)	1.5 (1.01)		1.0 (0.00)	1.0 (0.00)	1.0 (0.00)
Median	1.0	1.0	1.0	1.0		1.0	1.0	1.0
Min, Max	1, 1	1, 2	1, 5	1, 5		1, 1	1, 1	1, 1
Headache								
n	28	58	60	118	31	53	55	108
Mean (SD)	1.9 (1.94)	2.5 (2.31)	2.4 (2.53)	2.4 (2.42)	1.5 (0.81)	2.2 (1.84)	2.2 (2.13)	2.2 (1.99)
Median	1.0	2.0	2.0	2.0	1.0	1.0	2.0	1.5
Min, Max	1, 10	1, 13	1, 18	1, 18	1, 4	1, 9	1, 12	1, 12

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Fatigue								
n	28	50	70	120	33	63	68	131
Mean (SD)	2.4 (2.60)	2.6 (3.34)	2.8 (4.30)	2.8 (3.92)	1.8 (1.30)	2.8 (3.02)	2.0 (1.63)	2.4 (2.43)
Median	1.0	1.0	2.0	2.0	1.0	2.0	1.0	1.0
Min, Max	1, 10	1, 19	1, 33	1, 33	1, 7	1, 13	1, 8	1, 13
Myalgia								
n	10	46	59	105	16	41	52	93
Mean (SD)	1.9 (1.91)	2.2 (2.15)	2.1 (1.59)	2.1 (1.85)	2.0 (1.75)	2.2 (2.01)	1.7 (0.97)	1.9 (1.53)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 7	1, 11	1, 7	1, 11	1, 7	1, 9	1, 5	1, 9
Arthralgia								
n	7	32	39	71	14	42	40	82
Mean (SD)	2.4 (2.94)	2.2 (2.07)	2.4 (3.81)	2.3 (3.13)	2.4 (2.28)	2.5 (3.79)	1.9 (2.06)	2.2 (3.07)
Median	1.0	1.0	2.0	1.0	1.5	1.0	1.0	1.0
Min, Max	1, 9	1, 9	1, 24	1, 24	1, 9	1, 23	1, 13	1, 23

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.4.3
Summary of Number of Days Reporting Solicited Adverse Reactions After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting								
n	6	20	28	48	5	11	15	26
Mean (SD)	1.3 (0.52)	1.4 (0.82)	1.4 (1.00)	1.4 (0.92)	1.2 (0.45)	1.4 (0.67)	1.7 (1.44)	1.6 (1.17)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 4	1, 6	1, 6	1, 2	1, 3	1, 6	1, 6
Chills								
n	6	30	48	78	5	22	35	57
Mean (SD)	1.2 (0.41)	1.4 (0.61)	1.4 (0.85)	1.4 (0.76)	1.2 (0.45)	1.6 (1.26)	1.4 (0.98)	1.5 (1.09)
Median	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Min, Max	1, 2	1, 3	1, 5	1, 5	1, 2	1, 6	1, 5	1, 6
Rash								
n	4	10	8	18	2	4	3	7
Mean (SD)	2.5 (2.38)	2.2 (1.99)	1.6 (1.06)	1.9 (1.63)	1.0 (0.00)	3.5 (3.00)	1.7 (1.15)	2.7 (2.43)
Median	1.5	1.0	1.0	1.0	1.0	3.0	1.0	1.0
Min, Max	1, 6	1, 7	1, 4	1, 7	1, 1	1, 7	1, 3	1, 7

n = Number of exposed subjects who reported the event on any day within 7 days after any injection.
Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second injection is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=199) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Solicited Adverse Reactions - N1	199	200	200	400
1-2 days	57 (28.6)	75 (37.5)	101 (50.5)	176 (44.0)
3-4 days	13 (6.5)	47 (23.5)	53 (26.5)	100 (25.0)
5-6 days	2 (1.0)	11 (5.5)	12 (6.0)	23 (5.8)
>=7 days	5 (2.5)	9 (4.5)	10 (5.0)	19 (4.8)
Solicited Local Adverse Reactions - N1	199	200	200	400
1-2 days	24 (12.1)	97 (48.5)	103 (51.5)	200 (50.0)
3-4 days	2 (1.0)	33 (16.5)	59 (29.5)	92 (23.0)
5-6 days	0	1 (0.5)	2 (1.0)	3 (0.8)
>=7 days	1 (0.5)	0	4 (2.0)	4 (1.0)
Pain - N1	199	200	199	399
1-2 days	21 (10.6)	98 (49.0)	106 (53.3)	204 (51.1)
3-4 days	0	33 (16.5)	56 (28.1)	89 (22.3)
5-6 days	0	0	3 (1.5)	3 (0.8)
>=7 days	0	0	1 (0.5)	1 (0.3)
Erythema (Redness) - N1	199	200	199	399
1-2 days	0	4 (2.0)	4 (2.0)	8 (2.0)
3-4 days	0	1 (0.5)	1 (0.5)	2 (0.5)
5-6 days	0	0	0	0
>=7 days	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=199) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Swelling (Hardness) - N1	199	200	200	400
1-2 days	1 (0.5)	7 (3.5)	5 (2.5)	12 (3.0)
3-4 days	0	1 (0.5)	1 (0.5)	2 (0.5)
5-6 days	0	0	0	0
>=7 days	0	0	2 (1.0)	2 (0.5)
Lymphadenopathy - N1 [1]	199	200	199	399
1-2 days	3 (1.5)	10 (5.0)	14 (7.0)	24 (6.0)
3-4 days	2 (1.0)	0	2 (1.0)	2 (0.5)
5-6 days	0	0	2 (1.0)	2 (0.5)
>=7 days	0	0	0	0
Solicited Systemic Adverse Reactions - N1	199	200	199	399
1-2 days	48 (24.1)	55 (27.5)	71 (35.7)	126 (31.6)
3-4 days	10 (5.0)	15 (7.5)	7 (3.5)	22 (5.5)
5-6 days	2 (1.0)	5 (2.5)	7 (3.5)	12 (3.0)
>=7 days	4 (2.0)	8 (4.0)	4 (2.0)	12 (3.0)
Fever - N1	199	200	199	399
1-2 days	0	0	1 (0.5)	1 (0.3)
3-4 days	0	0	0	0
5-6 days	0	0	0	0
>=7 days	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Headache - N1	199	200	199	399
1-2 days	31 (15.6)	47 (23.5)	34 (17.1)	81 (20.3)
3-4 days	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
5-6 days	0	2 (1.0)	2 (1.0)	4 (1.0)
>=7 days	0	2 (1.0)	0	2 (0.5)
Fatigue - N1	199	200	199	399
1-2 days	29 (14.6)	35 (17.5)	37 (18.6)	72 (18.0)
3-4 days	3 (1.5)	7 (3.5)	6 (3.0)	13 (3.3)
5-6 days	0	1 (0.5)	3 (1.5)	4 (1.0)
>=7 days	3 (1.5)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia - N1	199	200	199	399
1-2 days	10 (5.0)	17 (8.5)	22 (11.1)	39 (9.8)
3-4 days	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)
5-6 days	0	1 (0.5)	1 (0.5)	2 (0.5)
>=7 days	1 (0.5)	1 (0.5)	0	1 (0.3)
Arthralgia - N1	199	200	199	399
1-2 days	7 (3.5)	14 (7.0)	16 (8.0)	30 (7.5)
3-4 days	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
5-6 days	1 (0.5)	0	1 (0.5)	1 (0.3)
>=7 days	1 (0.5)	2 (1.0)	0	2 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nausea/Vomiting - N1	199	200	199	399
1-2 days	10 (5.0)	10 (5.0)	5 (2.5)	15 (3.8)
3-4 days	0	1 (0.5)	1 (0.5)	2 (0.5)
5-6 days	0	0	0	0
>=7 days	0	0	0	0
Chills - N1	199	200	199	399
1-2 days	6 (3.0)	12 (6.0)	9 (4.5)	21 (5.3)
3-4 days	0	1 (0.5)	0	1 (0.3)
5-6 days	0	0	1 (0.5)	1 (0.3)
>=7 days	0	0	0	0
Rash - N1	199	200	199	399
1-2 days	4 (2.0)	3 (1.5)	5 (2.5)	8 (2.0)
3-4 days	0	1 (0.5)	0	1 (0.3)
5-6 days	1 (0.5)	1 (0.5)	0	1 (0.3)
>=7 days	0	1 (0.5)	0	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions - N1	100	100	100	200	99	100	100	200
1-2 days	28 (28.0)	44 (44.0)	48 (48.0)	92 (46.0)	29 (29.3)	31 (31.0)	53 (53.0)	84 (42.0)
3-4 days	4 (4.0)	27 (27.0)	29 (29.0)	56 (28.0)	9 (9.1)	20 (20.0)	24 (24.0)	44 (22.0)
5-6 days	0	6 (6.0)	8 (8.0)	14 (7.0)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
>=7 days	4 (4.0)	2 (2.0)	6 (6.0)	8 (4.0)	1 (1.0)	7 (7.0)	4 (4.0)	11 (5.5)
Solicited Local Adverse Reactions - N1	100	100	100	200	99	100	100	200
1-2 days	16 (16.0)	49 (49.0)	49 (49.0)	98 (49.0)	8 (8.1)	48 (48.0)	54 (54.0)	102 (51.0)
3-4 days	1 (1.0)	24 (24.0)	33 (33.0)	57 (28.5)	1 (1.0)	9 (9.0)	26 (26.0)	35 (17.5)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	0	0	4 (4.0)	4 (2.0)	1 (1.0)	0	0	0
Pain - N1	100	100	100	200	99	100	99	199
1-2 days	14 (14.0)	50 (50.0)	52 (52.0)	102 (51.0)	7 (7.1)	48 (48.0)	54 (54.5)	102 (51.3)
3-4 days	0	23 (23.0)	31 (31.0)	54 (27.0)	0	10 (10.0)	25 (25.3)	35 (17.6)
5-6 days	0	0	2 (2.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
>=7 days	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Erythema (Redness) - N1	100	100	100	200	99	100	99	199
1-2 days	0	1 (1.0)	2 (2.0)	3 (1.5)	0	3 (3.0)	2 (2.0)	5 (2.5)
3-4 days	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	0	0	1 (1.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	100	100	100	200	99	100	100	200
1-2 days	0	4 (4.0)	3 (3.0)	7 (3.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
3-4 days	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Lymphadenopathy - N1 [1]	100	100	100	200	99	100	99	199
1-2 days	3 (3.0)	7 (7.0)	11 (11.0)	18 (9.0)	0	3 (3.0)	3 (3.0)	6 (3.0)
3-4 days	1 (1.0)	0	2 (2.0)	2 (1.0)	1 (1.0)	0	0	0
5-6 days	0	0	2 (2.0)	2 (1.0)	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	100	200	99	100	99	199
1-2 days	23 (23.0)	35 (35.0)	44 (44.0)	79 (39.5)	25 (25.3)	20 (20.0)	27 (27.3)	47 (23.6)
3-4 days	3 (3.0)	7 (7.0)	3 (3.0)	10 (5.0)	7 (7.1)	8 (8.0)	4 (4.0)	12 (6.0)
5-6 days	0	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	2 (2.0)	4 (4.0)	6 (3.0)
>=7 days	4 (4.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	7 (7.0)	2 (2.0)	9 (4.5)
Fever - N1	100	100	100	200	99	100	99	199
1-2 days	0	0	0	0	0	0	1 (1.0)	1 (0.5)
3-4 days	0	0	0	0	0	0	0	0
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Headache - N1	100	100	100	200	99	100	99	199
1-2 days	16 (16.0)	24 (24.0)	20 (20.0)	44 (22.0)	15 (15.2)	23 (23.0)	14 (14.1)	37 (18.6)
3-4 days	2 (2.0)	3 (3.0)	5 (5.0)	8 (4.0)	3 (3.0)	4 (4.0)	2 (2.0)	6 (3.0)
5-6 days	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
>=7 days	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Fatigue - N1	100	100	100	200	99	100	99	199
1-2 days	14 (14.0)	19 (19.0)	23 (23.0)	42 (21.0)	15 (15.2)	16 (16.0)	14 (14.1)	30 (15.1)
3-4 days	0	4 (4.0)	4 (4.0)	8 (4.0)	3 (3.0)	3 (3.0)	2 (2.0)	5 (2.5)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	2 (2.0)	3 (1.5)
>=7 days	3 (3.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	4 (4.0)	2 (2.0)	6 (3.0)
Myalgia - N1	100	100	100	200	99	100	99	199
1-2 days	4 (4.0)	9 (9.0)	14 (14.0)	23 (11.5)	6 (6.1)	8 (8.0)	8 (8.1)	16 (8.0)
3-4 days	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	0	3 (3.0)	3 (1.5)
5-6 days	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Arthralgia - N1	100	100	100	200	99	100	99	199
1-2 days	3 (3.0)	6 (6.0)	9 (9.0)	15 (7.5)	4 (4.0)	8 (8.0)	7 (7.1)	15 (7.5)
3-4 days	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
5-6 days	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
>=7 days	1 (1.0)	0	0	0	0	2 (2.0)	0	2 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.1
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After First Injection
First Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=99)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	100	100	100	200	99	100	99	199
1-2 days	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	5 (5.1)	5 (5.0)	2 (2.0)	7 (3.5)
3-4 days	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0
Chills - N1	100	100	100	200	99	100	99	199
1-2 days	4 (4.0)	8 (8.0)	5 (5.0)	13 (6.5)	2 (2.0)	4 (4.0)	4 (4.0)	8 (4.0)
3-4 days	0	0	0	0	0	1 (1.0)	0	1 (0.5)
5-6 days	0	0	0	0	0	0	1 (1.0)	1 (0.5)
>=7 days	0	0	0	0	0	0	0	0
Rash - N1	100	100	100	200	99	100	99	199
1-2 days	3 (3.0)	3 (3.0)	4 (4.0)	7 (3.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
3-4 days	0	1 (1.0)	0	1 (0.5)	0	0	0	0
5-6 days	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
>=7 days	0	0	0	0	0	1 (1.0)	0	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Solicited Adverse Reactions - N1	194	195	198	393
1-2 days	49 (25.3)	75 (38.5)	72 (36.4)	147 (37.4)
3-4 days	11 (5.7)	62 (31.8)	67 (33.8)	129 (32.8)
5-6 days	2 (1.0)	18 (9.2)	22 (11.1)	40 (10.2)
>=7 days	4 (2.1)	16 (8.2)	17 (8.6)	33 (8.4)
Solicited Local Adverse Reactions - N1	194	195	198	393
1-2 days	14 (7.2)	87 (44.6)	94 (47.5)	181 (46.1)
3-4 days	0	53 (27.2)	58 (29.3)	111 (28.2)
5-6 days	1 (0.5)	14 (7.2)	11 (5.6)	25 (6.4)
>=7 days	1 (0.5)	2 (1.0)	7 (3.5)	9 (2.3)
Pain - N1	194	195	198	393
1-2 days	13 (6.7)	88 (45.1)	97 (49.0)	185 (47.1)
3-4 days	0	55 (28.2)	56 (28.3)	111 (28.2)
5-6 days	1 (0.5)	10 (5.1)	11 (5.6)	21 (5.3)
>=7 days	1 (0.5)	2 (1.0)	5 (2.5)	7 (1.8)
Erythema (Redness) - N1	194	195	198	393
1-2 days	0	8 (4.1)	12 (6.1)	20 (5.1)
3-4 days	0	2 (1.0)	3 (1.5)	5 (1.3)
5-6 days	0	0	0	0
>=7 days	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Swelling (Hardness) - N1	194	195	198	393
1-2 days	0	5 (2.6)	15 (7.6)	20 (5.1)
3-4 days	0	6 (3.1)	2 (1.0)	8 (2.0)
5-6 days	0	1 (0.5)	1 (0.5)	2 (0.5)
>=7 days	1 (0.5)	0	3 (1.5)	3 (0.8)
Lymphadenopathy - N1 [1]	194	195	198	393
1-2 days	1 (0.5)	15 (7.7)	18 (9.1)	33 (8.4)
3-4 days	0	2 (1.0)	2 (1.0)	4 (1.0)
5-6 days	0	2 (1.0)	0	2 (0.5)
>=7 days	0	0	0	0
Solicited Systemic Adverse Reactions - N1	194	195	198	393
1-2 days	44 (22.7)	77 (39.5)	100 (50.5)	177 (45.0)
3-4 days	9 (4.6)	36 (18.5)	31 (15.7)	67 (17.0)
5-6 days	2 (1.0)	11 (5.6)	10 (5.1)	21 (5.3)
>=7 days	3 (1.5)	11 (5.6)	12 (6.1)	23 (5.9)
Fever - N1	194	195	198	393
1-2 days	1 (0.5)	12 (6.2)	23 (11.6)	35 (8.9)
3-4 days	0	0	2 (1.0)	2 (0.5)
5-6 days	0	0	1 (0.5)	1 (0.3)
>=7 days	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=194) n (%)	mRNA-1273		Total (N=393) n (%)
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	
Headache - N1	194	195	198	393
1-2 days	29 (14.9)	65 (33.3)	77 (38.9)	142 (36.1)
3-4 days	2 (1.0)	20 (10.3)	17 (8.6)	37 (9.4)
5-6 days	1 (0.5)	7 (3.6)	5 (2.5)	12 (3.1)
>=7 days	1 (0.5)	4 (2.1)	5 (2.5)	9 (2.3)
Fatigue - N1	194	195	198	393
1-2 days	33 (17.0)	72 (36.9)	100 (50.5)	172 (43.8)
3-4 days	6 (3.1)	21 (10.8)	18 (9.1)	39 (9.9)
5-6 days	0	4 (2.1)	6 (3.0)	10 (2.5)
>=7 days	2 (1.0)	7 (3.6)	4 (2.0)	11 (2.8)
Myalgia - N1	194	195	198	393
1-2 days	13 (6.7)	60 (30.8)	86 (43.4)	146 (37.2)
3-4 days	0	15 (7.7)	12 (6.1)	27 (6.9)
5-6 days	1 (0.5)	1 (0.5)	5 (2.5)	6 (1.5)
>=7 days	1 (0.5)	5 (2.6)	1 (0.5)	6 (1.5)
Arthralgia - N1	194	195	198	393
1-2 days	11 (5.7)	52 (26.7)	64 (32.3)	116 (29.5)
3-4 days	1 (0.5)	10 (5.1)	9 (4.5)	19 (4.8)
5-6 days	0	3 (1.5)	1 (0.5)	4 (1.0)
>=7 days	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Nausea/Vomiting - N1	194	195	198	393
1-2 days	2 (1.0)	23 (11.8)	39 (19.7)	62 (15.8)
3-4 days	0	2 (1.0)	0	2 (0.5)
5-6 days	0	0	2 (1.0)	2 (0.5)
>=7 days	0	0	0	0
Chills - N1	194	195	198	393
1-2 days	5 (2.6)	45 (23.1)	72 (36.4)	117 (29.8)
3-4 days	0	3 (1.5)	5 (2.5)	8 (2.0)
5-6 days	0	1 (0.5)	1 (0.5)	2 (0.5)
>=7 days	0	0	0	0
Rash - N1	194	195	198	393
1-2 days	1 (0.5)	7 (3.6)	4 (2.0)	11 (2.8)
3-4 days	0	2 (1.0)	2 (1.0)	4 (1.0)
5-6 days	0	0	0	0
>=7 days	0	1 (0.5)	0	1 (0.3)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions - N1	94	97	99	196	100	98	99	197
1-2 days	20 (21.3)	40 (41.2)	35 (35.4)	75 (38.3)	29 (29.0)	35 (35.7)	37 (37.4)	72 (36.5)
3-4 days	4 (4.3)	29 (29.9)	36 (36.4)	65 (33.2)	7 (7.0)	33 (33.7)	31 (31.3)	64 (32.5)
5-6 days	1 (1.1)	7 (7.2)	11 (11.1)	18 (9.2)	1 (1.0)	11 (11.2)	11 (11.1)	22 (11.2)
>=7 days	3 (3.2)	10 (10.3)	10 (10.1)	20 (10.2)	1 (1.0)	6 (6.1)	7 (7.1)	13 (6.6)
Solicited Local Adverse Reactions - N1	94	97	99	196	100	98	99	197
1-2 days	8 (8.5)	46 (47.4)	49 (49.5)	95 (48.5)	6 (6.0)	41 (41.8)	45 (45.5)	86 (43.7)
3-4 days	0	25 (25.8)	32 (32.3)	57 (29.1)	0	28 (28.6)	26 (26.3)	54 (27.4)
5-6 days	1 (1.1)	6 (6.2)	4 (4.0)	10 (5.1)	0	8 (8.2)	7 (7.1)	15 (7.6)
>=7 days	1 (1.1)	1 (1.0)	4 (4.0)	5 (2.6)	0	1 (1.0)	3 (3.0)	4 (2.0)
Pain - N1	94	97	99	196	100	98	99	197
1-2 days	7 (7.4)	47 (48.5)	49 (49.5)	96 (49.0)	6 (6.0)	41 (41.8)	48 (48.5)	89 (45.2)
3-4 days	0	25 (25.8)	33 (33.3)	58 (29.6)	0	30 (30.6)	23 (23.2)	53 (26.9)
5-6 days	1 (1.1)	5 (5.2)	5 (5.1)	10 (5.1)	0	5 (5.1)	6 (6.1)	11 (5.6)
>=7 days	1 (1.1)	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
Erythema (Redness) - N1	94	97	99	196	100	98	99	197
1-2 days	0	4 (4.1)	8 (8.1)	12 (6.1)	0	4 (4.1)	4 (4.0)	8 (4.1)
3-4 days	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	94	97	99	196	100	98	99	197
1-2 days	0	4 (4.1)	9 (9.1)	13 (6.6)	0	1 (1.0)	6 (6.1)	7 (3.6)
3-4 days	0	2 (2.1)	0	2 (1.0)	0	4 (4.1)	2 (2.0)	6 (3.0)
5-6 days	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	1 (1.1)	0	2 (2.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Lymphadenopathy - N1 [1]	94	97	99	196	100	98	99	197
1-2 days	1 (1.1)	6 (6.2)	8 (8.1)	14 (7.1)	0	9 (9.2)	10 (10.1)	19 (9.6)
3-4 days	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
5-6 days	0	0	0	0	0	2 (2.0)	0	2 (1.0)
>=7 days	0	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	94	97	99	196	100	98	99	197
1-2 days	18 (19.1)	42 (43.3)	45 (45.5)	87 (44.4)	26 (26.0)	35 (35.7)	55 (55.6)	90 (45.7)
3-4 days	2 (2.1)	15 (15.5)	19 (19.2)	34 (17.3)	7 (7.0)	21 (21.4)	12 (12.1)	33 (16.8)
5-6 days	1 (1.1)	6 (6.2)	6 (6.1)	12 (6.1)	1 (1.0)	5 (5.1)	4 (4.0)	9 (4.6)
>=7 days	2 (2.1)	6 (6.2)	8 (8.1)	14 (7.1)	1 (1.0)	5 (5.1)	4 (4.0)	9 (4.6)
Fever - N1	94	97	99	196	100	98	99	197
1-2 days	1 (1.1)	7 (7.2)	12 (12.1)	19 (9.7)	0	5 (5.1)	11 (11.1)	16 (8.1)
3-4 days	0	0	2 (2.0)	2 (1.0)	0	0	0	0
5-6 days	0	0	1 (1.0)	1 (0.5)	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Headache - N1	94	97	99	196	100	98	99	197
1-2 days	12 (12.8)	30 (30.9)	39 (39.4)	69 (35.2)	17 (17.0)	35 (35.7)	38 (38.4)	73 (37.1)
3-4 days	0	12 (12.4)	11 (11.1)	23 (11.7)	2 (2.0)	8 (8.2)	6 (6.1)	14 (7.1)
5-6 days	1 (1.1)	4 (4.1)	3 (3.0)	7 (3.6)	0	3 (3.1)	2 (2.0)	5 (2.5)
>=7 days	1 (1.1)	3 (3.1)	2 (2.0)	5 (2.6)	0	1 (1.0)	3 (3.0)	4 (2.0)
Fatigue - N1	94	97	99	196	100	98	99	197
1-2 days	16 (17.0)	32 (33.0)	45 (45.5)	77 (39.3)	17 (17.0)	40 (40.8)	55 (55.6)	95 (48.2)
3-4 days	2 (2.1)	6 (6.2)	12 (12.1)	18 (9.2)	4 (4.0)	15 (15.3)	6 (6.1)	21 (10.7)
5-6 days	0	2 (2.1)	5 (5.1)	7 (3.6)	0	2 (2.0)	1 (1.0)	3 (1.5)
>=7 days	1 (1.1)	4 (4.1)	3 (3.0)	7 (3.6)	1 (1.0)	3 (3.1)	1 (1.0)	4 (2.0)
Myalgia - N1	94	97	99	196	100	98	99	197
1-2 days	4 (4.3)	31 (32.0)	46 (46.5)	77 (39.3)	9 (9.0)	29 (29.6)	40 (40.4)	69 (35.0)
3-4 days	0	8 (8.2)	5 (5.1)	13 (6.6)	0	7 (7.1)	7 (7.1)	14 (7.1)
5-6 days	0	0	5 (5.1)	5 (2.6)	1 (1.0)	1 (1.0)	0	1 (0.5)
>=7 days	0	3 (3.1)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Arthralgia - N1	94	97	99	196	100	98	99	197
1-2 days	3 (3.2)	21 (21.6)	32 (32.3)	53 (27.0)	8 (8.0)	31 (31.6)	32 (32.3)	63 (32.0)
3-4 days	0	6 (6.2)	4 (4.0)	10 (5.1)	1 (1.0)	4 (4.1)	5 (5.1)	9 (4.6)
5-6 days	0	1 (1.0)	1 (1.0)	2 (1.0)	0	2 (2.0)	0	2 (1.0)
>=7 days	0	2 (2.1)	2 (2.0)	4 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.2
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Second Injection
Second Injection Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	94	97	99	196	100	98	99	197
1-2 days	2 (2.1)	18 (18.6)	27 (27.3)	45 (23.0)	0	5 (5.1)	12 (12.1)	17 (8.6)
3-4 days	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
>=7 days	0	0	0	0	0	0	0	0
Chills - N1	94	97	99	196	100	98	99	197
1-2 days	2 (2.1)	26 (26.8)	43 (43.4)	69 (35.2)	3 (3.0)	19 (19.4)	29 (29.3)	48 (24.4)
3-4 days	0	2 (2.1)	3 (3.0)	5 (2.6)	0	1 (1.0)	2 (2.0)	3 (1.5)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
>=7 days	0	0	0	0	0	0	0	0
Rash - N1	94	97	99	196	100	98	99	197
1-2 days	0	5 (5.2)	3 (3.0)	8 (4.1)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
3-4 days	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	1 (1.0)	0	1 (0.5)	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Solicited Adverse Reactions - N1	200	200	200	400
1-2 days	71 (35.5)	70 (35.0)	67 (33.5)	137 (34.3)
3-4 days	19 (9.5)	69 (34.5)	74 (37.0)	143 (35.8)
5-6 days	4 (2.0)	22 (11.0)	27 (13.5)	49 (12.3)
>=7 days	9 (4.5)	21 (10.5)	24 (12.0)	45 (11.3)
Solicited Local Adverse Reactions - N1	200	200	200	400
1-2 days	33 (16.5)	91 (45.5)	82 (41.0)	173 (43.3)
3-4 days	2 (1.0)	63 (31.5)	82 (41.0)	145 (36.3)
5-6 days	1 (0.5)	15 (7.5)	12 (6.0)	27 (6.8)
>=7 days	2 (1.0)	2 (1.0)	9 (4.5)	11 (2.8)
Pain - N1	200	200	200	400
1-2 days	30 (15.0)	94 (47.0)	85 (42.5)	179 (44.8)
3-4 days	0	65 (32.5)	80 (40.0)	145 (36.3)
5-6 days	1 (0.5)	10 (5.0)	13 (6.5)	23 (5.8)
>=7 days	1 (0.5)	2 (1.0)	5 (2.5)	7 (1.8)
Erythema (Redness) - N1	200	200	200	400
1-2 days	0	9 (4.5)	15 (7.5)	24 (6.0)
3-4 days	0	3 (1.5)	4 (2.0)	7 (1.8)
5-6 days	0	0	0	0
>=7 days	1 (0.5)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Swelling (Hardness) - N1	200	200	200	400
1-2 days	1 (0.5)	8 (4.0)	17 (8.5)	25 (6.3)
3-4 days	0	7 (3.5)	3 (1.5)	10 (2.5)
5-6 days	0	1 (0.5)	1 (0.5)	2 (0.5)
>=7 days	1 (0.5)	0	4 (2.0)	4 (1.0)
Lymphadenopathy - N1 [1]	200	200	200	400
1-2 days	3 (1.5)	20 (10.0)	27 (13.5)	47 (11.8)
3-4 days	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
5-6 days	0	2 (1.0)	2 (1.0)	4 (1.0)
>=7 days	0	0	0	0
Solicited Systemic Adverse Reactions - N1	200	200	200	400
1-2 days	65 (32.5)	83 (41.5)	107 (53.5)	190 (47.5)
3-4 days	15 (7.5)	38 (19.0)	31 (15.5)	69 (17.3)
5-6 days	4 (2.0)	11 (5.5)	14 (7.0)	25 (6.3)
>=7 days	7 (3.5)	16 (8.0)	15 (7.5)	31 (7.8)
Fever - N1	200	200	200	400
1-2 days	1 (0.5)	12 (6.0)	23 (11.5)	35 (8.8)
3-4 days	0	0	2 (1.0)	2 (0.5)
5-6 days	0	0	1 (0.5)	1 (0.3)
>=7 days	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Headache - N1	200	200	200	400
1-2 days	51 (25.5)	76 (38.0)	85 (42.5)	161 (40.3)
3-4 days	6 (3.0)	23 (11.5)	19 (9.5)	42 (10.5)
5-6 days	1 (0.5)	7 (3.5)	6 (3.0)	13 (3.3)
>=7 days	1 (0.5)	5 (2.5)	5 (2.5)	10 (2.5)
Fatigue - N1	200	200	200	400
1-2 days	48 (24.0)	77 (38.5)	104 (52.0)	181 (45.3)
3-4 days	8 (4.0)	22 (11.0)	20 (10.0)	42 (10.5)
5-6 days	0	4 (2.0)	7 (3.5)	11 (2.8)
>=7 days	5 (2.5)	10 (5.0)	7 (3.5)	17 (4.3)
Myalgia - N1	200	200	200	400
1-2 days	20 (10.0)	66 (33.0)	89 (44.5)	155 (38.8)
3-4 days	3 (1.5)	14 (7.0)	15 (7.5)	29 (7.3)
5-6 days	1 (0.5)	1 (0.5)	6 (3.0)	7 (1.8)
>=7 days	2 (1.0)	6 (3.0)	1 (0.5)	7 (1.8)
Arthralgia - N1	200	200	200	400
1-2 days	16 (8.0)	57 (28.5)	65 (32.5)	122 (30.5)
3-4 days	2 (1.0)	10 (5.0)	9 (4.5)	19 (4.8)
5-6 days	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
>=7 days	2 (1.0)	5 (2.5)	3 (1.5)	8 (2.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nausea/Vomiting - N1	200	200	200	400
1-2 days	11 (5.5)	28 (14.0)	40 (20.0)	68 (17.0)
3-4 days	0	3 (1.5)	1 (0.5)	4 (1.0)
5-6 days	0	0	2 (1.0)	2 (0.5)
>=7 days	0	0	0	0
Chills - N1	200	200	200	400
1-2 days	11 (5.5)	47 (23.5)	76 (38.0)	123 (30.8)
3-4 days	0	4 (2.0)	5 (2.5)	9 (2.3)
5-6 days	0	1 (0.5)	2 (1.0)	3 (0.8)
>=7 days	0	0	0	0
Rash - N1	200	200	200	400
1-2 days	5 (2.5)	9 (4.5)	9 (4.5)	18 (4.5)
3-4 days	0	2 (1.0)	2 (1.0)	4 (1.0)
5-6 days	1 (0.5)	1 (0.5)	0	1 (0.3)
>=7 days	0	2 (1.0)	0	2 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Solicited Adverse Reactions - N1	100	100	100	200	100	100	100	200
1-2 days	34 (34.0)	36 (36.0)	30 (30.0)	66 (33.0)	37 (37.0)	34 (34.0)	37 (37.0)	71 (35.5)
3-4 days	6 (6.0)	35 (35.0)	39 (39.0)	74 (37.0)	13 (13.0)	34 (34.0)	35 (35.0)	69 (34.5)
5-6 days	1 (1.0)	10 (10.0)	13 (13.0)	23 (11.5)	3 (3.0)	12 (12.0)	14 (14.0)	26 (13.0)
>=7 days	7 (7.0)	11 (11.0)	13 (13.0)	24 (12.0)	2 (2.0)	10 (10.0)	11 (11.0)	21 (10.5)
Solicited Local Adverse Reactions - N1	100	100	100	200	100	100	100	200
1-2 days	20 (20.0)	45 (45.0)	37 (37.0)	82 (41.0)	13 (13.0)	46 (46.0)	45 (45.0)	91 (45.5)
3-4 days	1 (1.0)	34 (34.0)	46 (46.0)	80 (40.0)	1 (1.0)	29 (29.0)	36 (36.0)	65 (32.5)
5-6 days	1 (1.0)	6 (6.0)	4 (4.0)	10 (5.0)	0	9 (9.0)	8 (8.0)	17 (8.5)
>=7 days	1 (1.0)	1 (1.0)	6 (6.0)	7 (3.5)	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)
Pain - N1	100	100	100	200	100	100	100	200
1-2 days	18 (18.0)	47 (47.0)	39 (39.0)	86 (43.0)	12 (12.0)	47 (47.0)	46 (46.0)	93 (46.5)
3-4 days	0	33 (33.0)	46 (46.0)	79 (39.5)	0	32 (32.0)	34 (34.0)	66 (33.0)
5-6 days	1 (1.0)	5 (5.0)	6 (6.0)	11 (5.5)	0	5 (5.0)	7 (7.0)	12 (6.0)
>=7 days	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
Erythema (Redness) - N1	100	100	100	200	100	100	100	200
1-2 days	0	3 (3.0)	9 (9.0)	12 (6.0)	0	6 (6.0)	6 (6.0)	12 (6.0)
3-4 days	0	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	3 (3.0)	4 (2.0)
5-6 days	0	0	0	0	0	0	0	0
>=7 days	0	0	0	0	1 (1.0)	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Swelling (Hardness) - N1	100	100	100	200	100	100	100	200
1-2 days	0	5 (5.0)	10 (10.0)	15 (7.5)	1 (1.0)	3 (3.0)	7 (7.0)	10 (5.0)
3-4 days	0	3 (3.0)	0	3 (1.5)	0	4 (4.0)	3 (3.0)	7 (3.5)
5-6 days	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Lymphadenopathy - N1 [1]	100	100	100	200	100	100	100	200
1-2 days	3 (3.0)	10 (10.0)	14 (14.0)	24 (12.0)	0	10 (10.0)	13 (13.0)	23 (11.5)
3-4 days	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
5-6 days	0	0	2 (2.0)	2 (1.0)	0	2 (2.0)	0	2 (1.0)
>=7 days	0	0	0	0	0	0	0	0
Solicited Systemic Adverse Reactions - N1	100	100	100	200	100	100	100	200
1-2 days	29 (29.0)	47 (47.0)	50 (50.0)	97 (48.5)	36 (36.0)	36 (36.0)	57 (57.0)	93 (46.5)
3-4 days	4 (4.0)	15 (15.0)	18 (18.0)	33 (16.5)	11 (11.0)	23 (23.0)	13 (13.0)	36 (18.0)
5-6 days	1 (1.0)	8 (8.0)	7 (7.0)	15 (7.5)	3 (3.0)	3 (3.0)	7 (7.0)	10 (5.0)
>=7 days	6 (6.0)	6 (6.0)	9 (9.0)	15 (7.5)	1 (1.0)	10 (10.0)	6 (6.0)	16 (8.0)
Fever - N1	100	100	100	200	100	100	100	200
1-2 days	1 (1.0)	7 (7.0)	12 (12.0)	19 (9.5)	0	5 (5.0)	11 (11.0)	16 (8.0)
3-4 days	0	0	2 (2.0)	2 (1.0)	0	0	0	0
5-6 days	0	0	1 (1.0)	1 (0.5)	0	0	0	0
>=7 days	0	0	0	0	0	0	0	0

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Headache - N1	100	100	100	200	100	100	100	200
1-2 days	24 (24.0)	39 (39.0)	43 (43.0)	82 (41.0)	27 (27.0)	37 (37.0)	42 (42.0)	79 (39.5)
3-4 days	2 (2.0)	12 (12.0)	12 (12.0)	24 (12.0)	4 (4.0)	11 (11.0)	7 (7.0)	18 (9.0)
5-6 days	1 (1.0)	4 (4.0)	3 (3.0)	7 (3.5)	0	3 (3.0)	3 (3.0)	6 (3.0)
>=7 days	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	2 (2.0)	3 (3.0)	5 (2.5)
Fatigue - N1	100	100	100	200	100	100	100	200
1-2 days	22 (22.0)	37 (37.0)	49 (49.0)	86 (43.0)	26 (26.0)	40 (40.0)	55 (55.0)	95 (47.5)
3-4 days	2 (2.0)	7 (7.0)	13 (13.0)	20 (10.0)	6 (6.0)	15 (15.0)	7 (7.0)	22 (11.0)
5-6 days	0	2 (2.0)	4 (4.0)	6 (3.0)	0	2 (2.0)	3 (3.0)	5 (2.5)
>=7 days	4 (4.0)	4 (4.0)	4 (4.0)	8 (4.0)	1 (1.0)	6 (6.0)	3 (3.0)	9 (4.5)
Myalgia - N1	100	100	100	200	100	100	100	200
1-2 days	8 (8.0)	35 (35.0)	47 (47.0)	82 (41.0)	12 (12.0)	31 (31.0)	42 (42.0)	73 (36.5)
3-4 days	1 (1.0)	8 (8.0)	6 (6.0)	14 (7.0)	2 (2.0)	6 (6.0)	9 (9.0)	15 (7.5)
5-6 days	0	0	5 (5.0)	5 (2.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	3 (3.0)	0	3 (1.5)
Arthralgia - N1	100	100	100	200	100	100	100	200
1-2 days	6 (6.0)	23 (23.0)	32 (32.0)	55 (27.5)	10 (10.0)	34 (34.0)	33 (33.0)	67 (33.5)
3-4 days	0	6 (6.0)	4 (4.0)	10 (5.0)	2 (2.0)	4 (4.0)	5 (5.0)	9 (4.5)
5-6 days	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.5.3
Summary of Number of Days Reporting Solicited Adverse Reactions by Time Window After Any Injection
Solicited Safety Set

Solicited Adverse Reaction Category Time Window	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nausea/Vomiting - N1	100	100	100	200	100	100	100	200
1-2 days	6 (6.0)	18 (18.0)	27 (27.0)	45 (22.5)	5 (5.0)	10 (10.0)	13 (13.0)	23 (11.5)
3-4 days	0	2 (2.0)	0	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
>=7 days	0	0	0	0	0	0	0	0
Chills - N1	100	100	100	200	100	100	100	200
1-2 days	6 (6.0)	28 (28.0)	44 (44.0)	72 (36.0)	5 (5.0)	19 (19.0)	32 (32.0)	51 (25.5)
3-4 days	0	2 (2.0)	3 (3.0)	5 (2.5)	0	2 (2.0)	2 (2.0)	4 (2.0)
5-6 days	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
>=7 days	0	0	0	0	0	0	0	0
Rash - N1	100	100	100	200	100	100	100	200
1-2 days	3 (3.0)	7 (7.0)	7 (7.0)	14 (7.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
3-4 days	0	2 (2.0)	1 (1.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
5-6 days	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
>=7 days	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Number of days is calculated as the days of the solicited adverse reaction reported within the 7 days of injection including the day of injection. If the solicited AR continues beyond 7 days, the consecutive days a solicited adverse reaction is reported after 7 days are included. The number of days which is higher with solicited events after either the first or the second vaccination is summarized.

[1] Lymphadenopathy = Localized axillary swelling or tenderness ipsilateral to the vaccination arm.

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Table 14.3.1.6.1
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After First Injection
First Injection Solicited Safety Set

Category Grade	Overall			
	Placebo (N=199) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	1	5	2	7
Any	1 (100)	2 (40.0)	1 (50.0)	3 (42.9)
Grade 1	1 (100)	2 (40.0)	1 (50.0)	3 (42.9)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Lymphadenopathy - N1	2	6	7	13
Any	1 (50.0)	1 (16.7)	2 (28.6)	3 (23.1)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

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Table 14.3.1.6.1
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After First Injection
First Injection Solicited Safety Set

Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=99)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Rash - N1	1	3	2	5	0	2	0	2
Any	1 (100)	1 (33.3)	1 (50.0)	2 (40.0)	0	1 (50.0)	0	1 (50.0)
Grade 1	1 (100)	1 (33.3)	1 (50.0)	2 (40.0)	0	1 (50.0)	0	1 (50.0)
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1	2	3	6	9	0	3	1	4
Any	1 (50.0)	0	2 (33.3)	2 (22.2)	0	1 (33.3)	0	1 (25.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

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Table 14.3.1.6.2
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After Second Injection
Second Injection Solicited Safety Set

Category Grade	Overall			
	Placebo (N=194) n (%)	mRNA-1273		
		50 µg (N=195) n (%)	100 µg (N=198) n (%)	Total (N=393) n (%)
Rash - N1	1	6	0	6
Any	0	3 (50.0)	0	3 (50.0)
Grade 1	0	3 (50.0)	0	3 (50.0)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Lymphadenopathy - N1	0	10	10	20
Any	0	1 (10.0)	2 (20.0)	3 (15.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

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Table 14.3.1.6.2
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After Second Injection
Second Injection Solicited Safety Set

Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=94)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=97)	100 µg (N=99)	Total (N=196)		50 µg (N=98)	100 µg (N=99)	Total (N=197)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Rash - N1	0	4	0	4	1	2	0	2
Any	0	3 (75.0)	0	3 (75.0)	0	0	0	0
Grade 1	0	3 (75.0)	0	3 (75.0)	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1	0	4	6	10	0	6	4	10
Any	0	0	1 (16.7)	1 (10.0)	0	1 (16.7)	1 (25.0)	2 (20.0)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

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Table 14.3.1.6.3
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After Any Injection
Solicited Safety Set

Category Grade	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Rash - N1	2	10	2	12
Any	1 (50.0)	5 (50.0)	1 (50.0)	6 (50.0)
Grade 1	1 (50.0)	5 (50.0)	1 (50.0)	6 (50.0)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Lymphadenopathy - N1	2	14	15	29
Any	1 (50.0)	1 (7.1)	4 (26.7)	5 (17.2)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010603.sas 19NOV2020 02:25 Database Lock Date: 05NOV2020

Table 14.3.1.6.3
Summary of Rash and Lymphadenopathy Assessed by Healthcare Provider within 7 Days After Any Injection
Solicited Safety Set

Category Grade	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Rash - N1	1	7	2	9	1	3	0	3
Any	1 (100)	4 (57.1)	1 (50.0)	5 (55.6)	0	1 (33.3)	0	1 (33.3)
Grade 1	1 (100)	4 (57.1)	1 (50.0)	5 (55.6)	0	1 (33.3)	0	1 (33.3)
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Lymphadenopathy - N1	2	7	10	17	0	7	5	12
Any	1 (50.0)	0	3 (30.0)	3 (17.6)	0	1 (14.3)	1 (20.0)	2 (16.7)

N1 = Number of exposed subjects who submitted any data for the event.

Percentages are based on the number of exposed subjects who submitted any data for the event (N1).

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Table 14.3.1.7.1
Summary of Unsolicited TEAE up to 28 Days after Any Vaccination
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination				
All	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically-Attended	17 (8.5)	22 (11.0)	17 (8.5)	39 (9.8)
Leading to Discontinuation from Study Vaccine	0	0	0	0
Leading to Study Discontinuation	0	0	0	0
Severe	4 (2.0)	7 (3.5)	5 (2.5)	12 (3.0)
Unsolicited TEAEs Related to Study Vaccination				
All	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically-Attended	1 (0.5)	1 (0.5)	5 (2.5)	6 (1.5)
Leading to Discontinuation from Study Vaccine	0	0	0	0
Leading to Study Discontinuation	0	0	0	0
Severe	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)

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.
Percentages are based on the number of safety subjects.

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Table 14.3.1.7.1
Summary of Unsolicited TEAE up to 28 Days after Any Vaccination
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination								
All	24 (24.0)	27 (27.0)	26 (26.0)	53 (26.5)	27 (27.0)	30 (30.0)	30 (30.0)	60 (30.0)
Serious	0	0	0	0	0	0	0	0
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	10 (10.0)	11 (11.0)	8 (8.0)	19 (9.5)	7 (7.0)	11 (11.0)	9 (9.0)	20 (10.0)
Leading to Discontinuation from Study Vaccine	0	0	0	0	0	0	0	0
Leading to Study Discontinuation	0	0	0	0	0	0	0	0
Severe	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
Unsolicited TEAEs Related to Study Vaccination								
All	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Serious	0	0	0	0	0	0	0	0
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	0	1 (1.0)	4 (4.0)	5 (2.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Leading to Discontinuation from Study Vaccine	0	0	0	0	0	0	0	0
Leading to Study Discontinuation	0	0	0	0	0	0	0	0
Severe	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)

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.
Percentages are based on the number of safety subjects.

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Table 14.3.1.7.2
Summary of Unsolicited TEAE from Day 1 to Day 57 Visit
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination				
All	55 (27.5)	61 (30.5)	59 (29.5)	120 (30.0)
Serious	0	1 (0.5)	0	1 (0.3)
Fatal	0	0	0	0
Medically-Attended	19 (9.5)	24 (12.0)	18 (9.0)	42 (10.5)
Leading to Discontinuation from Study Vaccine	1 (0.5)	1 (0.5)	0	1 (0.3)
Leading to Study Discontinuation	0	0	0	0
Severe	4 (2.0)	8 (4.0)	5 (2.5)	13 (3.3)
Unsolicited TEAEs Related to Study Vaccination				
All	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically-Attended	1 (0.5)	1 (0.5)	5 (2.5)	6 (1.5)
Leading to Discontinuation from Study Vaccine	0	0	0	0
Leading to Study Discontinuation	0	0	0	0
Severe	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)

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.
Percentages are based on the number of safety subjects.

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Table 14.3.1.7.2
Summary of Unsolicited TEAE from Day 1 to Day 57 Visit
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination								
All	27 (27.0)	29 (29.0)	28 (28.0)	57 (28.5)	28 (28.0)	32 (32.0)	31 (31.0)	63 (31.5)
Serious	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	12 (12.0)	11 (11.0)	9 (9.0)	20 (10.0)	7 (7.0)	13 (13.0)	9 (9.0)	22 (11.0)
Leading to Discontinuation from Study Vaccine	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Leading to Study Discontinuation	0	0	0	0	0	0	0	0
Severe	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Unsolicited TEAEs Related to Study Vaccination								
All	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Serious	0	0	0	0	0	0	0	0
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	0	1 (1.0)	4 (4.0)	5 (2.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Leading to Discontinuation from Study Vaccine	0	0	0	0	0	0	0	0
Leading to Study Discontinuation	0	0	0	0	0	0	0	0
Severe	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)

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.
Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Number of Unsolicited Adverse Events	76	104	90	194
Infections and infestations	9 (4.5)	7 (3.5)	7 (3.5)	14 (3.5)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
COVID-19	2 (1.0)	2 (1.0)	0	2 (0.5)
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Cellulitis	1 (0.5)	0	0	0
Hordeolum	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Otitis media	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.5)	0	1 (0.3)
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Blood and lymphatic system disorders	1 (0.5)	0	0	0
Leukopenia	1 (0.5)	0	0	0
Immune system disorders	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Allergy to arthropod sting	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Hyperlipidaemia	1 (0.5)	0	0	0
Psychiatric disorders	0	1 (0.5)	2 (1.0)	3 (0.8)
Anxiety	0	0	1 (0.5)	1 (0.3)
Depression	0	0	1 (0.5)	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Nervous system disorders	6 (3.0)	12 (6.0)	12 (6.0)	24 (6.0)
Headache	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Dizziness	0	0	1 (0.5)	1 (0.3)
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Tension headache	0	1 (0.5)	0	1 (0.3)
Lethargy	1 (0.5)	0	0	0
Ear and labyrinth disorders	0	1 (0.5)	0	1 (0.3)
Ear pain	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)
Respiratory, thoracic and mediastinal disorders	5 (2.5)	3 (1.5)	3 (1.5)	6 (1.5)
Oropharyngeal pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Rhinorrhoea	0	1 (0.5)	2 (1.0)	3 (0.8)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)				
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Cough	2 (1.0)	0	0	0
Dry throat	1 (0.5)	0	0	0
Sinus congestion	1 (0.5)	0	0	0
Upper respiratory tract inflammation	1 (0.5)	0	0	0
Gastrointestinal disorders	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Diarrhoea	0	2 (1.0)	0	2 (0.5)
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dental caries	0	1 (0.5)	0	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Abdominal tenderness	1 (0.5)	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Odynophagia	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Skin and subcutaneous tissue disorders	8 (4.0)	11 (5.5)	6 (3.0)	17 (4.3)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	8 (4.0)	16 (8.0)	12 (6.0)	28 (7.0)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Back pain	0	2 (1.0)	1 (0.5)	3 (0.8)
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Joint swelling	0	1 (0.5)	0	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Bursitis	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Renal and urinary disorders	2 (1.0)	2 (1.0)	0	2 (0.5)
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Haematuria	1 (0.5)	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Reproductive system and breast disorders	1 (0.5)	0	0	0
Postmenopausal haemorrhage	1 (0.5)	0	0	0
General disorders and administration site conditions	10 (5.0)	17 (8.5)	17 (8.5)	34 (8.5)
Fatigue	6 (3.0)	11 (5.5)	3 (1.5)	14 (3.5)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Chest pain	0	1 (0.5)	0	1 (0.3)
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Injection site mass	0	0	1 (0.5)	1 (0.3)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Mass	0	0	1 (0.5)	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Investigations	5 (2.5)	2 (1.0)	3 (1.5)	5 (1.3)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Platelet count decreased	0	1 (0.5)	0	1 (0.3)
Cardiac murmur	1 (0.5)	0	0	0
Heart rate decreased	2 (1.0)	0	0	0
Injury, poisoning and procedural complications	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Joint injury	0	0	1 (0.5)	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Skin laceration	2 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	24 (24.0)	27 (27.0)	26 (26.0)	53 (26.5)	27 (27.0)	30 (30.0)	30 (30.0)	60 (30.0)
Number of Unsolicited Adverse Events	39	51	45	96	37	53	45	98
Infections and infestations	5 (5.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	2 (2.0)	5 (5.0)	7 (3.5)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
COVID-19	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010801.sas 19NOV2020 00:28 Database Lock Date: 05NOV2020

Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood and lymphatic system disorders	0	0	0	0	1 (1.0)	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Immune system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Anxiety	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders	4 (4.0)	6 (6.0)	4 (4.0)	10 (5.0)	2 (2.0)	6 (6.0)	8 (8.0)	14 (7.0)
Headache	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Ear and labyrinth disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vascular disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Oropharyngeal pain	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rhinorrhoea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)

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Table 14.3.1.8.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)								
Pharyngeal erythema	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Cough	2 (2.0)	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Sinus congestion	1 (1.0)	0	0	0	0	0	0	0
Upper respiratory tract inflammation	0	0	0	0	1 (1.0)	0	0	0
Gastrointestinal disorders	3 (3.0)	3 (3.0)	4 (4.0)	7 (3.5)	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)
Nausea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Diarrhoea	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Toothache	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	3 (3.0)	6 (6.0)	3 (3.0)	9 (4.5)
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
					mRNA-1273								mRNA-1273			
	Placebo (N=100)		50 µg (N=100)		100 µg (N=100)		Total (N=200)		Placebo (N=100)		50 µg (N=100)		100 µg (N=100)		Total (N=200)	
	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Musculoskeletal and connective tissue disorders	2 (2.0)		9 (9.0)		5 (5.0)		14 (7.0)		6 (6.0)		7 (7.0)		7 (7.0)		14 (7.0)	
Arthralgia	1 (1.0)		3 (3.0)		2 (2.0)		5 (2.5)		3 (3.0)		2 (2.0)		2 (2.0)		4 (2.0)	
Myalgia	2 (2.0)		4 (4.0)		2 (2.0)		6 (3.0)		1 (1.0)		2 (2.0)		0		2 (1.0)	
Back pain	0		1 (1.0)		0		1 (0.5)		0		1 (1.0)		1 (1.0)		2 (1.0)	
Muscle spasms	0		1 (1.0)		1 (1.0)		2 (1.0)		0		0		0		0	
Musculoskeletal pain	0		0		0		0		1 (1.0)		1 (1.0)		1 (1.0)		2 (1.0)	
Axillary mass	0		0		1 (1.0)		1 (0.5)		0		0		0		0	
Joint swelling	0		1 (1.0)		0		1 (0.5)		0		0		0		0	
Musculoskeletal chest pain	0		0		0		0		0		0		1 (1.0)		1 (0.5)	
Musculoskeletal stiffness	0		0		0		0		0		0		1 (1.0)		1 (0.5)	
Neck pain	0		0		0		0		1 (1.0)		0		1 (1.0)		1 (0.5)	
Plantar fasciitis	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Rotator cuff syndrome	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Spondylolisthesis	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Bursitis	0		0		0		0		1 (1.0)		0		0		0	
Exostosis	0		0		0		0		1 (1.0)		0		0		0	
Renal and urinary disorders	1 (1.0)		0		0		0		1 (1.0)		2 (2.0)		0		2 (1.0)	
Hypertonic bladder	1 (1.0)		0		0		0		0		1 (1.0)		0		1 (0.5)	
Nephrolithiasis	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Haematuria	0		0		0		0		1 (1.0)		0		0		0	

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Reproductive system and breast disorders	0	0	0	0	1 (1.0)	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
General disorders and administration site conditions	5 (5.0)	8 (8.0)	12 (12.0)	20 (10.0)	5 (5.0)	9 (9.0)	5 (5.0)	14 (7.0)
Fatigue	4 (4.0)	4 (4.0)	3 (3.0)	7 (3.5)	2 (2.0)	7 (7.0)	0	7 (3.5)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)

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MedDRA version 23.0

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Table 14.3.1.8.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations	1 (1.0)	1 (1.0)	0	1 (0.5)	4 (4.0)	1 (1.0)	3 (3.0)	4 (2.0)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Injury, poisoning and procedural complications	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	55 (27.5)	61 (30.5)	59 (29.5)	120 (30.0)
Number of Unsolicited Adverse Events	87	118	94	212
Infections and infestations	13 (6.5)	8 (4.0)	7 (3.5)	15 (3.8)
Urinary tract infection	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
COVID-19	5 (2.5)	2 (1.0)	0	2 (0.5)
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	2 (1.0)	1 (0.5)	0	1 (0.3)
Cellulitis	1 (0.5)	0	0	0
Hordeolum	1 (0.5)	0	0	0
Oral candidiasis	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
Otitis media	1 (0.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.5)	0	1 (0.3)
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Blood and lymphatic system disorders	1 (0.5)	0	0	0
Leukopenia	1 (0.5)	0	0	0
Immune system disorders	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Allergy to arthropod sting	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Hyperlipidaemia	1 (0.5)	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Psychiatric disorders	0	2 (1.0)	3 (1.5)	5 (1.3)
Anxiety	0	1 (0.5)	1 (0.5)	2 (0.5)
Depression	0	0	2 (1.0)	2 (0.5)
Insomnia	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	7 (3.5)	15 (7.5)	13 (6.5)	28 (7.0)
Headache	6 (3.0)	10 (5.0)	8 (4.0)	18 (4.5)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Dizziness	0	1 (0.5)	1 (0.5)	2 (0.5)
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Tension headache	0	1 (0.5)	0	1 (0.3)
Lethargy	1 (0.5)	0	0	0
Ear and labyrinth disorders	0	1 (0.5)	0	1 (0.3)
Ear pain	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)

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.

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Respiratory, thoracic and mediastinal disorders	7 (3.5)	5 (2.5)	4 (2.0)	9 (2.3)
Rhinorrhoea	0	1 (0.5)	3 (1.5)	4 (1.0)
Oropharyngeal pain	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Cough	3 (1.5)	1 (0.5)	0	1 (0.3)
Nasal congestion	0	1 (0.5)	0	1 (0.3)
Nasal pruritus	0	1 (0.5)	0	1 (0.3)
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Dry throat	1 (0.5)	0	0	0
Sinus congestion	2 (1.0)	0	0	0
Upper respiratory tract inflammation	1 (0.5)	0	0	0
Gastrointestinal disorders	6 (3.0)	9 (4.5)	7 (3.5)	16 (4.0)
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Diarrhoea	1 (0.5)	3 (1.5)	0	3 (0.8)
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dental caries	0	1 (0.5)	0	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Abdominal tenderness	1 (0.5)	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Odynophagia	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Skin and subcutaneous tissue disorders	8 (4.0)	11 (5.5)	6 (3.0)	17 (4.3)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	9 (4.5)	16 (8.0)	12 (6.0)	28 (7.0)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Back pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Joint swelling	0	1 (0.5)	0	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Bursitis	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Renal and urinary disorders	2 (1.0)	2 (1.0)	0	2 (0.5)
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Haematuria	1 (0.5)	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Reproductive system and breast disorders	1 (0.5)	0	0	0
Postmenopausal haemorrhage	1 (0.5)	0	0	0
General disorders and administration site conditions	10 (5.0)	19 (9.5)	17 (8.5)	36 (9.0)
Fatigue	6 (3.0)	12 (6.0)	3 (1.5)	15 (3.8)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Chest discomfort	0	1 (0.5)	0	1 (0.3)
Chest pain	0	1 (0.5)	0	1 (0.3)
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Injection site mass	0	0	1 (0.5)	1 (0.3)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Mass	0	0	1 (0.5)	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Investigations	5 (2.5)	3 (1.5)	4 (2.0)	7 (1.8)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Platelet count decreased	0	1 (0.5)	0	1 (0.3)
Platelet count increased	0	1 (0.5)	0	1 (0.3)
White blood cell count decreased	0	0	1 (0.5)	1 (0.3)
Cardiac murmur	1 (0.5)	0	0	0
Heart rate decreased	2 (1.0)	0	0	0
Injury, poisoning and procedural complications	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Joint injury	0	0	1 (0.5)	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (cont.)				
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Skin laceration	2 (1.0)	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	27 (27.0)	29 (29.0)	28 (28.0)	57 (28.5)	28 (28.0)	32 (32.0)	31 (31.0)	63 (31.5)
Number of Unsolicited Adverse Events	48	59	48	107	39	59	46	105
Infections and infestations	9 (9.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	3 (3.0)	5 (5.0)	8 (4.0)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
COVID-19	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Oral candidiasis	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)								
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood and lymphatic system disorders	0	0	0	0	1 (1.0)	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Immune system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Psychiatric disorders	0	0	3 (3.0)	3 (1.5)	0	2 (2.0)	0	2 (1.0)
Anxiety	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Depression	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nervous system disorders	5 (5.0)	8 (8.0)	5 (5.0)	13 (6.5)	2 (2.0)	7 (7.0)	8 (8.0)	15 (7.5)
Headache	4 (4.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Dizziness	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Ear and labyrinth disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vascular disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
					mRNA-1273								mRNA-1273			
	Placebo (N=100)		50 µg (N=100)		100 µg (N=100)		Total (N=200)		Placebo (N=100)		50 µg (N=100)		100 µg (N=100)		Total (N=200)	
	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Respiratory, thoracic and mediastinal disorders	4 (4.0)		3 (3.0)		2 (2.0)		5 (2.5)		3 (3.0)		2 (2.0)		2 (2.0)		4 (2.0)	
Rhinorrhoea	0		1 (1.0)		2 (2.0)		3 (1.5)		0		0		1 (1.0)		1 (0.5)	
Oropharyngeal pain	1 (1.0)		0		0		0		1 (1.0)		2 (2.0)		1 (1.0)		3 (1.5)	
Cough	3 (3.0)		1 (1.0)		0		1 (0.5)		0		0		0		0	
Nasal congestion	0		1 (1.0)		0		1 (0.5)		0		0		0		0	
Nasal pruritus	0		1 (1.0)		0		1 (0.5)		0		0		0		0	
Pharyngeal erythema	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Dry throat	1 (1.0)		0		0		0		0		0		0		0	
Sinus congestion	1 (1.0)		0		0		0		1 (1.0)		0		0		0	
Upper respiratory tract inflammation	0		0		0		0		1 (1.0)		0		0		0	
Gastrointestinal disorders	4 (4.0)		4 (4.0)		4 (4.0)		8 (4.0)		2 (2.0)		5 (5.0)		3 (3.0)		8 (4.0)	
Nausea	0		1 (1.0)		1 (1.0)		2 (1.0)		0		1 (1.0)		1 (1.0)		2 (1.0)	
Diarrhoea	1 (1.0)		2 (2.0)		0		2 (1.0)		0		1 (1.0)		0		1 (0.5)	
Toothache	1 (1.0)		1 (1.0)		0		1 (0.5)		0		1 (1.0)		0		1 (0.5)	
Abdominal discomfort	0		0		1 (1.0)		1 (0.5)		0		0		0		0	
Aphthous ulcer	0		0		0		0		0		0		1 (1.0)		1 (0.5)	
Dental caries	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Diverticulum	0		0		0		0		0		0		1 (1.0)		1 (0.5)	
Dry mouth	0		0		1 (1.0)		1 (0.5)		0		0		0		0	
Haemorrhoids	0		0		1 (1.0)		1 (0.5)		0		0		0		0	

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	3 (3.0)	6 (6.0)	3 (3.0)	9 (4.5)
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
	mRNA-1273				mRNA-1273				mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders	2 (2.0)	9 (9.0)	5 (5.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Back pain	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Muscle spasms	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0	0	0	0	0	0	0	0	0
Joint swelling	0	1 (1.0)	0	1 (0.5)	0	0	0	0	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Neck pain	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Plantar fasciitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Bursitis	0	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Renal and urinary disorders	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	1 (1.0)	0	1 (1.0)
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Haematuria	0	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Reproductive system and breast disorders	0	0	0	0	1 (1.0)	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
General disorders and administration site conditions	5 (5.0)	10 (10.0)	12 (12.0)	22 (11.0)	5 (5.0)	9 (9.0)	5 (5.0)	14 (7.0)
Fatigue	4 (4.0)	5 (5.0)	3 (3.0)	8 (4.0)	2 (2.0)	7 (7.0)	0	7 (3.5)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Chest discomfort	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations	1 (1.0)	1 (1.0)	0	1 (0.5)	4 (4.0)	2 (2.0)	4 (4.0)	6 (3.0)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
Blood alkaline phosphatase increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Platelet count increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
White blood cell count decreased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Injury, poisoning and procedural complications	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.
MedDRA version 23.0

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Number of Unsolicited Adverse Events	76	104	90	194
Headache	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Fatigue	6 (3.0)	11 (5.5)	3 (1.5)	14 (3.5)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Back pain	0	2 (1.0)	1 (0.5)	3 (0.8)
Oropharyngeal pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Rhinorrhoea	0	1 (0.5)	2 (1.0)	3 (0.8)

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MedDRA version 23.0

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
COVID-19	2 (1.0)	2 (1.0)	0	2 (0.5)
Diarrhoea	0	2 (1.0)	0	2 (0.5)
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Anxiety	0	0	1 (0.5)	1 (0.3)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Chest pain	0	1 (0.5)	0	1 (0.3)
Dental caries	0	1 (0.5)	0	1 (0.3)

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Depression	0	0	1 (0.5)	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Dizziness	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Ear pain	0	1 (0.5)	0	1 (0.3)
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Injection site mass	0	0	1 (0.5)	1 (0.3)

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Joint injury	0	0	1 (0.5)	1 (0.3)
Joint swelling	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Mass	0	0	1 (0.5)	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Platelet count decreased	0	1 (0.5)	0	1 (0.3)

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Tension headache	0	1 (0.5)	0	1 (0.3)
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Abdominal tenderness	1 (0.5)	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0
Angioedema	1 (0.5)	0	0	0
Bursitis	1 (0.5)	0	0	0
Cardiac murmur	1 (0.5)	0	0	0
Cellulitis	1 (0.5)	0	0	0
Cough	2 (1.0)	0	0	0
Dry throat	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Haematuria	1 (0.5)	0	0	0
Heart rate decreased	2 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Hordeolum	1 (0.5)	0	0	0
Hyperlipidaemia	1 (0.5)	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Lethargy	1 (0.5)	0	0	0
Leukopenia	1 (0.5)	0	0	0
Odynophagia	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Otitis media	1 (0.5)	0	0	0
Postmenopausal haemorrhage	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0
Sinus congestion	1 (0.5)	0	0	0
Skin laceration	2 (1.0)	0	0	0
Upper respiratory tract inflammation	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	24 (24.0)	27 (27.0)	26 (26.0)	53 (26.5)	27 (27.0)	30 (30.0)	30 (30.0)	60 (30.0)
Number of Unsolicited Adverse Events	39	51	45	96	37	53	45	98
Headache	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Fatigue	4 (4.0)	4 (4.0)	3 (3.0)	7 (3.5)	2 (2.0)	7 (7.0)	0	7 (3.5)
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Nausea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Back pain	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Oropharyngeal pain	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Rhinorrhoea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
COVID-19	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Diarrhoea	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Muscle spasms	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Toothache	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Anxiety	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Joint swelling	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Neck pain	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pharyngeal erythema	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Plantar fasciitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Cough	2 (2.0)	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Haematuria	0	0	0	0	1 (1.0)	0	0	0
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.9.1
Subject Incidence of Unsolicited TEAE by Preferred Term up to 28 Days after Any Vaccination
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Sinus congestion	1 (1.0)	0	0	0	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0
Upper respiratory tract inflammation	0	0	0	0	1 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	55 (27.5)	61 (30.5)	59 (29.5)	120 (30.0)
Number of Unsolicited Adverse Events	87	118	94	212
Headache	6 (3.0)	10 (5.0)	8 (4.0)	18 (4.5)
Fatigue	6 (3.0)	12 (6.0)	3 (1.5)	15 (3.8)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Rhinorrhoea	0	1 (0.5)	3 (1.5)	4 (1.0)
Urinary tract infection	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Back pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Diarrhoea	1 (0.5)	3 (1.5)	0	3 (0.8)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403010902.sas 19NOV2020 02:27 Database Lock Date: 05NOV2020

Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Oropharyngeal pain	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Anxiety	0	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
COVID-19	5 (2.5)	2 (1.0)	0	2 (0.5)
Depression	0	0	2 (1.0)	2 (0.5)
Dizziness	0	1 (0.5)	1 (0.5)	2 (0.5)
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Chest discomfort	0	1 (0.5)	0	1 (0.3)
Chest pain	0	1 (0.5)	0	1 (0.3)
Cough	3 (1.5)	1 (0.5)	0	1 (0.3)
Dental caries	0	1 (0.5)	0	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Ear pain	0	1 (0.5)	0	1 (0.3)
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Hypertension	0	1 (0.5)	0	1 (0.3)
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Injection site mass	0	0	1 (0.5)	1 (0.3)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Joint injury	0	0	1 (0.5)	1 (0.3)
Joint swelling	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Mass	0	0	1 (0.5)	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Nasal congestion	0	1 (0.5)	0	1 (0.3)
Nasal pruritus	0	1 (0.5)	0	1 (0.3)
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Pain	0	1 (0.5)	0	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Platelet count decreased	0	1 (0.5)	0	1 (0.3)
Platelet count increased	0	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Tension headache	0	1 (0.5)	0	1 (0.3)
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	2 (1.0)	1 (0.5)	0	1 (0.3)
White blood cell count decreased	0	0	1 (0.5)	1 (0.3)
Abdominal tenderness	1 (0.5)	0	0	0

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Allergy to arthropod sting	1 (0.5)	0	0	0
Angioedema	1 (0.5)	0	0	0
Bursitis	1 (0.5)	0	0	0
Cardiac murmur	1 (0.5)	0	0	0
Cellulitis	1 (0.5)	0	0	0
Dry throat	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Haematuria	1 (0.5)	0	0	0
Heart rate decreased	2 (1.0)	0	0	0
Hordeolum	1 (0.5)	0	0	0
Hyperlipidaemia	1 (0.5)	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Lethargy	1 (0.5)	0	0	0
Leukopenia	1 (0.5)	0	0	0
Odynophagia	1 (0.5)	0	0	0
Oral candidiasis	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Otitis media	1 (0.5)	0	0	0
Postmenopausal haemorrhage	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0
Sinus congestion	2 (1.0)	0	0	0

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Skin laceration	2 (1.0)	0	0	0
Upper respiratory tract inflammation	1 (0.5)	0	0	0

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	27 (27.0)	29 (29.0)	28 (28.0)	57 (28.5)	28 (28.0)	32 (32.0)	31 (31.0)	63 (31.5)
Number of Unsolicited Adverse Events	48	59	48	107	39	59	46	105
Headache	4 (4.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Fatigue	4 (4.0)	5 (5.0)	3 (3.0)	8 (4.0)	2 (2.0)	7 (7.0)	0	7 (3.5)
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Nausea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Rhinorrhoea	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Back pain	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Diarrhoea	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Oropharyngeal pain	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Anxiety	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
COVID-19	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Depression	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Dizziness	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Muscle spasms	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Toothache	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood alkaline phosphatase increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Chest discomfort	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Cough	3 (3.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Joint swelling	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nasal congestion	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Nasal pruritus	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Neck pain	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pharyngeal erythema	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Plantar fasciitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Platelet count increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
White blood cell count decreased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Haematuria	0	0	0	0	1 (1.0)	0	0	0
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Oral candidiasis	1 (1.0)	0	0	0	0	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Sinus congestion	1 (1.0)	0	0	0	1 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.9.2
Subject Incidence of Unsolicited TEAE by Preferred Term from Day 1 to Day 57 Visit
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin laceration	2 (2.0)	0	0	0	0	0	0	0
Upper respiratory tract inflammation	0	0	0	0	1 (1.0)	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	51 (25.5)	57 (28.5)	56 (28.0)	113 (28.3)
Mild	40 (20.0)	38 (19.0)	38 (19.0)	76 (19.0)
Moderate	7 (3.5)	12 (6.0)	13 (6.5)	25 (6.3)
Severe	4 (2.0)	7 (3.5)	5 (2.5)	12 (3.0)
Number of Unsolicited Adverse Events	76	104	90	194
Mild	61	82	72	154
Moderate	11	13	13	26
Severe	4	9	5	14
Infections and infestations	9 (4.5)	7 (3.5)	7 (3.5)	14 (3.5)
Mild	7 (3.5)	6 (3.0)	4 (2.0)	10 (2.5)
Moderate	2 (1.0)	1 (0.5)	3 (1.5)	4 (1.0)
Severe	0	0	0	0
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
COVID-19	2 (1.0)	2 (1.0)	0	2 (0.5)
Mild	1 (0.5)	2 (1.0)	0	2 (0.5)
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	1 (0.5)	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Tooth infection	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Infections and infestations (cont.)				
Upper respiratory tract infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Cellulitis	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Hordeolum	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Otitis externa	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Infections and infestations (cont.)				
Otitis media	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Blood and lymphatic system disorders	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Leukopenia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Immune system disorders	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	0	0
Severe	1 (0.5)	0	0	0
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Immune system disorders (cont.)				
Allergy to arthropod sting	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Gout	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Hyperlipidaemia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Psychiatric disorders	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Anxiety	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Depression	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nervous system disorders	6 (3.0)	12 (6.0)	12 (6.0)	24 (6.0)
Mild	4 (2.0)	10 (5.0)	11 (5.5)	21 (5.3)
Moderate	2 (1.0)	2 (1.0)	0	2 (0.5)
Severe	0	0	1 (0.5)	1 (0.3)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)				
Headache	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Mild	3 (1.5)	7 (3.5)	6 (3.0)	13 (3.3)
Moderate	2 (1.0)	1 (0.5)	0	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Dizziness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)				
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Tension headache	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)				
Lethargy	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Ear and labyrinth disorders	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Ear pain	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Vascular disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Vascular disorders (cont.)				
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Respiratory, thoracic and mediastinal disorders	5 (2.5)	3 (1.5)	3 (1.5)	6 (1.5)
Mild	4 (2.0)	2 (1.0)	1 (0.5)	3 (0.8)
Moderate	1 (0.5)	0	1 (0.5)	1 (0.3)
Severe	0	1 (0.5)	1 (0.5)	2 (0.5)
Oropharyngeal pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)				
Rhinorrhoea	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Cough	2 (1.0)	0	0	0
Mild	2 (1.0)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Dry throat	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)				
Sinus congestion	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Upper respiratory tract inflammation	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Gastrointestinal disorders	5 (2.5)	8 (4.0)	7 (3.5)	15 (3.8)
Mild	3 (1.5)	6 (3.0)	6 (3.0)	12 (3.0)
Moderate	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Severe	0	0	0	0
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Mild	0	2 (1.0)	2 (1.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0

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System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Diarrhoea	0	2 (1.0)	0	2 (0.5)
Mild	0	2 (1.0)	0	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Mild	1 (0.5)	0	0	0
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	0	0
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Dental caries	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Diverticulum	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dry mouth	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Abdominal tenderness	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Odynophagia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Oral disorder	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Skin and subcutaneous tissue disorders	8 (4.0)	11 (5.5)	6 (3.0)	17 (4.3)
Mild	7 (3.5)	9 (4.5)	4 (2.0)	13 (3.3)
Moderate	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
Severe	0	0	0	0
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Mild	2 (1.0)	4 (2.0)	1 (0.5)	5 (1.3)
Moderate	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Skin and subcutaneous tissue disorders (cont.)				
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Mild	2 (1.0)	2 (1.0)	0	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Dermatitis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Skin and subcutaneous tissue disorders (cont.)				
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Erythema	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Angioedema	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Skin and subcutaneous tissue disorders (cont.)				
Rash papular	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal and connective tissue disorders	8 (4.0)	16 (8.0)	12 (6.0)	28 (7.0)
Mild	6 (3.0)	10 (5.0)	11 (5.5)	21 (5.3)
Moderate	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
Severe	0	3 (1.5)	0	3 (0.8)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Mild	4 (2.0)	2 (1.0)	4 (2.0)	6 (1.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	2 (1.0)	0	2 (0.5)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Mild	2 (1.0)	6 (3.0)	2 (1.0)	8 (2.0)
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Back pain	0	2 (1.0)	1 (0.5)	3 (0.8)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	0	0
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Joint swelling	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Bursitis	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Exostosis	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Renal and urinary disorders	2 (1.0)	2 (1.0)	0	2 (0.5)
Mild	2 (1.0)	1 (0.5)	0	1 (0.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Renal and urinary disorders (cont.)				
Haematuria	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Reproductive system and breast disorders	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Postmenopausal haemorrhage	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
General disorders and administration site conditions	10 (5.0)	17 (8.5)	17 (8.5)	34 (8.5)
Mild	8 (4.0)	13 (6.5)	15 (7.5)	28 (7.0)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)
Severe	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	6 (3.0)	11 (5.5)	3 (1.5)	14 (3.5)
Mild	4 (2.0)	9 (4.5)	3 (1.5)	12 (3.0)
Moderate	0	0	0	0
Severe	2 (1.0)	2 (1.0)	0	2 (0.5)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Mild	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Mild	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Mild	1 (0.5)	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	0	2 (1.0)	2 (0.5)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Chest pain	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Mild	2 (1.0)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Injection site mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Malaise	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pain	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Investigations	5 (2.5)	2 (1.0)	3 (1.5)	5 (1.3)
Mild	4 (2.0)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Investigations (cont.)				
Platelet count decreased	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Cardiac murmur	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Heart rate decreased	2 (1.0)	0	0	0
Mild	2 (1.0)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Injury, poisoning and procedural complications	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Mild	5 (2.5)	3 (1.5)	2 (1.0)	5 (1.3)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (cont.)				
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Joint injury	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (cont.)				
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Skin laceration	2 (1.0)	0	0	0
Mild	2 (1.0)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	24 (24.0)	27 (27.0)	26 (26.0)	53 (26.5)	27 (27.0)	30 (30.0)	30 (30.0)	60 (30.0)
Mild	20 (20.0)	16 (16.0)	17 (17.0)	33 (16.5)	20 (20.0)	22 (22.0)	21 (21.0)	43 (21.5)
Moderate	2 (2.0)	6 (6.0)	5 (5.0)	11 (5.5)	5 (5.0)	6 (6.0)	8 (8.0)	14 (7.0)
Severe	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
Number of Unsolicited Adverse Events	39	51	45	96	37	53	45	98
Mild	32	37	36	73	29	45	36	81
Moderate	5	7	5	12	6	6	8	14
Severe	2	7	4	11	2	2	1	3
Infections and infestations	5 (5.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	2 (2.0)	5 (5.0)	7 (3.5)
Mild	4 (4.0)	4 (4.0)	1 (1.0)	5 (2.5)	3 (3.0)	2 (2.0)	3 (3.0)	5 (2.5)
Moderate	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	2 (2.0)	2 (1.0)
Severe	0	0	0	0	0	0	0	0
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Mild	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Infections and infestations (cont.)								
COVID-19	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Mild	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)								
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Infections and infestations (cont.)								
Upper respiratory tract infection	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)								
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Blood and lymphatic system disorders	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Immune system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	1 (1.0)	0	0	0
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Immune system disorders (cont.)								
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	1 (1.0)	0	0	0
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Psychiatric disorders	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Mild	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Anxiety	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nervous system disorders	4 (4.0)	6 (6.0)	4 (4.0)	10 (5.0)	2 (2.0)	6 (6.0)	8 (8.0)	14 (7.0)
Mild	3 (3.0)	5 (5.0)	3 (3.0)	8 (4.0)	1 (1.0)	5 (5.0)	8 (8.0)	13 (6.5)
Moderate	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Nervous system disorders (cont.)								
Headache	3 (3.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Mild	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)
Moderate	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)								
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)								
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	1 (1.0)	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Ear and labyrinth disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Vascular disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Vascular disorders (cont.)								
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Mild	2 (2.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Oropharyngeal pain	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Mild	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)								
Rhinorrhoea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Pharyngeal erythema	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Cough	2 (2.0)	0	0	0	0	0	0	0
Mild	2 (2.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)								
Sinus congestion	1 (1.0)	0	0	0	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	1 (1.0)	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Upper respiratory tract inflammation	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastrointestinal disorders	3 (3.0)	3 (3.0)	4 (4.0)	7 (3.5)	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)
Mild	3 (3.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	4 (4.0)	3 (3.0)	7 (3.5)
Moderate	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Nausea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Diarrhoea	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Mild	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Toothache	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	3 (3.0)	6 (6.0)	3 (3.0)	9 (4.5)
Mild	5 (5.0)	3 (3.0)	2 (2.0)	5 (2.5)	2 (2.0)	6 (6.0)	2 (2.0)	8 (4.0)
Moderate	0	2 (2.0)	1 (1.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Mild	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	2 (2.0)	0	2 (1.0)
Moderate	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

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Safety Set

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	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	2 (2.0)	9 (9.0)	5 (5.0)	14 (7.0)	6 (6.0)	7 (7.0)	7 (7.0)	14 (7.0)
Mild	1 (1.0)	4 (4.0)	5 (5.0)	9 (4.5)	5 (5.0)	6 (6.0)	6 (6.0)	12 (6.0)
Moderate	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Severe	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Mild	1 (1.0)	0	2 (2.0)	2 (1.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Moderate	1 (1.0)	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Back pain	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Muscle spasms	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Joint swelling	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neck pain	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Plantar fasciitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Renal and urinary disorders	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Renal and urinary disorders (cont.)								
Haematuria	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Reproductive system and breast disorders	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	mRNA-1273				mRNA-1273				mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions	5 (5.0)	8 (8.0)	12 (12.0)	20 (10.0)	5 (5.0)	9 (9.0)	5 (5.0)	14 (7.0)								
Mild	3 (3.0)	6 (6.0)	11 (11.0)	17 (8.5)	5 (5.0)	7 (7.0)	4 (4.0)	11 (5.5)								
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)								
Severe	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)								
Fatigue	4 (4.0)	4 (4.0)	3 (3.0)	7 (3.5)	2 (2.0)	7 (7.0)	0	7 (3.5)								
Mild	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	6 (6.0)	0	6 (3.0)								
Moderate	0	0	0	0	0	0	0	0								
Severe	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)								
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)								
Mild	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	0	0	0								
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)								
Severe	0	0	0	0	0	0	0	0								
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)								
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)								
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0								
Severe	0	0	0	0	0	0	0	0								

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions (cont.)								
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Mild	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions (cont.)								
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations	1 (1.0)	1 (1.0)	0	1 (0.5)	4 (4.0)	1 (1.0)	3 (3.0)	4 (2.0)
Mild	1 (1.0)	0	0	0	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Investigations (cont.)								
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Mild	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Mild	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (cont.)								
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.1

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0
Mild	2 (2.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	55 (27.5)	61 (30.5)	59 (29.5)	120 (30.0)
Mild	42 (21.0)	39 (19.5)	41 (20.5)	80 (20.0)
Moderate	9 (4.5)	14 (7.0)	13 (6.5)	27 (6.8)
Severe	4 (2.0)	8 (4.0)	5 (2.5)	13 (3.3)
Number of Unsolicited Adverse Events	87	118	94	212
Mild	68	89	76	165
Moderate	15	19	13	32
Severe	4	10	5	15
Infections and infestations	13 (6.5)	8 (4.0)	7 (3.5)	15 (3.8)
Mild	10 (5.0)	5 (2.5)	4 (2.0)	9 (2.3)
Moderate	3 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)
Severe	0	1 (0.5)	0	1 (0.3)
Urinary tract infection	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Mild	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
COVID-19	5 (2.5)	2 (1.0)	0	2 (0.5)
Mild	3 (1.5)	2 (1.0)	0	2 (0.5)
Moderate	2 (1.0)	0	0	0
Severe	0	0	0	0
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	1 (0.5)	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nasopharyngitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pneumonia	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		Total (N=400)
		50 µg (N=200)	100 µg (N=200)	
	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)				
Tooth infection	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Upper respiratory tract infection	2 (1.0)	1 (0.5)	0	1 (0.3)
Mild	2 (1.0)	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Cellulitis	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Hordeolum	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Infections and infestations (cont.)				
Oral candidiasis	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Otitis externa	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Otitis media	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)				
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Blood and lymphatic system disorders	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Leukopenia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Immune system disorders	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	0	0
Severe	1 (0.5)	0	0	0
Seasonal allergy	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	0	0
Severe	0	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Metabolism and nutrition disorders (cont.)				
Gout	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Hyperlipidaemia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Psychiatric disorders	0	2 (1.0)	3 (1.5)	5 (1.3)
Mild	0	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Anxiety	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Psychiatric disorders (cont.)				
Depression	0	0	2 (1.0)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nervous system disorders	7 (3.5)	15 (7.5)	13 (6.5)	28 (7.0)
Mild	4 (2.0)	11 (5.5)	12 (6.0)	23 (5.8)
Moderate	3 (1.5)	4 (2.0)	0	4 (1.0)
Severe	0	0	1 (0.5)	1 (0.3)
Headache	6 (3.0)	10 (5.0)	8 (4.0)	18 (4.5)
Mild	3 (1.5)	8 (4.0)	7 (3.5)	15 (3.8)
Moderate	3 (1.5)	2 (1.0)	0	2 (0.5)
Severe	0	0	1 (0.5)	1 (0.3)

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nervous system disorders (cont.)				
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Dizziness	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)				
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Sinus headache	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Tension headache	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Lethargy	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Ear and labyrinth disorders	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Ear pain	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Vascular disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	7 (3.5)	5 (2.5)	4 (2.0)	9 (2.3)
Mild	5 (2.5)	4 (2.0)	2 (1.0)	6 (1.5)
Moderate	2 (1.0)	0	1 (0.5)	1 (0.3)
Severe	0	1 (0.5)	1 (0.5)	2 (0.5)
Rhinorrhoea	0	1 (0.5)	3 (1.5)	4 (1.0)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Oropharyngeal pain	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	1 (0.5)	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Cough	3 (1.5)	1 (0.5)	0	1 (0.3)
Mild	2 (1.0)	1 (0.5)	0	1 (0.3)
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Nasal congestion	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)				
Nasal pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pharyngeal erythema	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dry throat	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Sinus congestion	2 (1.0)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)				
Upper respiratory tract inflammation	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Gastrointestinal disorders	6 (3.0)	9 (4.5)	7 (3.5)	16 (4.0)
Mild	4 (2.0)	7 (3.5)	6 (3.0)	13 (3.3)
Moderate	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Severe	0	0	0	0
Nausea	0	2 (1.0)	2 (1.0)	4 (1.0)
Mild	0	2 (1.0)	2 (1.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Diarrhoea	1 (0.5)	3 (1.5)	0	3 (0.8)
Mild	1 (0.5)	3 (1.5)	0	3 (0.8)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Mild	1 (0.5)	0	0	0
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	0	0
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dental caries	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders (cont.)				
Diverticulum	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dry mouth	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Abdominal tenderness	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Large intestine polyp	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Odynophagia	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders (cont.)				
Oral disorder	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Skin and subcutaneous tissue disorders	8 (4.0)	11 (5.5)	6 (3.0)	17 (4.3)
Mild	7 (3.5)	9 (4.5)	4 (2.0)	13 (3.3)
Moderate	1 (0.5)	2 (1.0)	2 (1.0)	4 (1.0)
Severe	0	0	0	0
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Mild	2 (1.0)	4 (2.0)	1 (0.5)	5 (1.3)
Moderate	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Severe	0	0	0	0
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)
Mild	2 (1.0)	2 (1.0)	0	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders (cont.)				
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Acne	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Dermatitis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Ecchymosis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders (cont.)				
Erythema	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Skin discolouration	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Angioedema	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Rash papular	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	9 (4.5)	16 (8.0)	12 (6.0)	28 (7.0)
Mild	7 (3.5)	10 (5.0)	11 (5.5)	21 (5.3)
Moderate	2 (1.0)	3 (1.5)	1 (0.5)	4 (1.0)
Severe	0	3 (1.5)	0	3 (0.8)
Arthralgia	4 (2.0)	5 (2.5)	4 (2.0)	9 (2.3)
Mild	4 (2.0)	2 (1.0)	4 (2.0)	6 (1.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	2 (1.0)	0	2 (0.5)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Mild	2 (1.0)	6 (3.0)	2 (1.0)	8 (2.0)
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Back pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	0	0
Muscle spasms	0	1 (0.5)	1 (0.5)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Musculoskeletal pain	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Joint swelling	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Neck pain	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Plantar fasciitis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Musculoskeletal and connective tissue disorders (cont.)				
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Bursitis	1 (0.5)	0	0	0
Mild	0	0	0	0
Moderate	1 (0.5)	0	0	0
Severe	0	0	0	0
Exostosis	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Renal and urinary disorders	2 (1.0)	2 (1.0)	0	2 (0.5)
Mild	2 (1.0)	1 (0.5)	0	1 (0.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Renal and urinary disorders (cont.)				
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Haematuria	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Reproductive system and breast disorders	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Reproductive system and breast disorders (cont.)				
Postmenopausal haemorrhage	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
General disorders and administration site conditions	10 (5.0)	19 (9.5)	17 (8.5)	36 (9.0)
Mild	8 (4.0)	15 (7.5)	15 (7.5)	30 (7.5)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)
Severe	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	6 (3.0)	12 (6.0)	3 (1.5)	15 (3.8)
Mild	4 (2.0)	10 (5.0)	3 (1.5)	13 (3.3)
Moderate	0	0	0	0
Severe	2 (1.0)	2 (1.0)	0	2 (0.5)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Mild	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Mild	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Mild	1 (0.5)	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	0	2 (1.0)	2 (0.5)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Chest discomfort	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Chest pain	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Injection site bruising	2 (1.0)	1 (0.5)	0	1 (0.3)
Mild	2 (1.0)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Injection site mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Malaise	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pain	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pyrexia	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Investigations	5 (2.5)	3 (1.5)	4 (2.0)	7 (1.8)
Mild	4 (2.0)	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)
Severe	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure increased	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

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	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Investigations (cont.)				
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Blood pressure diastolic increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Haematocrit increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Haemoglobin increased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Investigations (cont.)				
Platelet count decreased	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Platelet count increased	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
White blood cell count decreased	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Cardiac murmur	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Investigations (cont.)				
Heart rate decreased	2 (1.0)	0	0	0
Mild	2 (1.0)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Injury, poisoning and procedural complications	5 (2.5)	4 (2.0)	4 (2.0)	8 (2.0)
Mild	5 (2.5)	3 (1.5)	2 (1.0)	5 (1.3)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)
Severe	0	0	0	0
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Mild	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Joint injury	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Muscle strain	1 (0.5)	0	1 (0.5)	1 (0.3)
Mild	1 (0.5)	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Injury, poisoning and procedural complications (cont.)				
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Skin laceration	2 (1.0)	0	0	0
Mild	2 (1.0)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	27 (27.0)	29 (29.0)	28 (28.0)	57 (28.5)	28 (28.0)	32 (32.0)	31 (31.0)	63 (31.5)
Mild	21 (21.0)	17 (17.0)	19 (19.0)	36 (18.0)	21 (21.0)	22 (22.0)	22 (22.0)	44 (22.0)
Moderate	4 (4.0)	7 (7.0)	5 (5.0)	12 (6.0)	5 (5.0)	7 (7.0)	8 (8.0)	15 (7.5)
Severe	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Number of Unsolicited Adverse Events	48	59	48	107	39	59	46	105
Mild	37	44	39	83	31	45	37	82
Moderate	9	8	5	13	6	11	8	19
Severe	2	7	4	11	2	3	1	4
Infections and infestations	9 (9.0)	5 (5.0)	2 (2.0)	7 (3.5)	4 (4.0)	3 (3.0)	5 (5.0)	8 (4.0)
Mild	7 (7.0)	4 (4.0)	1 (1.0)	5 (2.5)	3 (3.0)	1 (1.0)	3 (3.0)	4 (2.0)
Moderate	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)
Severe	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Infections and infestations (cont.)								
COVID-19	3 (3.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	0	1 (0.5)
Mild	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)								
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Infections and infestations (cont.)								
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Upper respiratory tract infection	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	2 (2.0)	0	0	0	0	0	0	0
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Infections and infestations (cont.)								
Oral candidiasis	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) (cont.)								
Benign neoplasm of skin	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Leukopenia	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Immune system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	1 (1.0)	0	0	0
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	1 (1.0)	0	0	0
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Metabolism and nutrition disorders (cont.)								
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Psychiatric disorders	0	0	3 (3.0)	3 (1.5)	0	2 (2.0)	0	2 (1.0)
Mild	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Anxiety	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Psychiatric disorders (cont.)								
Depression	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nervous system disorders	5 (5.0)	8 (8.0)	5 (5.0)	13 (6.5)	2 (2.0)	7 (7.0)	8 (8.0)	15 (7.5)
Mild	3 (3.0)	6 (6.0)	4 (4.0)	10 (5.0)	1 (1.0)	5 (5.0)	8 (8.0)	13 (6.5)
Moderate	2 (2.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	4 (4.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)
Mild	2 (2.0)	3 (3.0)	3 (3.0)	6 (3.0)	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)
Moderate	2 (2.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders (cont.)								
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Dizziness	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Nervous system disorders (cont.)								
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Sinus headache	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Lethargy	1 (1.0)	0	0	0	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	1 (1.0)	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Ear and labyrinth disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Vascular disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
					mRNA-1273								mRNA-1273			
	Placebo		50 µg		100 µg		Total		Placebo		50 µg		100 µg		Total	
	(N=100)		(N=100)		(N=100)		(N=200)		(N=100)		(N=100)		(N=100)		(N=200)	
	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Respiratory, thoracic and mediastinal disorders	4 (4.0)		3 (3.0)		2 (2.0)		5 (2.5)		3 (3.0)		2 (2.0)		2 (2.0)		4 (2.0)	
Mild	2 (2.0)		3 (3.0)		1 (1.0)		4 (2.0)		3 (3.0)		1 (1.0)		1 (1.0)		2 (1.0)	
Moderate	2 (2.0)		0		0		0		0		0		1 (1.0)		1 (0.5)	
Severe	0		0		1 (1.0)		1 (0.5)		0		1 (1.0)		0		1 (0.5)	
Rhinorrhoea	0		1 (1.0)		2 (2.0)		3 (1.5)		0		0		1 (1.0)		1 (0.5)	
Mild	0		1 (1.0)		1 (1.0)		2 (1.0)		0		0		0		0	
Moderate	0		0		0		0		0		0		1 (1.0)		1 (0.5)	
Severe	0		0		1 (1.0)		1 (0.5)		0		0		0		0	
Oropharyngeal pain	1 (1.0)		0		0		0		1 (1.0)		2 (2.0)		1 (1.0)		3 (1.5)	
Mild	0		0		0		0		1 (1.0)		1 (1.0)		1 (1.0)		2 (1.0)	
Moderate	1 (1.0)		0		0		0		0		0		0		0	
Severe	0		0		0		0		0		1 (1.0)		0		1 (0.5)	
Cough	3 (3.0)		1 (1.0)		0		1 (0.5)		0		0		0		0	
Mild	2 (2.0)		1 (1.0)		0		1 (0.5)		0		0		0		0	
Moderate	1 (1.0)		0		0		0		0		0		0		0	
Severe	0		0		0		0		0		0		0		0	
Nasal congestion	0		1 (1.0)		0		1 (0.5)		0		0		0		0	
Mild	0		1 (1.0)		0		1 (0.5)		0		0		0		0	
Moderate	0		0		0		0		0		0		0		0	
Severe	0		0		0		0		0		0		0		0	

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders (cont.)								
Nasal pruritus	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pharyngeal erythema	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Sinus congestion	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	1 (1.0)	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders (cont.)								
Upper respiratory tract inflammation	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastrointestinal disorders	4 (4.0)	4 (4.0)	4 (4.0)	8 (4.0)	2 (2.0)	5 (5.0)	3 (3.0)	8 (4.0)
Mild	4 (4.0)	3 (3.0)	3 (3.0)	6 (3.0)	0	4 (4.0)	3 (3.0)	7 (3.5)
Moderate	0	1 (1.0)	1 (1.0)	2 (1.0)	2 (2.0)	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Nausea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Diarrhoea	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Toothache	1 (1.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Odynophagia	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders (cont.)								
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)	3 (3.0)	6 (6.0)	3 (3.0)	9 (4.5)
Mild	5 (5.0)	3 (3.0)	2 (2.0)	5 (2.5)	2 (2.0)	6 (6.0)	2 (2.0)	8 (4.0)
Moderate	0	2 (2.0)	1 (1.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Mild	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	2 (2.0)	0	2 (1.0)
Moderate	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Acne	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Ecchymosis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin discolouration	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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MedDRA version 23.0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
	mRNA-1273				mRNA-1273				mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders	2 (2.0)	9 (9.0)	5 (5.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)	7 (7.0)	7 (7.0)	7 (7.0)	14 (7.0)
Mild	1 (1.0)	4 (4.0)	5 (5.0)	9 (4.5)	6 (6.0)	6 (6.0)	6 (6.0)	12 (6.0)	6 (6.0)	6 (6.0)	6 (6.0)	12 (6.0)	6 (6.0)	6 (6.0)	6 (6.0)	12 (6.0)
Moderate	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Severe	0	3 (3.0)	0	3 (1.5)	0	0	0	0	0	0	0	0	0	0	0	0
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Mild	1 (1.0)	0	2 (2.0)	2 (1.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0	0	0	0	0	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0	0	0	0	0	0	0	0	0
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Moderate	1 (1.0)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Back pain	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Muscle spasms	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0	0	0	0	0	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Musculoskeletal pain	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Mild	0	0	0	0	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Joint swelling	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Neck pain	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Plantar fasciitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	1 (1.0)	0	0	0
Severe	0	0	0	0	0	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Renal and urinary disorders	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Renal and urinary disorders (cont.)								
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Haematuria	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Reproductive system and breast disorders	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Reproductive system and breast disorders (cont.)								
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
General disorders and administration site conditions	5 (5.0)	10 (10.0)	12 (12.0)	22 (11.0)	5 (5.0)	9 (9.0)	5 (5.0)	14 (7.0)
Mild	3 (3.0)	8 (8.0)	11 (11.0)	19 (9.5)	5 (5.0)	7 (7.0)	4 (4.0)	11 (5.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Severe	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Fatigue	4 (4.0)	5 (5.0)	3 (3.0)	8 (4.0)	2 (2.0)	7 (7.0)	0	7 (3.5)
Mild	2 (2.0)	4 (4.0)	3 (3.0)	7 (3.5)	2 (2.0)	6 (6.0)	0	6 (3.0)
Moderate	0	0	0	0	0	0	0	0
Severe	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Mild	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Chest discomfort	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site bruising	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	1 (1.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site mass	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions (cont.)								
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions (cont.)								
Peripheral swelling	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pyrexia	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Investigations	1 (1.0)	1 (1.0)	0	1 (0.5)	4 (4.0)	2 (2.0)	4 (4.0)	6 (3.0)
Mild	1 (1.0)	0	0	0	3 (3.0)	1 (1.0)	2 (2.0)	3 (1.5)
Moderate	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Severe	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)

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.

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (cont.)								
Blood alkaline phosphatase increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Blood pressure diastolic increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Haematocrit increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Haemoglobin increased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (cont.)								
Platelet count decreased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Platelet count increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
White blood cell count decreased	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations (cont.)								
Heart rate decreased	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Mild	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	3 (3.0)	2 (2.0)	2 (2.0)	4 (2.0)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Mild	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Severe	0	0	0	0	0	0	0	0
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	0	0	1 (1.0)	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Joint injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Muscle strain	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	1 (1.0)	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.10.2

Subject Incidence of Unsolicited TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Injury, poisoning and procedural complications (cont.)								
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Mild	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0
Mild	2 (2.0)	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Number of Unsolicited Adverse Events	18	33	46	79
Infections and infestations	0	0	1 (0.5)	1 (0.3)
Gastroenteritis	0	0	1 (0.5)	1 (0.3)
Nervous system disorders	1 (0.5)	5 (2.5)	8 (4.0)	13 (3.3)
Headache	1 (0.5)	5 (2.5)	6 (3.0)	11 (2.8)
Dizziness	0	0	1 (0.5)	1 (0.3)
Paraesthesia	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	0	2 (1.0)	2 (0.5)
Oropharyngeal pain	0	0	1 (0.5)	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Gastrointestinal disorders	0	0	4 (2.0)	4 (1.0)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Nausea	0	0	1 (0.5)	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Skin and subcutaneous tissue disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Pruritus	0	1 (0.5)	0	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
Arthralgia	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Musculoskeletal pain	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions	8 (4.0)	12 (6.0)	15 (7.5)	27 (6.8)
Fatigue	6 (3.0)	10 (5.0)	3 (1.5)	13 (3.3)
Injection site pain	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Number of Unsolicited Adverse Events	9	15	30	45	9	18	16	34
Infections and infestations	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nervous system disorders	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	3 (3.0)	5 (5.0)	8 (4.0)
Headache	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	0	3 (3.0)	4 (4.0)	7 (3.5)
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Paraesthesia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Oropharyngeal pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastrointestinal disorders	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Skin and subcutaneous tissue disorders	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Arthralgia	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Myalgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal pain	0	0	0	0	1 (1.0)	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.11.1

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
					mRNA-1273								mRNA-1273			
	Placebo		50 µg		100 µg		Total		Placebo		50 µg		100 µg		Total	
	(N=100)		(N=100)		(N=100)		(N=200)		(N=100)		(N=100)		(N=100)		(N=200)	
	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
General disorders and administration site conditions	5	(5.0)	5	(5.0)	11	(11.0)	16	(8.0)	3	(3.0)	7	(7.0)	4	(4.0)	11	(5.5)
Fatigue	4	(4.0)	3	(3.0)	3	(3.0)	6	(3.0)	2	(2.0)	7	(7.0)	0		7	(3.5)
Injection site pain	1	(1.0)	1	(1.0)	3	(3.0)	4	(2.0)	0		1	(1.0)	0		1	(0.5)
Injection site erythema	0		1	(1.0)	2	(2.0)	3	(1.5)	1	(1.0)	0		1	(1.0)	1	(0.5)
Injection site induration	0		1	(1.0)	2	(2.0)	3	(1.5)	0		0		1	(1.0)	1	(0.5)
Injection site swelling	1	(1.0)	0		3	(3.0)	3	(1.5)	0		0		1	(1.0)	1	(0.5)
Axillary pain	0		1	(1.0)	2	(2.0)	3	(1.5)	0		0		0		0	
Injection site pruritus	0		0		0		0		0		1	(1.0)	0		1	(0.5)
Malaise	0		0		0		0		0		0		1	(1.0)	1	(0.5)
Pain	0		1	(1.0)	0		1	(0.5)	0		0		0		0	
Pyrexia	0		0		0		0		0		0		1	(1.0)	1	(0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011101.sas 19NOV2020 02:28 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Number of Unsolicited Adverse Events	18	34	46	80
Infections and infestations	0	0	1 (0.5)	1 (0.3)
Gastroenteritis	0	0	1 (0.5)	1 (0.3)
Nervous system disorders	1 (0.5)	6 (3.0)	8 (4.0)	14 (3.5)
Headache	1 (0.5)	6 (3.0)	6 (3.0)	12 (3.0)
Dizziness	0	0	1 (0.5)	1 (0.3)
Paraesthesia	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	0	2 (1.0)	2 (0.5)
Oropharyngeal pain	0	0	1 (0.5)	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Gastrointestinal disorders	0	0	4 (2.0)	4 (1.0)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Nausea	0	0	1 (0.5)	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Skin and subcutaneous tissue disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Pruritus	0	1 (0.5)	0	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
Arthralgia	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Axillary mass	0	0	1 (0.5)	1 (0.3)
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Musculoskeletal pain	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions	8 (4.0)	12 (6.0)	15 (7.5)	27 (6.8)
Fatigue	6 (3.0)	10 (5.0)	3 (1.5)	13 (3.3)
Injection site pain	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Number of Unsolicited Adverse Events	9	16	30	46	9	18	16	34
Infections and infestations	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastroenteritis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nervous system disorders	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)	0	3 (3.0)	5 (5.0)	8 (4.0)
Headache	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	3 (3.0)	4 (4.0)	7 (3.5)
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Paraesthesia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Oropharyngeal pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastrointestinal disorders	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Skin and subcutaneous tissue disorders	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Arthralgia	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Myalgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Musculoskeletal pain	0	0	0	0	1 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.11.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)								Cohort 2 (Age >= 55)							
	mRNA-1273				mRNA-1273				mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
General disorders and administration site conditions	5 (5.0)	5 (5.0)	11 (11.0)	16 (8.0)	3 (3.0)	7 (7.0)	4 (4.0)	11 (5.5)								
Fatigue	4 (4.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	7 (7.0)	0	7 (3.5)								
Injection site pain	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)								
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)								
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)								
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)								
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0								
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)								
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)								
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0								
Pyrexia	0	0	0	0	0	0	1 (1.0)	1 (0.5)								

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011102.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Mild	11 (5.5)	11 (5.5)	23 (11.5)	34 (8.5)
Moderate	0	1 (0.5)	2 (1.0)	3 (0.8)
Severe	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Number of Unsolicited Adverse Events	18	33	46	79
Mild	16	25	42	67
Moderate	0	2	2	4
Severe	2	6	2	8
Infections and infestations	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Gastroenteritis	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nervous system disorders	1 (0.5)	5 (2.5)	8 (4.0)	13 (3.3)
Mild	1 (0.5)	4 (2.0)	7 (3.5)	11 (2.8)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Headache	1 (0.5)	5 (2.5)	6 (3.0)	11 (2.8)
Mild	1 (0.5)	4 (2.0)	5 (2.5)	9 (2.3)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	1 (0.5)	1 (0.3)
Dizziness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Paraesthesia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	0	0	2 (1.0)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Oropharyngeal pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Gastrointestinal disorders	0	0	4 (2.0)	4 (1.0)
Mild	0	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days
after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dry mouth	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nausea	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Skin and subcutaneous tissue disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Angioedema	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal and connective tissue disorders	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
Mild	5 (2.5)	5 (2.5)	7 (3.5)	12 (3.0)
Moderate	0	0	0	0
Severe	0	2 (1.0)	0	2 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Arthralgia	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)
Mild	4 (2.0)	2 (1.0)	3 (1.5)	5 (1.3)
Moderate	0	0	0	0
Severe	0	2 (1.0)	0	2 (0.5)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Mild	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal pain	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
General disorders and administration site conditions	8 (4.0)	12 (6.0)	15 (7.5)	27 (6.8)
Mild	6 (3.0)	8 (4.0)	14 (7.0)	22 (5.5)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)
Severe	2 (1.0)	3 (1.5)	0	3 (0.8)

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Fatigue	6 (3.0)	10 (5.0)	3 (1.5)	13 (3.3)
Mild	4 (2.0)	8 (4.0)	3 (1.5)	11 (2.8)
Moderate	0	0	0	0
Severe	2 (1.0)	2 (1.0)	0	2 (0.5)
Injection site pain	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Mild	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Mild	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

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	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Mild	1 (0.5)	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	0	2 (1.0)	2 (0.5)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Malaise	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
General disorders and administration site conditions (cont.)				
Pain	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Mild	4 (4.0)	4 (4.0)	14 (14.0)	18 (9.0)	7 (7.0)	7 (7.0)	9 (9.0)	16 (8.0)
Moderate	0	0	2 (2.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Severe	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Number of Unsolicited Adverse Events	9	15	30	45	9	18	16	34
Mild	7	9	26	35	9	16	16	32
Moderate	0	1	2	3	0	1	0	1
Severe	2	5	2	7	0	1	0	1
Infections and infestations	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Nervous system disorders	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	3 (3.0)	5 (5.0)	8 (4.0)
Mild	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	3 (3.0)	5 (5.0)	8 (4.0)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	0	3 (3.0)	4 (4.0)	7 (3.5)
Mild	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	3 (3.0)	4 (4.0)	7 (3.5)
Moderate	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Paraesthesia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oropharyngeal pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastrointestinal disorders	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Mild	1 (1.0)	3 (3.0)	4 (4.0)	7 (3.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0

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Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Arthralgia	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Mild	1 (1.0)	0	2 (2.0)	2 (1.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Myalgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
General disorders and administration site conditions	5 (5.0)	5 (5.0)	11 (11.0)	16 (8.0)	3 (3.0)	7 (7.0)	4 (4.0)	11 (5.5)
Mild	3 (3.0)	3 (3.0)	10 (10.0)	13 (6.5)	3 (3.0)	5 (5.0)	4 (4.0)	9 (4.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)

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Safety Set

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	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Fatigue	4 (4.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	7 (7.0)	0	7 (3.5)
Mild	2 (2.0)	2 (2.0)	3 (3.0)	5 (2.5)	2 (2.0)	6 (6.0)	0	6 (3.0)
Moderate	0	0	0	0	0	0	0	0
Severe	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Injection site pain	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Mild	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.1
Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pyrexia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011201.sas 19NOV2020 00:30 Database Lock Date: 05NOV2020

Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	13 (6.5)	16 (8.0)	27 (13.5)	43 (10.8)
Mild	11 (5.5)	10 (5.0)	23 (11.5)	33 (8.3)
Moderate	0	2 (1.0)	2 (1.0)	4 (1.0)
Severe	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Number of Unsolicited Adverse Events	18	34	46	80
Mild	16	25	42	67
Moderate	0	3	2	5
Severe	2	6	2	8
Infections and infestations	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Gastroenteritis	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011202.sas 19NOV2020 02:29 Database Lock Date: 05NOV2020

Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nervous system disorders	1 (0.5)	6 (3.0)	8 (4.0)	14 (3.5)
Mild	1 (0.5)	4 (2.0)	7 (3.5)	11 (2.8)
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	1 (0.5)	1 (0.3)
Headache	1 (0.5)	6 (3.0)	6 (3.0)	12 (3.0)
Mild	1 (0.5)	4 (2.0)	5 (2.5)	9 (2.3)
Moderate	0	2 (1.0)	0	2 (0.5)
Severe	0	0	1 (0.5)	1 (0.3)
Dizziness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Paraesthesia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	0	0	2 (1.0)	2 (0.5)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Oropharyngeal pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	0	1 (0.5)	1 (0.3)
Gastrointestinal disorders	0	0	4 (2.0)	4 (1.0)
Mild	0	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)				
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Dry mouth	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Nausea	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Skin and subcutaneous tissue disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Mild	1 (0.5)	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Angioedema	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal and connective tissue disorders	5 (2.5)	7 (3.5)	7 (3.5)	14 (3.5)
Mild	5 (2.5)	5 (2.5)	7 (3.5)	12 (3.0)
Moderate	0	0	0	0
Severe	0	2 (1.0)	0	2 (0.5)

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Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Arthralgia	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)
Mild	4 (2.0)	2 (1.0)	3 (1.5)	5 (1.3)
Moderate	0	0	0	0
Severe	0	2 (1.0)	0	2 (0.5)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Mild	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary mass	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal chest pain	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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MedDRA version 23.0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Musculoskeletal stiffness	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Musculoskeletal pain	1 (0.5)	0	0	0
Mild	1 (0.5)	0	0	0
Moderate	0	0	0	0
Severe	0	0	0	0
General disorders and administration site conditions	8 (4.0)	12 (6.0)	15 (7.5)	27 (6.8)
Mild	6 (3.0)	8 (4.0)	14 (7.0)	22 (5.5)
Moderate	0	1 (0.5)	1 (0.5)	2 (0.5)
Severe	2 (1.0)	3 (1.5)	0	3 (0.8)

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Fatigue	6 (3.0)	10 (5.0)	3 (1.5)	13 (3.3)
Mild	4 (2.0)	8 (4.0)	3 (1.5)	11 (2.8)
Moderate	0	0	0	0
Severe	2 (1.0)	2 (1.0)	0	2 (0.5)
Injection site pain	1 (0.5)	2 (1.0)	3 (1.5)	5 (1.3)
Mild	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	1 (0.5)	0	1 (0.3)
Severe	0	0	0	0
Injection site erythema	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Mild	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Moderate	0	0	1 (0.5)	1 (0.3)
Severe	0	0	0	0
Injection site induration	0	1 (0.5)	3 (1.5)	4 (1.0)
Mild	0	1 (0.5)	3 (1.5)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site swelling	1 (0.5)	0	4 (2.0)	4 (1.0)
Mild	1 (0.5)	0	4 (2.0)	4 (1.0)
Moderate	0	0	0	0
Severe	0	0	0	0
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)
Mild	0	0	2 (1.0)	2 (0.5)
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Injection site pruritus	0	1 (0.5)	0	1 (0.3)
Mild	0	1 (0.5)	0	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0
Malaise	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions (cont.)				
Pain	0	1 (0.5)	0	1 (0.3)
Mild	0	0	0	0
Moderate	0	0	0	0
Severe	0	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)
Mild	0	0	1 (0.5)	1 (0.3)
Moderate	0	0	0	0
Severe	0	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	6 (6.0)	7 (7.0)	18 (18.0)	25 (12.5)	7 (7.0)	9 (9.0)	9 (9.0)	18 (9.0)
Mild	4 (4.0)	3 (3.0)	14 (14.0)	17 (8.5)	7 (7.0)	7 (7.0)	9 (9.0)	16 (8.0)
Moderate	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	0	1 (0.5)
Severe	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Number of Unsolicited Adverse Events	9	16	30	46	9	18	16	34
Mild	7	9	26	35	9	16	16	32
Moderate	0	2	2	4	0	1	0	1
Severe	2	5	2	7	0	1	0	1
Infections and infestations	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Gastroenteritis	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
		n (%)	n (%)	n (%)		n (%)	n (%)	n (%)
Nervous system disorders	1 (1.0)	3 (3.0)	3 (3.0)	6 (3.0)	0	3 (3.0)	5 (5.0)	8 (4.0)
Mild	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	0	3 (3.0)	5 (5.0)	8 (4.0)
Moderate	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	3 (3.0)	4 (4.0)	7 (3.5)
Mild	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	3 (3.0)	4 (4.0)	7 (3.5)
Moderate	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Paraesthesia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100) n (%)	mRNA-1273			Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oropharyngeal pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Gastrointestinal disorders	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Gastrointestinal disorders (cont.)								
Aphthous ulcer	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Dry mouth	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.0)	5 (5.0)	4 (4.0)	9 (4.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Mild	1 (1.0)	3 (3.0)	4 (4.0)	7 (3.5)	4 (4.0)	2 (2.0)	3 (3.0)	5 (2.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Arthralgia	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Mild	1 (1.0)	0	2 (2.0)	2 (1.0)	3 (3.0)	2 (2.0)	1 (1.0)	3 (1.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Myalgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Mild	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary mass	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Mild	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal chest pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Musculoskeletal stiffness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	0	0	0
Mild	0	0	0	0	1 (1.0)	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
General disorders and administration site conditions	5 (5.0)	5 (5.0)	11 (11.0)	16 (8.0)	3 (3.0)	7 (7.0)	4 (4.0)	11 (5.5)
Mild	3 (3.0)	3 (3.0)	10 (10.0)	13 (6.5)	3 (3.0)	5 (5.0)	4 (4.0)	9 (4.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Severe	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Fatigue	4 (4.0)	3 (3.0)	3 (3.0)	6 (3.0)	2 (2.0)	7 (7.0)	0	7 (3.5)
Mild	2 (2.0)	2 (2.0)	3 (3.0)	5 (2.5)	2 (2.0)	6 (6.0)	0	6 (3.0)
Moderate	0	0	0	0	0	0	0	0
Severe	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Injection site pain	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Mild	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	0	0	0	0
Moderate	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Severe	0	0	0	0	0	0	0	0
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Moderate	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Mild	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Mild	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Injection site pruritus	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Mild	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Table 14.3.1.12.2

Subject Incidence of Unsolicited Treatment-Related TEAE by System Organ Class, Preferred Term, and Severity from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term Severity	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Mild	0	0	0	0	0	0	0	0
Moderate	0	0	0	0	0	0	0	0
Severe	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pyrexia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Mild	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Moderate	0	0	0	0	0	0	0	0
Severe	0	0	0	0	0	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Number of Subjects Received	200	200	200	400
First Injection - N1				
Any eDiary Data after First Injection	199 (99.5)	200 (100)	199 (99.5)	399 (99.8)
Day 1, 1 Hour after Vaccination (at Study Clinic)	193 (96.5)	198 (99.0)	195 (97.5)	393 (98.3)
Day 1, after Vaccination (at Home)	193 (96.5)	192 (96.0)	194 (97.0)	386 (96.5)
Day 2	197 (98.5)	197 (98.5)	198 (99.0)	395 (98.8)
Day 3	194 (97.0)	195 (97.5)	195 (97.5)	390 (97.5)
Day 4	192 (96.0)	195 (97.5)	195 (97.5)	390 (97.5)
Day 5	194 (97.0)	193 (96.5)	189 (94.5)	382 (95.5)
Day 6	192 (96.0)	192 (96.0)	192 (96.0)	384 (96.0)
Day 7	196 (98.0)	193 (96.5)	194 (97.0)	387 (96.8)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Number of Subjects Received	194	195	198	393
Second Injection - N1				
Any eDiary Data after Second	194 (100)	195 (100)	198 (100)	393 (100)
Injection				
Day 1, 1 Hour after	189 (97.4)	184 (94.4)	188 (94.9)	372 (94.7)
Vaccination (at Study				
Clinic)				
Day 1, after Vaccination	180 (92.8)	188 (96.4)	191 (96.5)	379 (96.4)
(at Home)				
Day 2	190 (97.9)	193 (99.0)	198 (100)	391 (99.5)
Day 3	181 (93.3)	185 (94.9)	191 (96.5)	376 (95.7)
Day 4	183 (94.3)	180 (92.3)	189 (95.5)	369 (93.9)
Day 5	181 (93.3)	180 (92.3)	189 (95.5)	369 (93.9)
Day 6	183 (94.3)	182 (93.3)	188 (94.9)	370 (94.1)
Day 7	184 (94.8)	190 (97.4)	196 (99.0)	386 (98.2)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Overall			
	Placebo (N=200) n (%)	mRNA-1273		Total (N=400) n (%)
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	
Number of Subjects Received Any Injection - N1	200	200	200	400
Any eDiary Data after Any Injection	200 (100)	200 (100)	200 (100)	400 (100)
Day 1, 1 Hour after Vaccination (at Study Clinic)	198 (99.0)	199 (99.5)	200 (100)	399 (99.8)
Day 1, after Vaccination (at Home)	198 (99.0)	199 (99.5)	198 (99.0)	397 (99.3)
Day 2	200 (100)	200 (100)	200 (100)	400 (100)
Day 3	197 (98.5)	200 (100)	198 (99.0)	398 (99.5)
Day 4	198 (99.0)	199 (99.5)	200 (100)	399 (99.8)
Day 5	197 (98.5)	200 (100)	197 (98.5)	397 (99.3)
Day 6	199 (99.5)	197 (98.5)	198 (99.0)	395 (98.8)
Day 7	199 (99.5)	198 (99.0)	200 (100)	398 (99.5)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Received	100	100	100	200	100	100	100	200
First Injection - N1								
Any eDiary Data after First Injection	100 (100)	100 (100)	100 (100)	200 (100)	99 (99.0)	100 (100)	99 (99.0)	199 (99.5)
Day 1, 1 Hour after Vaccination (at Study Clinic)	99 (99.0)	99 (99.0)	99 (99.0)	198 (99.0)	94 (94.0)	99 (99.0)	96 (96.0)	195 (97.5)
Day 1, after Vaccination (at Home)	95 (95.0)	95 (95.0)	98 (98.0)	193 (96.5)	98 (98.0)	97 (97.0)	96 (96.0)	193 (96.5)
Day 2	98 (98.0)	98 (98.0)	99 (99.0)	197 (98.5)	99 (99.0)	99 (99.0)	99 (99.0)	198 (99.0)
Day 3	99 (99.0)	98 (98.0)	97 (97.0)	195 (97.5)	95 (95.0)	97 (97.0)	98 (98.0)	195 (97.5)
Day 4	93 (93.0)	97 (97.0)	98 (98.0)	195 (97.5)	99 (99.0)	98 (98.0)	97 (97.0)	195 (97.5)
Day 5	97 (97.0)	96 (96.0)	93 (93.0)	189 (94.5)	97 (97.0)	97 (97.0)	96 (96.0)	193 (96.5)
Day 6	96 (96.0)	95 (95.0)	95 (95.0)	190 (95.0)	96 (96.0)	97 (97.0)	97 (97.0)	194 (97.0)
Day 7	98 (98.0)	98 (98.0)	98 (98.0)	196 (98.0)	98 (98.0)	95 (95.0)	96 (96.0)	191 (95.5)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Received Second Injection - N1	94	97	99	196	100	98	99	197
Any eDiary Data after Second Injection	94 (100)	97 (100)	99 (100)	196 (100)	100 (100)	98 (100)	99 (100)	197 (100)
Day 1, 1 Hour after Vaccination (at Study Clinic)	94 (100)	94 (96.9)	95 (96.0)	189 (96.4)	95 (95.0)	90 (91.8)	93 (93.9)	183 (92.9)
Day 1, after Vaccination (at Home)	85 (90.4)	95 (97.9)	96 (97.0)	191 (97.4)	95 (95.0)	93 (94.9)	95 (96.0)	188 (95.4)
Day 2	93 (98.9)	96 (99.0)	99 (100)	195 (99.5)	97 (97.0)	97 (99.0)	99 (100)	196 (99.5)
Day 3	87 (92.6)	90 (92.8)	92 (92.9)	182 (92.9)	94 (94.0)	95 (96.9)	99 (100)	194 (98.5)
Day 4	89 (94.7)	85 (87.6)	93 (93.9)	178 (90.8)	94 (94.0)	95 (96.9)	96 (97.0)	191 (97.0)
Day 5	84 (89.4)	86 (88.7)	93 (93.9)	179 (91.3)	97 (97.0)	94 (95.9)	96 (97.0)	190 (96.4)
Day 6	88 (93.6)	91 (93.8)	92 (92.9)	183 (93.4)	95 (95.0)	91 (92.9)	96 (97.0)	187 (94.9)
Day 7	87 (92.6)	95 (97.9)	99 (100)	194 (99.0)	97 (97.0)	95 (96.9)	97 (98.0)	192 (97.5)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.19
Summary of Compliance of eDiary Data
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Received Any Injection - N1	100	100	100	200	100	100	100	200
Any eDiary Data after Any Injection	100 (100)	100 (100)	100 (100)	200 (100)	100 (100)	100 (100)	100 (100)	200 (100)
Day 1, 1 Hour after Vaccination (at Study Clinic)	100 (100)	100 (100)	100 (100)	200 (100)	98 (98.0)	99 (99.0)	100 (100)	199 (99.5)
Day 1, after Vaccination (at Home)	98 (98.0)	99 (99.0)	98 (98.0)	197 (98.5)	100 (100)	100 (100)	100 (100)	200 (100)
Day 2	100 (100)	100 (100)	100 (100)	200 (100)	100 (100)	100 (100)	100 (100)	200 (100)
Day 3	99 (99.0)	100 (100)	98 (98.0)	198 (99.0)	98 (98.0)	100 (100)	100 (100)	200 (100)
Day 4	98 (98.0)	99 (99.0)	100 (100)	199 (99.5)	100 (100)	100 (100)	100 (100)	200 (100)
Day 5	97 (97.0)	100 (100)	98 (98.0)	198 (99.0)	100 (100)	100 (100)	99 (99.0)	199 (99.5)
Day 6	100 (100)	98 (98.0)	98 (98.0)	196 (98.0)	99 (99.0)	99 (99.0)	100 (100)	199 (99.5)
Day 7	99 (99.0)	99 (99.0)	100 (100)	199 (99.5)	100 (100)	99 (99.0)	100 (100)	199 (99.5)

Percentages are based on the number of participants who received respective injection (N1).

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Table 14.3.1.20

Subject Incidence of Solicited Adverse Reactions Ongoing 7 Days after Injection or Due to SAE by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	8 (4.0)	14 (7.0)	14 (7.0)	28 (7.0)
Number of Unsolicited Adverse Events	13	31	24	55
Nervous system disorders	1 (0.5)	6 (3.0)	5 (2.5)	11 (2.8)
Headache	1 (0.5)	6 (3.0)	5 (2.5)	11 (2.8)
Gastrointestinal disorders	0	0	1 (0.5)	1 (0.3)
Nausea	0	0	1 (0.5)	1 (0.3)
Musculoskeletal and connective tissue disorders	2 (1.0)	7 (3.5)	4 (2.0)	11 (2.8)
Arthralgia	2 (1.0)	4 (2.0)	3 (1.5)	7 (1.8)
Myalgia	2 (1.0)	5 (2.5)	2 (1.0)	7 (1.8)
General disorders and administration site conditions	7 (3.5)	12 (6.0)	8 (4.0)	20 (5.0)
Fatigue	5 (2.5)	11 (5.5)	3 (1.5)	14 (3.5)
Axillary pain	0	1 (0.5)	2 (1.0)	3 (0.8)

This table is based on solicited adverse reactions ongoing 7 days after injection or due to SAE which are collected on AE eCRF.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030120.sas 19NOV2020 02:35 Database Lock Date: 05NOV2020

Table 14.3.1.20

Subject Incidence of Solicited Adverse Reactions Ongoing 7 Days after Injection or Due to SAE by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Injection site induration	0	0	3 (1.5)	3 (0.8)
Injection site swelling	1 (0.5)	0	3 (1.5)	3 (0.8)
Injection site pain	1 (0.5)	1 (0.5)	0	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Injection site erythema	1 (0.5)	0	0	0

This table is based on solicited adverse reactions ongoing 7 days after injection or due to SAE which are collected on AE eCRF.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030120.sas 19NOV2020 02:35 Database Lock Date: 05NOV2020

Table 14.3.1.20

Subject Incidence of Solicited Adverse Reactions Ongoing 7 Days after Injection or Due to SAE by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	5 (5.0)	6 (6.0)	10 (10.0)	16 (8.0)	3 (3.0)	8 (8.0)	4 (4.0)	12 (6.0)
Number of Unsolicited Adverse Events	8	15	18	33	5	16	6	22
Nervous system disorders	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	3 (3.0)	3 (3.0)	6 (3.0)
Headache	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	3 (3.0)	3 (3.0)	6 (3.0)
Gastrointestinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal and connective tissue disorders	1 (1.0)	5 (5.0)	3 (3.0)	8 (4.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Arthralgia	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Myalgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
General disorders and administration site conditions	4 (4.0)	5 (5.0)	7 (7.0)	12 (6.0)	3 (3.0)	7 (7.0)	1 (1.0)	8 (4.0)
Fatigue	3 (3.0)	4 (4.0)	3 (3.0)	7 (3.5)	2 (2.0)	7 (7.0)	0	7 (3.5)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0

This table is based on solicited adverse reactions ongoing 7 days after injection or due to SAE which are collected on AE eCRF.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.20

Subject Incidence of Solicited Adverse Reactions Ongoing 7 Days after Injection or Due to SAE by System Organ Class and Preferred Term
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Injection site induration	0	0	2 (2.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Injection site swelling	1 (1.0)	0	2 (2.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Injection site pain	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Injection site erythema	0	0	0	0	1 (1.0)	0	0	0

This table is based on solicited adverse reactions ongoing 7 days after injection or due to SAE which are collected on AE eCRF.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Ad-hoc Table 14.3.1.22.1
Subject Incidence of Unsolicited Adverse Event of Special Interest - Vasculitis by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Vasculitis is identified through selected SMQ.

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Ad-hoc Table 14.3.1.22.1
Subject Incidence of Unsolicited Adverse Event of Special Interest - Vasculitis by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Vasculitis is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012201.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.2
Subject Incidence of Unsolicited Adverse Event of Special Interest - Hypersensitivity by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Hypersensitivity [1]	6 (3.0)	9 (4.5)	2 (1.0)	11 (2.8)
Number of Hypersensitivity [1]	6	9	2	11
Angioedema	1 (0.5)	0	0	0
Dermatitis	0	1 (0.5)	0	1 (0.3)
Dermatitis contact	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Rash	2 (1.0)	3 (1.5)	0	3 (0.8)

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Hypersensitivity is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012202.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.2
Subject Incidence of Unsolicited Adverse Event of Special Interest - Hypersensitivity by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Hypersensitivity [1]	3 (3.0)	5 (5.0)	1 (1.0)	6 (3.0)	3 (3.0)	4 (4.0)	1 (1.0)	5 (2.5)
Number of Hypersensitivity [1]	3	5	1	6	3	4	1	5
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Dermatitis contact	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	1 (1.0)	0	1 (0.5)

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Hypersensitivity is identified through selected SMQ.

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Ad-hoc Table 14.3.1.22.3
Subject Incidence of Unsolicited Adverse Event of Special Interest - Arthritis by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Arthritis [1]	0	0	1 (0.5)	1 (0.3)
Number of Arthritis [1]	0	0	1	1
Gout	0	0	1 (0.5)	1 (0.3)

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Arthritis is identified through selected SMQ.

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Ad-hoc Table 14.3.1.22.3
Subject Incidence of Unsolicited Adverse Event of Special Interest - Arthritis by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Arthritis [1]	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Number of Arthritis [1]	0	0	0	0	0	0	1	1
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Arthritis is identified through selected SMQ.

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Ad-hoc Table 14.3.1.22.4
Subject Incidence of Unsolicited Adverse Event of Special Interest - Angioedema by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Angioedema [1]	1 (0.5)	0	0	0
Number of Angioedema [1]	1	0	0	0
Angioedema	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Angioedema is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012204.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.4
Subject Incidence of Unsolicited Adverse Event of Special Interest - Angioedema by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Angioedema [1]	0	0	0	0	1 (1.0)	0	0	0
Number of Angioedema [1]	0	0	0	0	1	0	0	0
Angioedema	0	0	0	0	1 (1.0)	0	0	0

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Angioedema is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012204.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.5
Subject Incidence of Unsolicited Adverse Event of Special Interest - Peripheral Neuropathy by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Peripheral Neuropathy is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012205.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.5
Subject Incidence of Unsolicited Adverse Event of Special Interest - Peripheral Neuropathy by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Peripheral Neuropathy is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012205.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.6

Subject Incidence of Unsolicited Adverse Event of Special Interest - Demyelinating Disease of Central Nervous System by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012206.sas 13JAN2021 16:58

Ad-hoc Table 14.3.1.22.6

Subject Incidence of Unsolicited Adverse Event of Special Interest - Demyelinating Disease of Central Nervous System by SMQ
Safety Set

Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

[1] Demyelinating Disease of Central Nervous System is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012206.sas 13JAN2021 16:58

Ad-hoc Table 14.3.1.22.7
Subject Incidence of Unsolicited Adverse Event of Special Interest - Convulsions by SMQ
Safety Set

Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Convulsions is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012207.sas 13JAN2021 15:54

Ad-hoc Table 14.3.1.22.7
Subject Incidence of Unsolicited Adverse Event of Special Interest - Convulsions by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Convulsions is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403012207.sas 13JAN2021 15:54

Table 14.3.1.13.1

Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011301.sas 19NOV2020 00:31 Database Lock Date: 05NOV2020

Table 14.3.1.13.1

Subject Incidence of Serious TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011301.sas 19NOV2020 00:31 Database Lock Date: 05NOV2020

Table 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	1 (0.5)	0	1 (0.3)
Number of Unsolicited Adverse Events	0	1	0	1
Infections and infestations	0	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011302.sas 19NOV2020 02:30 Database Lock Date: 05NOV2020

Table 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Number of Unsolicited Adverse Events	0	0	0	0	0	1	0	1
Infections and infestations	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011302.sas 19NOV2020 02:30 Database Lock Date: 05NOV2020

Table 14.3.1.14.1

Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011401.sas 19NOV2020 00:31 Database Lock Date: 05NOV2020

Table 14.3.1.14.1

Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
System Organ Class Preferred Term	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011401.sas 19NOV2020 00:31 Database Lock Date: 05NOV2020

Table 14.3.1.14.2

Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011402.sas 19NOV2020 02:31 Database Lock Date: 05NOV2020

Table 14.3.1.14.2

Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011402.sas 19NOV2020 02:31 Database Lock Date: 05NOV2020

Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
		n (%)	n (%)	n (%)

There are no observations for this table.

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.
Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011501.sas 19NOV2020 00:32 Database Lock Date: 05NOV2020

Table 14.3.1.15.1

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011501.sas 19NOV2020 00:32 Database Lock Date: 05NOV2020

Table 14.3.1.15.2

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.
Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011502.sas 19NOV2020 02:31 Database Lock Date: 05NOV2020

Table 14.3.1.15.2

Subject Incidence of Unsolicited TEAE Leading to Discontinuation from Participation in the Study by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)

There are no observations for this table.

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011502.sas 19NOV2020 02:31 Database Lock Date: 05NOV2020

Table 14.3.1.16.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4 (2.0)	7 (3.5)	5 (2.5)	12 (3.0)
Number of Unsolicited Adverse Events	4	9	5	14
Immune system disorders	1 (0.5)	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0
Psychiatric disorders	0	0	1 (0.5)	1 (0.3)
Depression	0	0	1 (0.5)	1 (0.3)
Nervous system disorders	0	0	1 (0.5)	1 (0.3)
Headache	0	0	1 (0.5)	1 (0.3)
Vascular disorders	0	0	1 (0.5)	1 (0.3)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Oropharyngeal pain	0	1 (0.5)	0	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011601.sas 19NOV2020 00:33 Database Lock Date: 05NOV2020

Table 14.3.1.16.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders	0	3 (1.5)	0	3 (0.8)
Arthralgia	0	2 (1.0)	0	2 (0.5)
Muscle spasms	0	1 (0.5)	0	1 (0.3)
General disorders and administration site conditions	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	2 (1.0)	2 (1.0)	0	2 (0.5)
Axillary pain	0	1 (0.5)	0	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Investigations	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure increased	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.16.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)
Number of Unsolicited Adverse Events	2	7	4	11	2	2	1	3
Immune system disorders	0	0	0	0	1 (1.0)	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nervous system disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Vascular disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Oropharyngeal pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.16.1

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Musculoskeletal and connective tissue disorders	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Arthralgia	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Muscle spasms	0	1 (1.0)	0	1 (0.5)	0	0	0	0
General disorders and administration site conditions	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Fatigue	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Axillary pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Investigations	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.16.2

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	4 (2.0)	8 (4.0)	5 (2.5)	13 (3.3)
Number of Unsolicited Adverse Events	4	10	5	15
Infections and infestations	0	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Immune system disorders	1 (0.5)	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0
Psychiatric disorders	0	0	1 (0.5)	1 (0.3)
Depression	0	0	1 (0.5)	1 (0.3)
Nervous system disorders	0	0	1 (0.5)	1 (0.3)
Headache	0	0	1 (0.5)	1 (0.3)
Vascular disorders	0	0	1 (0.5)	1 (0.3)
Diastolic hypertension	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011602.sas 19NOV2020 02:32 Database Lock Date: 05NOV2020

Table 14.3.1.16.2

Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Oropharyngeal pain	0	1 (0.5)	0	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Musculoskeletal and connective tissue disorders	0	3 (1.5)	0	3 (0.8)
Arthralgia	0	2 (1.0)	0	2 (0.5)
Muscle spasms	0	1 (0.5)	0	1 (0.3)
General disorders and administration site conditions	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	2 (1.0)	2 (1.0)	0	2 (0.5)
Axillary pain	0	1 (0.5)	0	1 (0.3)
Pain	0	1 (0.5)	0	1 (0.3)
Investigations	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Blood pressure increased	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.16.2
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (2.0)	5 (5.0)	4 (4.0)	9 (4.5)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Number of Unsolicited Adverse Events	2	7	4	11	2	3	1	4
Infections and infestations	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Immune system disorders	0	0	0	0	1 (1.0)	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nervous system disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Vascular disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Diastolic hypertension	0	0	1 (1.0)	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.16.2
Subject Incidence of Unsolicited Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Oropharyngeal pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal and connective tissue disorders	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Arthralgia	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Muscle spasms	0	1 (1.0)	0	1 (0.5)	0	0	0	0
General disorders and administration site conditions	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Fatigue	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Axillary pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Investigations	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011602.sas 19NOV2020 02:32 Database Lock Date: 05NOV2020

Table 14.3.1.17.1

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Number of Unsolicited Adverse Events	2	6	2	8
Nervous system disorders	0	0	1 (0.5)	1 (0.3)
Headache	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	0	1 (0.5)	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Musculoskeletal and connective tissue disorders	0	2 (1.0)	0	2 (0.5)
Arthralgia	0	2 (1.0)	0	2 (0.5)
General disorders and administration site conditions	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	2 (1.0)	2 (1.0)	0	2 (0.5)
Axillary pain	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011701.sas 19NOV2020 00:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.1

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Pain	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011701.sas 19NOV2020 00:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.1

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Number of Unsolicited Adverse Events	2	5	2	7	0	1	0	1
Nervous system disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal and connective tissue disorders	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Arthralgia	0	2 (2.0)	0	2 (1.0)	0	0	0	0
General disorders and administration site conditions	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Fatigue	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Axillary pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011701.sas 19NOV2020 00:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.1

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011701.sas 19NOV2020 00:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.2

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (1.0)	4 (2.0)	2 (1.0)	6 (1.5)
Number of Unsolicited Adverse Events	2	6	2	8
Nervous system disorders	0	0	1 (0.5)	1 (0.3)
Headache	0	0	1 (0.5)	1 (0.3)
Respiratory, thoracic and mediastinal disorders	0	0	1 (0.5)	1 (0.3)
Rhinorrhoea	0	0	1 (0.5)	1 (0.3)
Musculoskeletal and connective tissue disorders	0	2 (1.0)	0	2 (0.5)
Arthralgia	0	2 (1.0)	0	2 (0.5)
General disorders and administration site conditions	2 (1.0)	3 (1.5)	0	3 (0.8)
Fatigue	2 (1.0)	2 (1.0)	0	2 (0.5)
Axillary pain	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011702.sas 19NOV2020 02:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.2

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Pain	0	1 (0.5)	0	1 (0.3)

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.
Percentages are based on the number of safety subjects.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011702.sas 19NOV2020 02:33 Database Lock Date: 05NOV2020

Table 14.3.1.17.2

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)
Number of Unsolicited Adverse Events	2	5	2	7	0	1	0	1
Nervous system disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Headache	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Rhinorrhoea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal and connective tissue disorders	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Arthralgia	0	2 (2.0)	0	2 (1.0)	0	0	0	0
General disorders and administration site conditions	2 (2.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Fatigue	2 (2.0)	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Axillary pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.17.2

Subject Incidence of Unsolicited Treatment-Related Severe TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

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Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	17 (8.5)	22 (11.0)	17 (8.5)	39 (9.8)
Number of Unsolicited Adverse Events	22	28	21	49
Infections and infestations	6 (3.0)	5 (2.5)	5 (2.5)	10 (2.5)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
COVID-19	1 (0.5)	2 (1.0)	0	2 (0.5)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Cellulitis	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Otitis media	1 (0.5)	0	0	0
Immune system disorders	1 (0.5)	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011801.sas 19NOV2020 00:34 Database Lock Date: 05NOV2020

Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Hyperlipidaemia	1 (0.5)	0	0	0
Psychiatric disorders	0	1 (0.5)	0	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	0	3 (1.5)	3 (1.5)	6 (1.5)
Headache	0	1 (0.5)	2 (1.0)	3 (0.8)
Dizziness	0	0	1 (0.5)	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Paraesthesia	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	1 (0.5)	0	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)
Respiratory, thoracic and mediastinal disorders	1 (0.5)	0	0	0
Cough	1 (0.5)	0	0	0
Dry throat	1 (0.5)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011801.sas 19NOV2020 00:34 Database Lock Date: 05NOV2020

Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders	3 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)
Dental caries	0	1 (0.5)	0	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Nausea	0	0	1 (0.5)	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Large intestine polyp	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Toothache	1 (0.5)	0	0	0
Skin and subcutaneous tissue disorders	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Dermatitis contact	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Rash	0	2 (1.0)	0	2 (0.5)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
Arthralgia	0	0	2 (1.0)	2 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011801.sas 19NOV2020 00:34 Database Lock Date: 05NOV2020

Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Back pain	0	1 (0.5)	0	1 (0.3)
Myalgia	0	1 (0.5)	0	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Bursitis	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Renal and urinary disorders	0	1 (0.5)	0	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
General disorders and administration site conditions	0	2 (1.0)	3 (1.5)	5 (1.3)
Axillary pain	0	0	2 (1.0)	2 (0.5)
Chest pain	0	1 (0.5)	0	1 (0.3)
Fatigue	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011801.sas 19NOV2020 00:34 Database Lock Date: 05NOV2020

Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Investigations	0	1 (0.5)	0	1 (0.3)
Blood pressure increased	0	1 (0.5)	0	1 (0.3)
Injury, poisoning and procedural complications	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Arthropod bite	0	1 (0.5)	0	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle strain	0	0	1 (0.5)	1 (0.3)
Skin laceration	2 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of Subjects Reporting Unsolicited Adverse Events	10 (10.0)	11 (11.0)	8 (8.0)	19 (9.5)	7 (7.0)	11 (11.0)	9 (9.0)	20 (10.0)
Number of Unsolicited Adverse Events	14	14	10	24	8	14	11	25
Infections and infestations	4 (4.0)	4 (4.0)	2 (2.0)	6 (3.0)	2 (2.0)	1 (1.0)	3 (3.0)	4 (2.0)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
COVID-19	0	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0
Immune system disorders	0	0	0	0	1 (1.0)	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011801.sas 19NOV2020 00:34 Database Lock Date: 05NOV2020

Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nervous system disorders	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Headache	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Dizziness	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Paraesthesia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Vascular disorders	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (1.0)	0	0	0	0	0	0	0
Cough	1 (1.0)	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0

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Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Gastrointestinal disorders	2 (2.0)	0	2 (2.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Toothache	1 (1.0)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (2.0)	3 (3.0)	0	3 (1.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Dermatitis contact	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Rash	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
Arthralgia	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)

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Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Musculoskeletal and connective tissue disorders (cont.)								
Back pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Myalgia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Renal and urinary disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
General disorders and administration site conditions	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Axillary pain	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Fatigue	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)

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Table 14.3.1.18.1

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term up to 28 Days after Any Vaccination
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Investigations	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Injury, poisoning and procedural complications	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Arthropod bite	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle strain	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	19 (9.5)	24 (12.0)	18 (9.0)	42 (10.5)
Number of Unsolicited Adverse Events	25	33	22	55
Infections and infestations	8 (4.0)	6 (3.0)	5 (2.5)	11 (2.8)
Urinary tract infection	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
COVID-19	3 (1.5)	2 (1.0)	0	2 (0.5)
Gastroenteritis	1 (0.5)	0	1 (0.5)	1 (0.3)
Herpes simplex	0	0	1 (0.5)	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Sinusitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Upper respiratory tract infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Cellulitis	1 (0.5)	0	0	0
Oral candidiasis	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Otitis media	1 (0.5)	0	0	0

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Percentages are based on the number of safety subjects.

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Immune system disorders	1 (0.5)	0	0	0
Allergy to arthropod sting	1 (0.5)	0	0	0
Metabolism and nutrition disorders	1 (0.5)	0	1 (0.5)	1 (0.3)
Gout	0	0	1 (0.5)	1 (0.3)
Hyperlipidaemia	1 (0.5)	0	0	0
Psychiatric disorders	0	2 (1.0)	1 (0.5)	3 (0.8)
Anxiety	0	1 (0.5)	0	1 (0.3)
Depression	0	0	1 (0.5)	1 (0.3)
Insomnia	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	0	4 (2.0)	3 (1.5)	7 (1.8)
Headache	0	1 (0.5)	2 (1.0)	3 (0.8)
Dizziness	0	1 (0.5)	1 (0.5)	2 (0.5)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Paraesthesia	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	1 (0.5)	0	1 (0.3)
Hypertension	0	1 (0.5)	0	1 (0.3)

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.

Percentages are based on the number of safety subjects.

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200) n (%)	mRNA-1273		
		50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	1 (0.5)	0	0	0
Cough	1 (0.5)	0	0	0
Dry throat	1 (0.5)	0	0	0
Gastrointestinal disorders	3 (1.5)	2 (1.0)	3 (1.5)	5 (1.3)
Dental caries	0	1 (0.5)	0	1 (0.3)
Diverticulum	0	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Nausea	0	0	1 (0.5)	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Large intestine polyp	1 (0.5)	0	0	0
Oral disorder	1 (0.5)	0	0	0
Toothache	1 (0.5)	0	0	0
Skin and subcutaneous tissue disorders	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Dermatitis contact	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Rash	0	2 (1.0)	0	2 (0.5)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Erythema	0	0	1 (0.5)	1 (0.3)
Angioedema	1 (0.5)	0	0	0

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
Skin and subcutaneous tissue disorders (cont.)				
Rash papular	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	1 (0.5)	4 (2.0)	2 (1.0)	6 (1.5)
Arthralgia	0	0	2 (1.0)	2 (0.5)
Back pain	0	1 (0.5)	0	1 (0.3)
Myalgia	0	1 (0.5)	0	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Bursitis	1 (0.5)	0	0	0
Exostosis	1 (0.5)	0	0	0
Renal and urinary disorders	0	1 (0.5)	0	1 (0.3)
Nephrolithiasis	0	1 (0.5)	0	1 (0.3)
General disorders and administration site conditions	0	2 (1.0)	3 (1.5)	5 (1.3)
Axillary pain	0	0	2 (1.0)	2 (0.5)
Chest pain	0	1 (0.5)	0	1 (0.3)

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Percentages are based on the number of safety subjects.

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)				
Fatigue	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Investigations	0	2 (1.0)	0	2 (0.5)
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)
Blood pressure increased	0	1 (0.5)	0	1 (0.3)
Platelet count increased	0	1 (0.5)	0	1 (0.3)
Injury, poisoning and procedural complications	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Arthropod bite	0	1 (0.5)	0	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Meniscus injury	0	0	1 (0.5)	1 (0.3)
Muscle strain	0	0	1 (0.5)	1 (0.3)
Skin laceration	2 (1.0)	0	0	0

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	12 (12.0)	11 (11.0)	9 (9.0)	20 (10.0)	7 (7.0)	13 (13.0)	9 (9.0)	22 (11.0)
Number of Unsolicited Adverse Events	17	14	11	25	8	19	11	30
Infections and infestations	6 (6.0)	4 (4.0)	2 (2.0)	6 (3.0)	2 (2.0)	2 (2.0)	3 (3.0)	5 (2.5)
Urinary tract infection	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	0	0	0
COVID-19	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	1 (1.0)	0	1 (0.5)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	0	0
Herpes simplex	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Pneumonia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Sinusitis	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Upper respiratory tract infection	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Cellulitis	0	0	0	0	1 (1.0)	0	0	0
Oral candidiasis	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Otitis media	1 (1.0)	0	0	0	0	0	0	0

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.

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Immune system disorders	0	0	0	0	1 (1.0)	0	0	0
Allergy to arthropod sting	0	0	0	0	1 (1.0)	0	0	0
Metabolism and nutrition disorders	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hyperlipidaemia	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	0	0	1 (1.0)	1 (0.5)	0	2 (2.0)	0	2 (1.0)
Anxiety	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Depression	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Insomnia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nervous system disorders	0	2 (2.0)	2 (2.0)	4 (2.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
Headache	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Dizziness	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Nervous system cyst	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Paraesthesia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Vascular disorders	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Hypertension	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Respiratory, thoracic and mediastinal disorders	1 (1.0)	0	0	0	0	0	0	0
Cough	1 (1.0)	0	0	0	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Gastrointestinal disorders	2 (2.0)	0	2 (2.0)	2 (1.0)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Dental caries	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diverticulum	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nausea	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oesophageal food impaction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Large intestine polyp	0	0	0	0	1 (1.0)	0	0	0
Oral disorder	1 (1.0)	0	0	0	0	0	0	0
Toothache	1 (1.0)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (2.0)	3 (3.0)	0	3 (1.5)	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)
Dermatitis contact	1 (1.0)	2 (2.0)	0	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Rash	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Erythema	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Angioedema	0	0	0	0	1 (1.0)	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011802.sas 19NOV2020 02:33 Database Lock Date: 05NOV2020

Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)	Placebo (N=100) n (%)	50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Skin and subcutaneous tissue disorders (cont.)								
Rash papular	1 (1.0)	0	0	0	0	0	0	0
Musculoskeletal and connective tissue disorders	0	1 (1.0)	1 (1.0)	2 (1.0)	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)
Arthralgia	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Back pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Myalgia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Rotator cuff syndrome	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Bursitis	0	0	0	0	1 (1.0)	0	0	0
Exostosis	0	0	0	0	1 (1.0)	0	0	0
Renal and urinary disorders	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
General disorders and administration site conditions	0	1 (1.0)	2 (2.0)	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Axillary pain	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Chest pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011802.sas 19NOV2020 02:33 Database Lock Date: 05NOV2020

Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to Day 57 Visit
Safety Set

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
General disorders and administration site conditions (cont.)								
Fatigue	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Malaise	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Investigations	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Blood alkaline phosphatase increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Platelet count increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Injury, poisoning and procedural complications	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Arthropod bite	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Meniscus injury	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Muscle strain	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0

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.

Percentages are based on the number of safety subjects.

MedDRA version 23.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1403011802.sas 19NOV2020 02:33 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Basophils ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.0422 (0.02053)	0.0445 (0.02155)	0.0420 (0.01876)	0.0432 (0.02019)
Median	0.0400	0.0400	0.0400	0.0400
Min, Max	0.015, 0.100	0.015, 0.120	0.015, 0.100	0.015, 0.120
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.0422 (0.01937)	0.0441 (0.02067)	0.0402 (0.01906)	0.0422 (0.01994)
Median	0.0400	0.0400	0.0400	0.0400
Min, Max	0.015, 0.090	0.015, 0.110	0.015, 0.100	0.015, 0.110
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.0005 (0.01355)	-0.0003 (0.01250)	-0.0019 (0.01205)	-0.0011 (0.01227)
Median	0.0000	0.0000	0.0000	0.0000
Min, Max	-0.050, 0.040	-0.030, 0.035	-0.030, 0.030	-0.030, 0.035
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.0423 (0.01917)	0.0435 (0.02065)	0.0429 (0.01766)	0.0432 (0.01917)
Median	0.0400	0.0400	0.0400	0.0400
Min, Max	0.015, 0.090	0.015, 0.100	0.015, 0.100	0.015, 0.100
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.0001 (0.01375)	-0.0010 (0.01365)	0.0011 (0.01433)	0.0000 (0.01399)
Median	0.0000	0.0000	0.0000	0.0000
Min, Max	-0.050, 0.035	-0.050, 0.035	-0.055, 0.040	-0.055, 0.040

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Basophils/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.74 (0.341)	0.76 (0.329)	0.73 (0.307)	0.74 (0.318)
Median	0.70	0.70	0.70	0.70
Min, Max	0.2, 2.1	0.0, 1.9	0.1, 1.6	0.0, 1.9
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.78 (0.330)	0.78 (0.340)	0.75 (0.327)	0.76 (0.333)
Median	0.70	0.70	0.70	0.70
Min, Max	0.2, 2.1	0.0, 1.7	0.2, 1.9	0.0, 1.9
Change from Baseline				
n	94	97	94	191
Mean (SD)	0.03 (0.251)	0.02 (0.236)	0.02 (0.227)	0.02 (0.231)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.7, 1.1	-0.7, 0.6	-0.4, 0.5	-0.7, 0.6
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.79 (0.334)	0.79 (0.371)	0.79 (0.333)	0.79 (0.351)
Median	0.70	0.70	0.70	0.70
Min, Max	0.2, 1.8	0.0, 1.8	0.1, 1.6	0.0, 1.8
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.04 (0.272)	0.04 (0.265)	0.06 (0.268)	0.05 (0.266)
Median	0.00	0.00	0.05	0.00
Min, Max	-0.9, 0.8	-0.9, 1.1	-0.9, 0.8	-0.9, 1.1

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Eosinophils ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.1374 (0.08977)	0.1481 (0.10675)	0.1335 (0.07880)	0.1408 (0.09387)
Median	0.1200	0.1200	0.1300	0.1250
Min, Max	0.015, 0.520	0.015, 0.780	0.015, 0.320	0.015, 0.780
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.1686 (0.30735)	0.1612 (0.10332)	0.1376 (0.08622)	0.1496 (0.09578)
Median	0.1200	0.1300	0.1200	0.1300
Min, Max	0.015, 3.020	0.015, 0.660	0.015, 0.470	0.015, 0.660
Change from Baseline				
n	94	97	94	191
Mean (SD)	0.0290 (0.30501)	0.0141 (0.09096)	0.0032 (0.05530)	0.0088 (0.07555)
Median	0.0000	0.0100	0.0050	0.0100
Min, Max	-0.300, 2.890	-0.560, 0.310	-0.200, 0.220	-0.560, 0.310
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.1393 (0.07302)	0.1669 (0.10246)	0.1567 (0.09696)	0.1618 (0.09962)
Median	0.1300	0.1450	0.1350	0.1400
Min, Max	0.015, 0.370	0.015, 0.730	0.015, 0.550	0.015, 0.730
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.0014 (0.06032)	0.0162 (0.09859)	0.0222 (0.06639)	0.0192 (0.08388)
Median	0.0100	0.0150	0.0125	0.0125
Min, Max	-0.270, 0.120	-0.520, 0.310	-0.190, 0.380	-0.520, 0.380

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Eosinophils/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	2.37 (1.617)	2.47 (1.571)	2.27 (1.374)	2.37 (1.475)
Median	2.10	2.15	2.10	2.10
Min, Max	0.1, 12.0	0.0, 10.9	0.0, 6.1	0.0, 10.9
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	2.76 (2.709)	2.82 (1.716)	2.51 (1.578)	2.67 (1.652)
Median	2.00	2.40	2.35	2.40
Min, Max	0.3, 24.0	0.0, 8.4	0.0, 8.2	0.0, 8.4
Change from Baseline				
n	94	97	94	191
Mean (SD)	0.35 (2.502)	0.36 (1.403)	0.22 (1.116)	0.29 (1.269)
Median	0.20	0.10	0.10	0.10
Min, Max	-3.9, 22.0	-7.6, 5.3	-2.9, 4.9	-7.6, 5.3
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	2.59 (1.432)	2.99 (1.646)	2.76 (1.571)	2.88 (1.609)
Median	2.40	2.50	2.40	2.50
Min, Max	0.4, 8.0	0.0, 8.0	0.0, 7.4	0.0, 8.0
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.21 (1.035)	0.48 (1.501)	0.47 (1.196)	0.48 (1.353)
Median	0.30	0.30	0.30	0.30
Min, Max	-4.1, 2.3	-6.3, 4.5	-3.4, 4.4	-6.3, 4.5

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Erythrocytes (10¹²/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	4.624 (0.3875)	4.606 (0.3564)	4.662 (0.4443)	4.634 (0.4027)
Median	4.615	4.550	4.720	4.595
Min, Max	3.30, 5.86	3.82, 5.86	3.63, 5.76	3.63, 5.86
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	4.523 (0.3928)	4.447 (0.3639)	4.566 (0.4284)	4.506 (0.4004)
Median	4.510	4.410	4.610	4.460
Min, Max	3.44, 5.41	3.63, 5.76	3.47, 5.26	3.47, 5.76
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.099 (0.2108)	-0.153 (0.1871)	-0.106 (0.2330)	-0.130 (0.2117)
Median	-0.105	-0.140	-0.125	-0.140
Min, Max	-0.53, 0.40	-0.65, 0.25	-0.87, 0.39	-0.87, 0.39
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	4.483 (0.4119)	4.417 (0.3399)	4.534 (0.4411)	4.476 (0.3971)
Median	4.490	4.395	4.555	4.450
Min, Max	3.28, 5.30	3.63, 5.44	3.59, 5.55	3.59, 5.55
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.144 (0.2586)	-0.188 (0.1967)	-0.121 (0.2076)	-0.154 (0.2044)
Median	-0.110	-0.190	-0.115	-0.150
Min, Max	-0.76, 0.66	-0.60, 0.34	-0.78, 0.32	-0.78, 0.34

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Hematocrit (L/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.4583 (0.03402)	0.4534 (0.03061)	0.4618 (0.04176)	0.4576 (0.03676)
Median	0.4570	0.4490	0.4565	0.4540
Min, Max	0.392, 0.583	0.390, 0.534	0.365, 0.596	0.365, 0.596
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.4512 (0.03758)	0.4437 (0.03296)	0.4549 (0.04089)	0.4492 (0.03740)
Median	0.4460	0.4450	0.4570	0.4500
Min, Max	0.356, 0.556	0.375, 0.523	0.342, 0.549	0.342, 0.549
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.0059 (0.02344)	-0.0095 (0.02311)	-0.0073 (0.02512)	-0.0084 (0.02408)
Median	-0.0025	-0.0110	-0.0045	-0.0080
Min, Max	-0.058, 0.082	-0.066, 0.050	-0.103, 0.051	-0.103, 0.051
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.4522 (0.03960)	0.4433 (0.03205)	0.4576 (0.04417)	0.4505 (0.03915)
Median	0.4530	0.4415	0.4585	0.4505
Min, Max	0.357, 0.527	0.382, 0.520	0.356, 0.564	0.356, 0.564
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.0064 (0.02838)	-0.0097 (0.02301)	-0.0038 (0.02744)	-0.0067 (0.02542)
Median	-0.0080	-0.0110	-0.0025	-0.0080
Min, Max	-0.079, 0.058	-0.075, 0.055	-0.058, 0.071	-0.075, 0.071

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Hemoglobin (g/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	142.1 (11.38)	140.5 (10.61)	143.9 (13.19)	142.2 (12.06)
Median	142.0	139.0	142.5	140.0
Min, Max	117, 170	116, 173	116, 183	116, 183
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	138.9 (11.43)	136.3 (10.43)	140.8 (13.01)	138.5 (11.95)
Median	138.0	136.0	142.0	137.0
Min, Max	107, 173	115, 169	111, 177	111, 177
Change from Baseline				
n	94	97	94	191
Mean (SD)	-3.1 (6.15)	-4.2 (6.11)	-3.5 (6.83)	-3.9 (6.46)
Median	-3.0	-3.0	-4.0	-4.0
Min, Max	-16, 11	-22, 9	-26, 15	-26, 15
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	138.0 (12.30)	134.8 (10.64)	139.7 (13.31)	137.3 (12.27)
Median	137.0	133.0	139.5	136.5
Min, Max	99, 165	113, 167	109, 173	109, 173
Change from Baseline				
n	99	94	94	188
Mean (SD)	-4.2 (7.29)	-5.6 (6.37)	-4.2 (6.18)	-4.9 (6.30)
Median	-3.0	-5.0	-4.0	-4.0
Min, Max	-23, 18	-23, 8	-24, 11	-24, 11

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Immature Granulocytes ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.0196 (0.01178)	0.0175 (0.00770)	0.0187 (0.01405)	0.0181 (0.01132)
Median	0.0150	0.0150	0.0150	0.0150
Min, Max	0.015, 0.080	0.015, 0.060	0.015, 0.120	0.015, 0.120
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.0180 (0.00931)	0.0196 (0.01071)	0.0195 (0.01416)	0.0196 (0.01250)
Median	0.0150	0.0150	0.0150	0.0150
Min, Max	0.015, 0.080	0.015, 0.070	0.015, 0.120	0.015, 0.120
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.0016 (0.01001)	0.0021 (0.01018)	0.0006 (0.00752)	0.0014 (0.00898)
Median	0.0000	0.0000	0.0000	0.0000
Min, Max	-0.055, 0.025	-0.025, 0.055	-0.025, 0.025	-0.025, 0.055
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.0191 (0.00904)	0.0195 (0.00939)	0.0199 (0.01396)	0.0197 (0.01187)
Median	0.0150	0.0150	0.0150	0.0150
Min, Max	0.015, 0.060	0.015, 0.060	0.015, 0.110	0.015, 0.110
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.0005 (0.00973)	0.0025 (0.00944)	0.0022 (0.01261)	0.0023 (0.01111)
Median	0.0000	0.0000	0.0000	0.0000
Min, Max	-0.030, 0.025	-0.020, 0.045	-0.025, 0.095	-0.025, 0.095

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Immature Granulocytes/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.29 (0.185)	0.25 (0.153)	0.27 (0.208)	0.26 (0.182)
Median	0.20	0.20	0.20	0.20
Min, Max	0.0, 1.2	0.0, 1.0	0.0, 1.5	0.0, 1.5
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.29 (0.161)	0.30 (0.235)	0.31 (0.281)	0.31 (0.258)
Median	0.25	0.20	0.20	0.20
Min, Max	0.0, 1.2	0.0, 1.3	0.0, 2.1	0.0, 2.1
Change from Baseline				
n	94	97	94	191
Mean (SD)	0.00 (0.170)	0.05 (0.218)	0.04 (0.184)	0.04 (0.201)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.6, 0.4	-0.4, 0.9	-0.3, 0.6	-0.4, 0.9
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.29 (0.202)	0.30 (0.175)	0.30 (0.260)	0.30 (0.221)
Median	0.20	0.20	0.20	0.20
Min, Max	0.0, 1.0	0.0, 0.7	0.0, 2.0	0.0, 2.0
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.01 (0.203)	0.05 (0.195)	0.04 (0.250)	0.05 (0.224)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.4, 0.7	-0.3, 0.6	-0.5, 1.7	-0.5, 1.7

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Leukocytes (10⁹/L)

	mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	5.976 (1.3727)	5.989 (1.3586)	5.973 (1.2680)	5.981 (1.3108)
Median	5.850	5.745	5.855	5.820
Min, Max	3.47, 10.70	3.53, 9.95	3.70, 10.22	3.53, 10.22
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	5.729 (1.4723)	5.764 (1.2999)	5.590 (1.2272)	5.678 (1.2643)
Median	5.665	5.590	5.410	5.550
Min, Max	2.66, 12.57	3.35, 9.43	3.32, 8.89	3.32, 9.43
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.240 (1.1904)	-0.207 (1.1852)	-0.392 (1.1044)	-0.298 (1.1469)
Median	-0.125	-0.140	-0.360	-0.230
Min, Max	-4.07, 6.20	-3.30, 4.24	-3.35, 3.33	-3.35, 4.24
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	5.573 (1.3501)	5.647 (1.2587)	5.616 (1.1545)	5.631 (1.2046)
Median	5.550	5.595	5.435	5.510
Min, Max	2.81, 9.34	3.03, 9.19	3.13, 8.72	3.03, 9.19
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.396 (1.0835)	-0.327 (1.0455)	-0.307 (1.1125)	-0.317 (1.0767)
Median	-0.350	-0.495	-0.150	-0.335
Min, Max	-3.54, 3.19	-3.07, 3.75	-4.09, 2.51	-4.09, 3.75

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Lymphocytes ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	1.704 (0.4682)	1.757 (0.4280)	1.771 (0.5034)	1.764 (0.4661)
Median	1.625	1.690	1.770	1.730
Min, Max	0.91, 3.67	1.00, 3.03	0.78, 3.23	0.78, 3.23
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	1.690 (0.4985)	1.721 (0.4444)	1.678 (0.4955)	1.700 (0.4695)
Median	1.600	1.690	1.675	1.680
Min, Max	0.79, 3.01	0.97, 3.01	0.81, 2.85	0.81, 3.01
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.010 (0.2918)	-0.042 (0.2963)	-0.081 (0.3457)	-0.061 (0.3213)
Median	-0.025	-0.090	-0.045	-0.070
Min, Max	-0.72, 0.71	-0.62, 0.85	-1.10, 1.59	-1.10, 1.59
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	1.642 (0.4778)	1.733 (0.4789)	1.767 (0.4295)	1.750 (0.4540)
Median	1.570	1.660	1.715	1.700
Min, Max	0.78, 3.48	0.97, 3.03	0.90, 2.86	0.90, 3.03
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.061 (0.2971)	-0.026 (0.3716)	-0.009 (0.3103)	-0.018 (0.3415)
Median	-0.060	-0.085	-0.020	-0.040
Min, Max	-1.00, 0.70	-1.29, 1.00	-0.79, 1.05	-1.29, 1.05

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Lymphocytes/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	29.14 (7.335)	29.93 (6.417)	30.02 (7.398)	29.98 (6.907)
Median	28.30	29.85	29.95	29.85
Min, Max	13.4, 50.0	15.9, 44.0	16.6, 46.6	15.9, 46.6
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	30.21 (7.750)	30.32 (6.355)	30.38 (7.707)	30.35 (7.035)
Median	30.05	30.00	28.65	29.70
Min, Max	9.9, 51.4	14.6, 44.6	13.0, 51.5	13.0, 51.5
Change from Baseline				
n	94	97	94	191
Mean (SD)	1.13 (5.447)	0.20 (5.529)	0.65 (6.370)	0.42 (5.946)
Median	0.50	0.20	1.40	0.80
Min, Max	-12.4, 17.6	-14.4, 13.5	-19.2, 25.5	-19.2, 25.5
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	30.04 (7.354)	31.28 (7.347)	32.05 (7.450)	31.66 (7.389)
Median	29.40	30.90	31.60	31.10
Min, Max	17.8, 48.1	13.5, 47.5	17.3, 52.0	13.5, 52.0
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.88 (5.139)	1.28 (5.730)	1.77 (6.362)	1.53 (6.043)
Median	0.20	1.05	1.15	1.05
Min, Max	-10.9, 13.6	-18.2, 13.0	-17.1, 19.9	-18.2, 19.9

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Monocytes ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.504 (0.1284)	0.497 (0.1586)	0.498 (0.1221)	0.497 (0.1412)
Median	0.480	0.470	0.490	0.480
Min, Max	0.27, 0.98	0.23, 1.10	0.25, 0.98	0.23, 1.10
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	0.482 (0.1197)	0.464 (0.1332)	0.448 (0.1053)	0.456 (0.1202)
Median	0.470	0.440	0.435	0.440
Min, Max	0.26, 0.93	0.24, 1.02	0.24, 0.76	0.24, 1.02
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.026 (0.1125)	-0.030 (0.1018)	-0.050 (0.1066)	-0.040 (0.1044)
Median	-0.030	-0.040	-0.040	-0.040
Min, Max	-0.40, 0.30	-0.27, 0.20	-0.43, 0.20	-0.43, 0.20
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	0.474 (0.1340)	0.455 (0.1415)	0.458 (0.1250)	0.456 (0.1331)
Median	0.460	0.440	0.450	0.445
Min, Max	0.21, 1.01	0.19, 1.11	0.22, 0.95	0.19, 1.11
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.030 (0.1070)	-0.041 (0.1082)	-0.035 (0.0960)	-0.038 (0.1021)
Median	-0.030	-0.040	-0.025	-0.035
Min, Max	-0.39, 0.22	-0.38, 0.26	-0.28, 0.28	-0.38, 0.28

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Monocytes/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	8.59 (1.763)	8.32 (1.936)	8.48 (1.902)	8.40 (1.916)
Median	8.30	8.20	8.40	8.40
Min, Max	4.6, 13.4	4.8, 15.9	4.4, 15.5	4.4, 15.9
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	8.62 (1.791)	8.20 (2.126)	8.18 (1.828)	8.19 (1.980)
Median	8.75	7.90	7.90	7.90
Min, Max	5.1, 13.8	3.9, 16.7	4.2, 13.2	3.9, 16.7
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.02 (1.683)	-0.10 (1.474)	-0.29 (1.685)	-0.19 (1.580)
Median	-0.10	-0.10	-0.20	-0.20
Min, Max	-5.4, 4.3	-3.7, 2.8	-4.4, 5.4	-4.4, 5.4
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	8.64 (1.836)	8.11 (1.975)	8.32 (2.212)	8.22 (2.094)
Median	8.40	7.80	8.10	7.95
Min, Max	4.5, 13.5	4.2, 16.6	3.4, 16.1	3.4, 16.6
Change from Baseline				
n	99	94	94	188
Mean (SD)	0.06 (1.598)	-0.19 (1.585)	-0.17 (1.816)	-0.18 (1.700)
Median	0.20	-0.15	-0.10	-0.10
Min, Max	-4.2, 4.3	-4.4, 4.7	-6.6, 4.9	-6.6, 4.9

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Neutrophils ($10^9/L$)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	3.569 (1.1783)	3.527 (1.0484)	3.513 (1.0389)	3.520 (1.0411)
Median	3.310	3.470	3.385	3.395
Min, Max	1.46, 8.12	1.79, 7.44	1.64, 7.17	1.64, 7.44
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	3.329 (1.1293)	3.356 (0.9998)	3.269 (1.0157)	3.313 (1.0059)
Median	3.310	3.320	3.155	3.170
Min, Max	1.32, 8.67	1.57, 6.03	1.61, 5.94	1.57, 6.03
Change from Baseline				
n	94	97	94	191
Mean (SD)	-0.231 (0.9193)	-0.151 (1.0098)	-0.264 (1.0422)	-0.207 (1.0247)
Median	-0.080	-0.160	-0.315	-0.220
Min, Max	-3.58, 2.39	-2.91, 3.52	-3.31, 3.51	-3.31, 3.52
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	3.258 (1.0814)	3.232 (1.0237)	3.174 (0.9590)	3.203 (0.9897)
Median	3.160	3.105	3.040	3.065
Min, Max	1.43, 6.61	1.57, 6.78	1.40, 6.45	1.40, 6.78
Change from Baseline				
n	99	94	94	188
Mean (SD)	-0.305 (0.9493)	-0.277 (0.9204)	-0.287 (1.0580)	-0.282 (0.9890)
Median	-0.290	-0.285	-0.230	-0.260
Min, Max	-3.46, 2.72	-2.85, 3.46	-3.88, 3.05	-3.88, 3.46

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Neutrophils/Leukocytes (%)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	58.89 (8.157)	58.28 (6.848)	58.23 (7.799)	58.25 (7.321)
Median	59.05	58.60	57.40	57.95
Min, Max	33.8, 79.6	42.7, 74.8	42.2, 75.8	42.2, 75.8
Day 29				
Absolute Result				
n	94	97	94	191
Mean (SD)	57.36 (8.566)	57.59 (7.014)	57.88 (8.533)	57.73 (7.779)
Median	57.45	57.60	57.55	57.60
Min, Max	35.0, 81.9	38.5, 74.0	30.8, 80.1	30.8, 80.1
Change from Baseline				
n	94	97	94	191
Mean (SD)	-1.50 (6.509)	-0.54 (6.679)	-0.63 (7.936)	-0.58 (7.306)
Median	-0.70	-0.90	-1.05	-0.90
Min, Max	-20.9, 12.9	-17.8, 15.2	-24.6, 23.2	-24.6, 23.2
Day 57				
Absolute Result				
n	99	94	94	188
Mean (SD)	57.65 (7.970)	56.53 (8.126)	55.78 (8.064)	56.15 (8.082)
Median	57.70	56.75	56.70	56.75
Min, Max	39.9, 73.3	38.5, 80.3	36.1, 74.0	36.1, 80.3
Change from Baseline				
n	99	94	94	188
Mean (SD)	-1.20 (6.398)	-1.66 (7.045)	-2.17 (8.079)	-1.92 (7.564)
Median	-2.10	-1.60	-1.85	-1.75
Min, Max	-14.0, 12.8	-16.7, 26.4	-22.4, 19.2	-22.4, 26.4

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

HEMATOLOGY: Platelets (10⁹/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	99	99	198
Mean (SD)	242.5 (54.70)	248.8 (52.44)	241.1 (45.85)	244.9 (49.28)
Median	240.0	247.0	239.0	240.0
Min, Max	135, 497	141, 453	148, 372	141, 453
Day 29				
Absolute Result				
n	94	96	94	190
Mean (SD)	246.1 (60.25)	250.9 (85.50)	232.1 (48.12)	241.6 (70.02)
Median	241.0	238.5	228.0	237.0
Min, Max	141, 537	93, 901	127, 379	93, 901
Change from Baseline				
n	94	95	93	188
Mean (SD)	0.9 (22.05)	4.5 (73.82)	-8.6 (31.52)	-2.0 (57.19)
Median	2.0	0.0	-6.0	-4.0
Min, Max	-72, 54	-85, 684	-131, 141	-131, 684
Day 57				
Absolute Result				
n	98	94	93	187
Mean (SD)	238.9 (51.47)	238.8 (54.07)	235.0 (52.35)	236.9 (53.11)
Median	232.0	236.0	234.0	236.0
Min, Max	134, 394	82, 443	130, 529	82, 529
Change from Baseline				
n	98	93	92	185
Mean (SD)	-3.3 (34.38)	-8.8 (26.35)	-5.3 (32.66)	-7.1 (29.63)
Median	-1.0	-7.0	-2.0	-4.0
Min, Max	-165, 102	-106, 46	-106, 196	-106, 196

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Alanine Aminotransferase (U/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	18.8 (6.46)	19.3 (10.39)	19.2 (6.89)	19.2 (8.79)
Median	18.0	17.0	17.5	17.0
Min, Max	8, 47	7, 104	7, 47	7, 104
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	18.2 (7.14)	18.0 (9.55)	18.8 (8.96)	18.4 (9.25)
Median	17.0	16.0	17.0	16.0
Min, Max	5, 55	6, 80	6, 77	6, 80
Change from Baseline				
n	96	98	94	192
Mean (SD)	-0.7 (5.85)	-1.3 (6.25)	-0.1 (7.89)	-0.7 (7.11)
Median	0.0	-1.0	-1.0	-1.0
Min, Max	-16, 31	-24, 22	-17, 61	-24, 61
Day 57				
Absolute Result				
n	100	98	97	195
Mean (SD)	18.4 (8.19)	18.1 (8.81)	19.3 (7.21)	18.7 (8.05)
Median	17.0	16.0	18.0	17.0
Min, Max	7, 80	7, 84	7, 49	7, 84
Change from Baseline				
n	100	98	97	195
Mean (SD)	-0.4 (7.47)	-1.2 (5.22)	0.2 (5.66)	-0.5 (5.48)
Median	0.0	-1.0	0.0	0.0
Min, Max	-25, 56	-20, 10	-23, 25	-23, 25

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Alkaline Phosphatase (U/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	70.8 (18.53)	72.2 (16.60)	70.6 (18.04)	71.4 (17.31)
Median	69.0	73.0	67.0	71.0
Min, Max	29, 118	38, 113	33, 112	33, 113
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	67.3 (17.34)	73.3 (44.01)	69.2 (19.22)	71.3 (34.17)
Median	65.0	69.0	65.0	67.0
Min, Max	30, 111	36, 477	33, 131	33, 477
Change from Baseline				
n	96	98	94	192
Mean (SD)	-2.9 (7.16)	1.4 (44.95)	-0.9 (9.93)	0.3 (32.80)
Median	-3.0	-2.5	-2.0	-2.0
Min, Max	-24, 23	-26, 436	-18, 70	-26, 436
Day 57				
Absolute Result				
n	100	98	98	196
Mean (SD)	68.3 (17.57)	69.1 (14.71)	69.6 (18.80)	69.4 (16.84)
Median	67.0	69.5	67.0	69.0
Min, Max	29, 106	35, 128	35, 119	35, 128
Change from Baseline				
n	100	98	98	196
Mean (SD)	-2.5 (7.26)	-3.1 (7.38)	-0.5 (7.30)	-1.8 (7.44)
Median	-2.0	-2.0	-1.0	-1.0
Min, Max	-29, 11	-26, 18	-20, 22	-26, 22

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Aspartate Aminotransferase (U/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	22.8 (6.98)	23.2 (8.13)	23.1 (6.53)	23.1 (7.36)
Median	22.0	22.0	22.0	22.0
Min, Max	13, 71	12, 86	14, 56	12, 86
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	21.8 (7.25)	21.7 (7.34)	22.1 (7.03)	21.9 (7.17)
Median	21.0	20.5	21.0	21.0
Min, Max	10, 60	12, 69	12, 61	12, 69
Change from Baseline				
n	96	98	94	192
Mean (SD)	-1.2 (5.31)	-1.5 (5.22)	-0.7 (7.07)	-1.1 (6.19)
Median	-1.5	-1.0	-1.0	-1.0
Min, Max	-13, 23	-17, 20	-18, 42	-18, 42
Day 57				
Absolute Result				
n	100	98	97	195
Mean (SD)	20.7 (6.41)	20.5 (6.79)	21.4 (5.44)	20.9 (6.15)
Median	19.0	20.0	21.0	21.0
Min, Max	12, 55	10, 65	11, 39	10, 65
Change from Baseline				
n	100	98	97	195
Mean (SD)	-2.1 (6.69)	-2.6 (4.58)	-1.6 (4.64)	-2.1 (4.63)
Median	-2.0	-2.0	-1.0	-2.0
Min, Max	-43, 30	-21, 10	-20, 10	-21, 10

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Bilirubin (umol/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	7.39 (3.221)	7.43 (3.690)	7.64 (3.858)	7.53 (3.767)
Median	6.70	6.40	6.70	6.50
Min, Max	2.7, 19.7	1.3, 19.0	1.3, 26.5	1.3, 26.5
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	6.72 (2.948)	6.92 (3.555)	6.78 (3.491)	6.85 (3.515)
Median	6.30	6.20	5.80	5.90
Min, Max	1.3, 14.4	1.3, 25.0	2.6, 21.5	1.3, 25.0
Change from Baseline				
n	96	98	94	192
Mean (SD)	-0.60 (2.593)	-0.49 (2.788)	-0.87 (2.579)	-0.68 (2.687)
Median	-0.50	-0.50	-1.10	-0.70
Min, Max	-7.0, 6.2	-8.4, 7.6	-6.0, 13.0	-8.4, 13.0
Day 57				
Absolute Result				
n	100	98	97	195
Mean (SD)	7.35 (3.824)	6.59 (3.339)	6.33 (3.187)	6.46 (3.258)
Median	6.50	6.40	5.60	6.00
Min, Max	1.3, 25.8	1.3, 22.9	1.3, 16.4	1.3, 22.9
Change from Baseline				
n	100	98	97	195
Mean (SD)	-0.03 (2.915)	-0.82 (3.078)	-1.25 (2.637)	-1.03 (2.867)
Median	-0.35	-0.40	-1.30	-0.80
Min, Max	-10.2, 16.2	-12.0, 6.5	-10.1, 4.8	-12.0, 6.5

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Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Creatinine (umol/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	65.2 (14.83)	64.1 (14.87)	64.1 (13.58)	64.1 (14.20)
Median	62.0	62.0	62.0	62.0
Min, Max	35, 106	35, 106	44, 106	35, 106
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	64.5 (14.55)	62.3 (15.51)	63.6 (13.33)	63.0 (14.46)
Median	62.0	62.0	62.0	62.0
Min, Max	35, 97	35, 106	35, 97	35, 106
Change from Baseline				
n	96	98	94	192
Mean (SD)	-0.6 (9.26)	-1.5 (10.60)	-1.1 (11.64)	-1.3 (11.10)
Median	0.0	0.0	0.0	0.0
Min, Max	-44, 17	-53, 26	-53, 27	-53, 27
Day 57				
Absolute Result				
n	100	98	98	196
Mean (SD)	63.8 (14.54)	63.0 (13.78)	61.6 (11.47)	62.3 (12.66)
Median	62.0	62.0	62.0	62.0
Min, Max	35, 97	35, 106	35, 97	35, 106
Change from Baseline				
n	100	98	98	196
Mean (SD)	-1.4 (9.73)	-1.2 (10.52)	-2.5 (10.44)	-1.9 (10.47)
Median	0.0	0.0	0.0	0.0
Min, Max	-44, 18	-53, 26	-53, 26	-53, 26

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Direct Bilirubin (umol/L)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	1.77 (0.362)	1.87 (0.576)	1.88 (0.620)	1.87 (0.597)
Median	1.70	1.70	1.70	1.70
Min, Max	1.7, 3.9	1.7, 4.4	1.7, 5.3	1.7, 5.3
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	1.72 (0.174)	1.81 (0.517)	1.83 (0.595)	1.82 (0.555)
Median	1.70	1.70	1.70	1.70
Min, Max	1.7, 3.4	1.7, 5.3	1.7, 5.8	1.7, 5.8
Change from Baseline				
n	96	98	94	192
Mean (SD)	-0.06 (0.301)	-0.06 (0.512)	-0.04 (0.536)	-0.05 (0.522)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.7, 0.0	-2.7, 2.2	-2.6, 1.9	-2.7, 2.2
Day 57				
Absolute Result				
n	100	98	97	195
Mean (SD)	1.88 (0.611)	1.82 (0.536)	1.81 (0.502)	1.82 (0.518)
Median	1.70	1.70	1.70	1.70
Min, Max	1.7, 4.8	1.7, 5.1	1.7, 5.1	1.7, 5.1
Change from Baseline				
n	100	98	97	195
Mean (SD)	0.10 (0.619)	-0.05 (0.648)	-0.05 (0.379)	-0.05 (0.530)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.7, 3.1	-2.7, 2.1	-1.9, 1.7	-2.7, 2.1

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Urea Nitrogen (mmol/L)

	mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	5.237 (1.3378)	5.329 (1.2333)	5.258 (1.1605)	5.294 (1.1950)
Median	5.350	5.350	5.175	5.350
Min, Max	2.14, 7.85	2.86, 7.85	2.50, 7.85	2.50, 7.85
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	5.459 (1.4659)	5.533 (1.5226)	5.461 (1.3510)	5.498 (1.4378)
Median	5.710	5.350	5.350	5.350
Min, Max	2.14, 10.71	2.86, 10.71	1.43, 8.57	1.43, 10.71
Change from Baseline				
n	96	98	94	192
Mean (SD)	0.234 (1.2802)	0.204 (1.3671)	0.156 (1.2623)	0.181 (1.3136)
Median	0.000	0.350	0.000	0.000
Min, Max	-3.57, 5.00	-2.86, 5.36	-2.86, 3.57	-2.86, 5.36
Day 57				
Absolute Result				
n	100	98	98	196
Mean (SD)	5.512 (1.4382)	5.486 (1.3566)	5.339 (1.3682)	5.413 (1.3609)
Median	5.350	5.710	5.350	5.350
Min, Max	2.14, 9.64	2.86, 9.28	2.50, 11.07	2.50, 11.07
Change from Baseline				
n	100	98	98	196
Mean (SD)	0.275 (1.3570)	0.168 (1.1849)	0.051 (1.2505)	0.109 (1.2165)
Median	0.000	0.000	0.000	0.000
Min, Max	-3.92, 3.93	-2.50, 3.93	-2.50, 5.36	-2.50, 5.36

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

CHEMISTRY: Urea Nitrogen/Creatinine

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	20.73 (6.558)	21.30 (5.563)	20.92 (5.339)	21.11 (5.442)
Median	20.00	21.40	20.00	21.20
Min, Max	7.5, 42.0	11.0, 38.0	10.0, 36.0	10.0, 38.0
Day 29				
Absolute Result				
n	96	98	94	192
Mean (SD)	21.75 (6.954)	22.87 (7.151)	22.25 (7.687)	22.57 (7.405)
Median	20.60	21.40	20.55	21.20
Min, Max	8.6, 50.0	8.9, 50.0	6.7, 52.5	6.7, 52.5
Change from Baseline				
n	96	98	94	192
Mean (SD)	1.05 (6.019)	1.48 (5.781)	1.36 (6.679)	1.42 (6.220)
Median	0.75	1.50	1.20	1.35
Min, Max	-16.3, 23.3	-8.6, 26.0	-13.3, 25.0	-13.3, 26.0
Day 57				
Absolute Result				
n	100	98	98	196
Mean (SD)	22.36 (7.490)	22.26 (6.403)	22.06 (6.460)	22.16 (6.416)
Median	20.00	21.70	21.30	21.40
Min, Max	10.0, 45.0	12.0, 45.0	10.0, 44.0	10.0, 45.0
Change from Baseline				
n	100	98	98	196
Mean (SD)	1.62 (6.258)	1.05 (5.615)	1.02 (5.232)	1.03 (5.413)
Median	1.70	0.60	0.45	0.50
Min, Max	-17.7, 15.8	-10.0, 20.0	-13.6, 16.0	-13.6, 20.0

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

COAGULATION: Activated Partial Thromboplastin Time (sec)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	31.92 (2.951)	32.27 (2.833)	32.16 (2.957)	32.22 (2.889)
Median	31.80	32.05	32.10	32.05
Min, Max	26.0, 40.7	24.4, 42.6	24.3, 45.5	24.3, 45.5
Day 29				
Absolute Result				
n	96	92	94	186
Mean (SD)	30.50 (3.485)	30.85 (3.575)	30.14 (3.218)	30.49 (3.409)
Median	30.20	30.45	29.80	30.00
Min, Max	24.1, 41.7	24.0, 45.4	22.4, 40.8	22.4, 45.4
Change from Baseline				
n	96	92	94	186
Mean (SD)	-1.39 (3.184)	-1.43 (3.373)	-2.09 (3.565)	-1.77 (3.477)
Median	-1.55	-1.60	-2.00	-1.70
Min, Max	-13.0, 6.8	-11.7, 7.2	-18.5, 12.0	-18.5, 12.0
Day 57				
Absolute Result				
n	92	88	85	173
Mean (SD)	30.57 (4.363)	31.18 (4.484)	31.25 (4.969)	31.21 (4.715)
Median	29.90	30.75	29.70	30.40
Min, Max	21.4, 46.9	19.2, 51.2	23.9, 49.2	19.2, 51.2
Change from Baseline				
n	92	88	85	173
Mean (SD)	-1.40 (4.428)	-1.28 (3.660)	-1.00 (4.943)	-1.14 (4.327)
Median	-1.90	-1.95	-2.00	-2.00
Min, Max	-15.2, 13.6	-11.4, 9.2	-9.6, 23.6	-11.4, 23.6

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

COAGULATION: Prothrombin Intl. Normalized Ratio

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	0.96 (0.059)	0.96 (0.063)	0.96 (0.071)	0.96 (0.067)
Median	1.00	1.00	1.00	1.00
Min, Max	0.8, 1.1	0.8, 1.1	0.8, 1.1	0.8, 1.1
Day 29				
Absolute Result				
n	96	92	94	186
Mean (SD)	0.97 (0.066)	0.97 (0.096)	0.95 (0.068)	0.96 (0.084)
Median	1.00	1.00	0.90	1.00
Min, Max	0.9, 1.2	0.8, 1.6	0.8, 1.1	0.8, 1.6
Change from Baseline				
n	96	92	94	186
Mean (SD)	0.01 (0.070)	0.01 (0.088)	-0.01 (0.073)	0.00 (0.081)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.2, 0.2	-0.2, 0.6	-0.2, 0.2	-0.2, 0.6
Day 57				
Absolute Result				
n	92	88	84	172
Mean (SD)	0.97 (0.070)	0.97 (0.067)	0.97 (0.083)	0.97 (0.075)
Median	1.00	1.00	1.00	1.00
Min, Max	0.8, 1.2	0.8, 1.1	0.8, 1.2	0.8, 1.2
Change from Baseline				
n	92	88	84	172
Mean (SD)	0.01 (0.074)	0.01 (0.072)	0.01 (0.081)	0.01 (0.076)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.2, 0.2	-0.1, 0.2	-0.2, 0.2	-0.2, 0.2

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030201.sas 19NOV2020 02:36 Database Lock Date: 05NOV2020

Table 14.3.2.1

Summary of Hematology, Chemistry and Coagulation Laboratory Tests and Change from Baseline for Subjects in Cohort 2 by Visit
Safety Set

COAGULATION: Prothrombin Time (sec)

	Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline				
n	100	100	100	200
Mean (SD)	11.13 (0.579)	11.20 (0.608)	11.17 (0.693)	11.18 (0.650)
Median	11.20	11.20	11.20	11.20
Min, Max	9.6, 12.5	9.4, 12.7	9.7, 13.0	9.4, 13.0
Day 29				
Absolute Result				
n	96	92	94	186
Mean (SD)	11.52 (0.755)	11.59 (1.175)	11.35 (0.794)	11.47 (1.005)
Median	11.50	11.50	11.30	11.45
Min, Max	10.1, 13.8	9.8, 20.2	9.8, 13.4	9.8, 20.2
Change from Baseline				
n	96	92	94	186
Mean (SD)	0.38 (0.682)	0.39 (1.065)	0.19 (0.677)	0.29 (0.894)
Median	0.30	0.30	0.20	0.20
Min, Max	-1.4, 3.0	-1.2, 8.8	-1.8, 2.2	-1.8, 8.8
Day 57				
Absolute Result				
n	92	88	84	172
Mean (SD)	11.68 (0.821)	11.75 (0.758)	11.71 (0.923)	11.73 (0.841)
Median	11.60	11.75	11.55	11.60
Min, Max	10.2, 15.0	9.9, 13.7	9.4, 14.0	9.4, 14.0
Change from Baseline				
n	92	88	84	172
Mean (SD)	0.54 (0.760)	0.55 (0.707)	0.54 (0.851)	0.54 (0.779)
Median	0.50	0.50	0.50	0.50
Min, Max	-1.4, 3.7	-0.8, 2.7	-1.7, 2.8	-1.7, 2.8

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Eosinophils ($10^9/L$), Eosinophils Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	0	1 (1.0)	0		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	94	97	94		191
Grade 1	0	1 (1.0)	0		1 (0.5)
Grade 2	1 (1.1)	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	99	94	94		188
Grade 1	0	1 (1.1)	0		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Hemoglobin (g/L), Hemoglobin Decreased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
		n (%)	n (%)	n (%)
Baseline				
n [1]	100	100	100	200
Grade 1	2 (2.0)	8 (8.0)	4 (4.0)	12 (6.0)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	94	97	94	191
Grade 1	59 (62.8)	66 (68.0)	63 (67.0)	129 (67.5)
Grade 2	3 (3.2)	5 (5.2)	3 (3.2)	8 (4.2)
Grade 3	1 (1.1)	2 (2.1)	1 (1.1)	3 (1.6)
Grade 4	0	0	0	0
Day 57				
n [1]	99	94	94	188
Grade 1	61 (61.6)	69 (73.4)	66 (70.2)	135 (71.8)
Grade 2	6 (6.1)	4 (4.3)	2 (2.1)	6 (3.2)
Grade 3	1 (1.0)	3 (3.2)	1 (1.1)	4 (2.1)
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage
Safety Set

HEMATOLOGY: Leukocytes ($10^9/L$), WBC Decreased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	1 (1.0)	0	0		0
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	94	97	94		191
Grade 1	5 (5.3)	2 (2.1)	1 (1.1)		3 (1.6)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	99	94	94		188
Grade 1	6 (6.1)	3 (3.2)	3 (3.2)		6 (3.2)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Leukocytes ($10^9/L$), WBC Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
Baseline				
n [1]	100	100	100	200
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	94	97	94	191
Grade 1	1 (1.1)	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 57				
n [1]	99	94	94	188
Grade 1	0	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Lymphocytes ($10^9/L$), Lymphocytes Decreased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	3 (3.0)	1 (1.0)	4 (4.0)		5 (2.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	94	97	94		191
Grade 1	5 (5.3)	2 (2.1)	5 (5.3)		7 (3.7)
Grade 2	0	1 (1.0)	0		1 (0.5)
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	99	94	94		188
Grade 1	8 (8.1)	1 (1.1)	2 (2.1)		3 (1.6)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Neutrophils ($10^9/L$), Neutrophils Decreased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
		n (%)	n (%)	n (%)
Baseline				
n [1]	100	100	100	200
Grade 1	5 (5.0)	5 (5.0)	3 (3.0)	8 (4.0)
Grade 2	1 (1.0)	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	94	97	94	191
Grade 1	6 (6.4)	6 (6.2)	7 (7.4)	13 (6.8)
Grade 2	4 (4.3)	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 57				
n [1]	99	94	94	188
Grade 1	12 (12.1)	9 (9.6)	5 (5.3)	14 (7.4)
Grade 2	1 (1.0)	0	1 (1.1)	1 (0.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

HEMATOLOGY: Platelets ($10^9/L$), Platelets Decreased

		mRNA-1273		
Visit	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Grade	n (%)	n (%)	n (%)	n (%)
Baseline				
n [1]	100	99	99	198
Grade 1	1 (1.0)	0	0	0
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	94	96	94	190
Grade 1	0	0	1 (1.1)	1 (0.5)
Grade 2	0	1 (1.0)	0	1 (0.5)
Grade 3	0	1 (1.0)	0	1 (0.5)
Grade 4	0	0	0	0
Day 57				
n [1]	98	94	93	187
Grade 1	1 (1.0)	2 (2.1)	1 (1.1)	3 (1.6)
Grade 2	0	0	0	0
Grade 3	0	1 (1.1)	0	1 (0.5)
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

CHEMISTRY: Alanine Aminotransferase (U/L), Alanine Aminotransferase Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	1 (1.0)	1 (1.0)	1 (1.0)		2 (1.0)
Grade 2	0	1 (1.0)	0		1 (0.5)
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	96	98	94		192
Grade 1	1 (1.0)	5 (5.1)	2 (2.1)		7 (3.6)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	100	98	97		195
Grade 1	1 (1.0)	1 (1.0)	3 (3.1)		4 (2.1)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

CHEMISTRY: Alkaline Phosphatase (U/L), Alkaline Phosphatase Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
		n (%)	n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	0	0	0		0
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	96	98	94		192
Grade 1	0	0	1 (1.1)		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	1 (1.0)	0		1 (0.5)
Grade 4	0	0	0		0
Day 57					
n [1]	100	98	98		196
Grade 1	0	1 (1.0)	0		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

CHEMISTRY: Aspartate Aminotransferase (U/L), Aspartate Aminotransferase Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	1 (1.0)	1 (1.0)	2 (2.0)		3 (1.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	96	98	94		192
Grade 1	2 (2.1)	2 (2.0)	2 (2.1)		4 (2.1)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	100	98	97		195
Grade 1	2 (2.0)	1 (1.0)	0		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

CHEMISTRY: Bilirubin (umol/L), Bilirubin Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
		n (%)	n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	0	0	1 (1.0)		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	96	98	94		192
Grade 1	0	1 (1.0)	1 (1.1)		2 (1.0)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	100	98	97		195
Grade 1	1 (1.0)	1 (1.0)	0		1 (0.5)
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

CHEMISTRY: Urea Nitrogen (mmol/L), Blood Urea Nitrogen Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273			Total (N=200) n (%)
		50 µg (N=100) n (%)	100 µg (N=100) n (%)		
Baseline					
n [1]	100	100	100		200
Grade 1	0	0	0		0
Grade 2	0	0	0		0
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 29					
n [1]	96	98	94		192
Grade 1	2 (2.1)	4 (4.1)	4 (4.3)		8 (4.2)
Grade 2	1 (1.0)	2 (2.0)	0		2 (1.0)
Grade 3	0	0	0		0
Grade 4	0	0	0		0
Day 57					
n [1]	100	98	98		196
Grade 1	5 (5.0)	3 (3.1)	1 (1.0)		4 (2.0)
Grade 2	1 (1.0)	0	2 (2.0)		2 (1.0)
Grade 3	0	0	0		0
Grade 4	0	0	0		0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

COAGULATION: Activated Partial Thromboplastin Time (sec), Activated Partial Thromboplastin Time Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
		n (%)	n (%)	n (%)
Baseline				
n [1]	100	100	100	200
Grade 1	6 (6.0)	5 (5.0)	2 (2.0)	7 (3.5)
Grade 2	0	0	1 (1.0)	1 (0.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	96	92	94	186
Grade 1	7 (7.3)	4 (4.3)	3 (3.2)	7 (3.8)
Grade 2	0	1 (1.1)	0	1 (0.5)
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 57				
n [1]	92	88	85	173
Grade 1	4 (4.3)	5 (5.7)	9 (10.6)	14 (8.1)
Grade 2	2 (2.2)	1 (1.1)	3 (3.5)	4 (2.3)
Grade 3	0	1 (1.1)	0	1 (0.6)
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.2

Summary of Abnormal Hematology, Chemistry and Coagulation Laboratory Test for Subjects in Cohort 2 by Visit and Toxicity Grades in Vaccination Stage

Safety Set

COAGULATION: Prothrombin Time (sec), Prothrombin Time Increased

Visit Grade	Placebo (N=100) n (%)	mRNA-1273		
		50 µg (N=100) n (%)	100 µg (N=100) n (%)	Total (N=200) n (%)
		n (%)	n (%)	n (%)
Baseline				
n [1]	100	100	100	200
Grade 1	0	3 (3.0)	1 (1.0)	4 (2.0)
Grade 2	0	0	0	0
Grade 3	0	0	0	0
Grade 4	0	0	0	0
Day 29				
n [1]	96	92	94	186
Grade 1	5 (5.2)	6 (6.5)	9 (9.6)	15 (8.1)
Grade 2	1 (1.0)	1 (1.1)	0	1 (0.5)
Grade 3	0	0	0	0
Grade 4	0	1 (1.1)	0	1 (0.5)
Day 57				
n [1]	92	88	84	172
Grade 1	11 (12.0)	11 (12.5)	11 (13.1)	22 (12.8)
Grade 2	1 (1.1)	0	2 (2.4)	2 (1.2)
Grade 3	0	0	0	0
Grade 4	0	0	0	0

Percentages are based on n [1].

[1] Number of subjects in the Safety Set with non-missing results at the corresponding visit.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Eosinophils ($10^9/L$) - Eosinophils Increased

		Baseline Grade						
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
	UNK	0	0	0	0	0	0	0
	Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)
	Grade 1	0	0	0	0	0	0	0
	Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)
	Grade 3	0	0	0	0	0	0	0
	Grade 4	0	0	0	0	0	0	0
	Total	0	100 (100)	0	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Hemoglobin (g/L) - Hemoglobin Decreased

		Baseline Grade						
Worst Post-Baseline Grade		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
UNK		0	0	0	0	0	0	0
Grade 0		0	19 (19.0)	1 (1.0)	0	0	0	20 (20.0)
Grade 1		0	71 (71.0)	0	0	0	0	71 (71.0)
Grade 2		0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)
Grade 3		0	2 (2.0)	0	0	0	0	2 (2.0)
Grade 4		0	0	0	0	0	0	0
Total		0	98 (98.0)	2 (2.0)	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Leukocytes (10⁹/L) - WBC Decreased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	93 (93.0)	0	0	0	0	93	(93.0)
Grade 1	0	6 (6.0)	1 (1.0)	0	0	0	7	(7.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Leukocytes (10⁹/L) - WBC Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Lymphocytes (10⁹/L) - Lymphocytes Decreased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	89 (89.0)	0	0	0	0	89 (89.0)
Grade 1	0	8 (8.0)	3 (3.0)	0	0	0	11 (11.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Neutrophils ($10^9/L$) - Neutrophils Decreased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	82 (82.0)	0	0	0	0	82 (82.0)
Grade 1	0	10 (10.0)	4 (4.0)	0	0	0	14 (14.0)
Grade 2	0	2 (2.0)	1 (1.0)	1 (1.0)	0	0	4 (4.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	94 (94.0)	5 (5.0)	1 (1.0)	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Hematology: Platelets (10⁹/L) - Platelets Decreased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Alanine Aminotransferase (U/L) - Alanine Aminotransferase Increased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Alkaline Phosphatase (U/L) - Alkaline Phosphatase Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Aspartate Aminotransferase (U/L) - Aspartate Aminotransferase Increased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	97 (97.0)	0	0	0	0	97 (97.0)
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Bilirubin (umol/L) - Bilirubin Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Creatinine (umol/L) - Creatinine Increased

		Baseline Grade						
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
UNK		0	0	0	0	0	0	0
Grade 0		0	100 (100)	0	0	0	0	100 (100)
Grade 1		0	0	0	0	0	0	0
Grade 2		0	0	0	0	0	0	0
Grade 3		0	0	0	0	0	0	0
Grade 4		0	0	0	0	0	0	0
Total		0	100 (100)	0	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Chemistry: Urea Nitrogen (mmol/L) - Blood Urea Nitrogen Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	92 (92.0)	0	0	0	0	92	(92.0)
Grade 1	0	6 (6.0)	0	0	0	0	6	(6.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Coagulation: Activated Partial Thromboplastin Time (sec) - Activated Partial Thromboplastin Time Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	3 (3.0)	0	0	0	88	(88.0)
Grade 1	0	7 (7.0)	3 (3.0)	0	0	0	10	(10.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: Placebo (N=100)

Coagulation: Prothrombin Time (sec) - Prothrombin Time Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	0	0	0	0	85 (85.0)	
Grade 1	0	13 (13.0)	0	0	0	0	13 (13.0)	
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Eosinophils (10⁹/L) - Eosinophils Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Hemoglobin (g/L) - Hemoglobin Decreased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	9 (9.0)	2 (2.0)	0	0	0	11	(11.0)
Grade 1	0	75 (75.0)	5 (5.0)	0	0	0	80	(80.0)
Grade 2	0	3 (3.0)	1 (1.0)	0	0	0	4	(4.0)
Grade 3	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Leukocytes (10⁹/L) - WBC Decreased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	95 (95.0)	0	0	0	0	95 (95.0)	
Grade 1	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Leukocytes (10⁹/L) - WBC Increased

		Baseline Grade						
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
	UNK	0	0	0	0	0	0	0
	Grade 0	0	100 (100)	0	0	0	0	100 (100)
	Grade 1	0	0	0	0	0	0	0
	Grade 2	0	0	0	0	0	0	0
	Grade 3	0	0	0	0	0	0	0
	Grade 4	0	0	0	0	0	0	0
	Total	0	100 (100)	0	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Lymphocytes (10⁹/L) - Lymphocytes Decreased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	95 (95.0)	1 (1.0)	0	0	0	96	(96.0)
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Neutrophils (10⁹/L) - Neutrophils Decreased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	3 (3.0)	0	0	0	88	(88.0)
Grade 1	0	10 (10.0)	2 (2.0)	0	0	0	12	(12.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Hematology: Platelets (10⁹/L) - Platelets Decreased

Worst Post-Baseline Grade		Baseline Grade													
		UNK n (%)		Grade 0 n (%)		Grade 1 n (%)		Grade 2 n (%)		Grade 3 n (%)		Grade 4 n (%)		Total n (%)	
UNK		0		1 (1.0)		0		0		0		0		1 (1.0)	
Grade 0		0		95 (95.0)		0		0		0		0		95 (95.0)	
Grade 1		0		2 (2.0)		0		0		0		0		2 (2.0)	
Grade 2		0		1 (1.0)		0		0		0		0		1 (1.0)	
Grade 3		1 (1.0)		0		0		0		0		0		1 (1.0)	
Grade 4		0		0		0		0		0		0		0	
Total		1 (1.0)		99 (99.0)		0		0		0		0		100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Chemistry: Alanine Aminotransferase (U/L) - Alanine Aminotransferase Increased

Worst Post-Baseline Grade	Baseline Grade						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
UNK	0	0	0	0	0	0	0
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)
Grade 1	0	4 (4.0)	0	1 (1.0)	0	0	5 (5.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	98 (98.0)	1 (1.0)	1 (1.0)	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Chemistry: Alkaline Phosphatase (U/L) - Alkaline Phosphatase Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Chemistry: Aspartate Aminotransferase (U/L) - Aspartate Aminotransferase Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Chemistry: Bilirubin (umol/L) - Bilirubin Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)
Chemistry: Creatinine (umol/L) - Creatinine Increased

		Baseline Grade						
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
UNK		0	0	0	0	0	0	0
Grade 0		0	100 (100)	0	0	0	0	100 (100)
Grade 1		0	0	0	0	0	0	0
Grade 2		0	0	0	0	0	0	0
Grade 3		0	0	0	0	0	0	0
Grade 4		0	0	0	0	0	0	0
Total		0	100 (100)	0	0	0	0	100 (100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Chemistry: Urea Nitrogen (mmol/L) - Blood Urea Nitrogen Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	0	0	0	0	0	0	
Grade 0	0	92 (92.0)	0	0	0	0	92	(92.0)
Grade 1	0	6 (6.0)	0	0	0	0	6	(6.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Coagulation: Activated Partial Thromboplastin Time (sec) - Activated Partial Thromboplastin Time Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0		0	84 (84.0)	3 (3.0)	0	0	0	87	(87.0)
Grade 1		0	9 (9.0)	0	0	0	0	9	(9.0)
Grade 2		0	0	1 (1.0)	0	0	0	1	(1.0)
Grade 3		0	0	1 (1.0)	0	0	0	1	(1.0)
Grade 4		0	0	0	0	0	0	0	
Total		0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 50 µg (N=100)

Coagulation: Prothrombin Time (sec) - Prothrombin Time Increased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0		0	81 (81.0)	1 (1.0)	0	0	0	82 (82.0)	
Grade 1		0	12 (12.0)	2 (2.0)	0	0	0	14 (14.0)	
Grade 2		0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	1 (1.0)	0	0	0	0	1 (1.0)	
Total		0	97 (97.0)	3 (3.0)	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Hematology: Eosinophils (10⁹/L) - Eosinophils Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0		0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1		0	0	0	0	0	0	0	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Hematology: Hemoglobin (g/L) - Hemoglobin Decreased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0		0	14 (14.0)	0	0	0	0	14 (14.0)	
Grade 1		0	77 (77.0)	3 (3.0)	0	0	0	80 (80.0)	
Grade 2		0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 3		0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 4		0	0	0	0	0	0	0	
Total		0	96 (96.0)	4 (4.0)	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Hematology: Leukocytes (10⁹/L) - WBC Decreased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
	Grade 1	0	4 (4.0)	0	0	0	0	4	(4.0)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Hematology: Leukocytes (10⁹/L) - WBC Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0		0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1		0	0	0	0	0	0	0	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Hematology: Lymphocytes (10⁹/L) - Lymphocytes Decreased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	92 (92.0)	1 (1.0)	0	0	0	93	(93.0)
	Grade 1	0	3 (3.0)	3 (3.0)	0	0	0	6	(6.0)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	96 (96.0)	4 (4.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Hematology: Neutrophils (10⁹/L) - Neutrophils Decreased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0		0	88 (88.0)	1 (1.0)	0	0	0	89 (89.0)	
Grade 1		0	7 (7.0)	2 (2.0)	0	0	0	9 (9.0)	
Grade 2		0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	97 (97.0)	3 (3.0)	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Hematology: Platelets (10⁹/L) - Platelets Decreased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0		0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1		1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		1 (1.0)	99 (99.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Chemistry: Alanine Aminotransferase (U/L) - Alanine Aminotransferase Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0		0	94 (94.0)	1 (1.0)	0	0	0	95	(95.0)
Grade 1		0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Chemistry: Alkaline Phosphatase (U/L) - Alkaline Phosphatase Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
	Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Chemistry: Aspartate Aminotransferase (U/L) - Aspartate Aminotransferase Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0		0	95 (95.0)	2 (2.0)	0	0	0	97	(97.0)
Grade 1		0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	98 (98.0)	2 (2.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Chemistry: Bilirubin (umol/L) - Bilirubin Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
	Grade 1	0	0	1 (1.0)	0	0	0	1	(1.0)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)
Chemistry: Creatinine (umol/L) - Creatinine Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
	Grade 1	0	0	0	0	0	0	0	
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Chemistry: Urea Nitrogen (mmol/L) - Blood Urea Nitrogen Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
	Grade 0	0	93 (93.0)	0	0	0	0	93	(93.0)
	Grade 1	0	4 (4.0)	0	0	0	0	4	(4.0)
	Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Coagulation: Activated Partial Thromboplastin Time (sec) - Activated Partial Thromboplastin Time Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0		0	80 (80.0)	2 (2.0)	0	0	0	82	(82.0)
Grade 1		0	10 (10.0)	0	1 (1.0)	0	0	11	(11.0)
Grade 2		0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 100 µg (N=100)

Coagulation: Prothrombin Time (sec) - Prothrombin Time Increased

Worst Post-Baseline Grade	Baseline Grade						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	76 (76.0)	0	0	0	0	76	(76.0)
Grade 1	0	17 (17.0)	1 (1.0)	0	0	0	18	(18.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Eosinophils (10⁹/L) - Eosinophils Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
	Grade 0	0	197 (98.5)	1 (0.5)	0	0	0	198	(99.0)
	Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Hemoglobin (g/L) - Hemoglobin Decreased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0		0	23 (11.5)	2 (1.0)	0	0	0	25 (12.5)	
Grade 1		0	152 (76.0)	8 (4.0)	0	0	0	160 (80.0)	
Grade 2		0	5 (2.5)	2 (1.0)	0	0	0	7 (3.5)	
Grade 3		0	7 (3.5)	0	0	0	0	7 (3.5)	
Grade 4		0	0	0	0	0	0	0	
Total		0	188 (94.0)	12 (6.0)	0	0	0	200 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030203.sas 19NOV2020 02:37 Database Lock Date: 05NOV2020

Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Leukocytes (10⁹/L) - WBC Decreased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	190 (95.0)	0	0	0	0	190	(95.0)
Grade 1		0	9 (4.5)	0	0	0	0	9	(4.5)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Leukocytes (10⁹/L) - WBC Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	199 (99.5)	0	0	0	0	199	(99.5)
Grade 1		0	0	0	0	0	0	0	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Lymphocytes (10⁹/L) - Lymphocytes Decreased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	187 (93.5)	2 (1.0)	0	0	0	189	(94.5)
Grade 1		0	6 (3.0)	3 (1.5)	0	0	0	9	(4.5)
Grade 2		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	195 (97.5)	5 (2.5)	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030203.sas 19NOV2020 02:37 Database Lock Date: 05NOV2020

Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Neutrophils (10⁹/L) - Neutrophils Decreased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	173 (86.5)	4 (2.0)	0	0	0	177	(88.5)
Grade 1		0	17 (8.5)	4 (2.0)	0	0	0	21	(10.5)
Grade 2		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	192 (96.0)	8 (4.0)	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Hematology: Platelets ($10^9/L$) - Platelets Decreased

Worst Post-Baseline Grade		Baseline Grade													
		UNK n (%)		Grade 0 n (%)		Grade 1 n (%)		Grade 2 n (%)		Grade 3 n (%)		Grade 4 n (%)		Total n (%)	
UNK		0		2	(1.0)	0		0		0		0		2	(1.0)
Grade 0		0		193	(96.5)	0		0		0		0		193	(96.5)
Grade 1		1	(0.5)	2	(1.0)	0		0		0		0		3	(1.5)
Grade 2		0		1	(0.5)	0		0		0		0		1	(0.5)
Grade 3		1	(0.5)	0		0		0		0		0		1	(0.5)
Grade 4		0		0		0		0		0		0		0	
Total		2	(1.0)	198	(99.0)	0		0		0		0		200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Alanine Aminotransferase (U/L) - Alanine Aminotransferase Increased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0		0	188 (94.0)	2 (1.0)	0	0	0	190 (95.0)	
Grade 1		0	8 (4.0)	0	1 (0.5)	0	0	9 (4.5)	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	197 (98.5)	2 (1.0)	1 (0.5)	0	0	200 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Alkaline Phosphatase (U/L) - Alkaline Phosphatase Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
	Grade 0	0	196 (98.0)	0	0	0	0	196	(98.0)
	Grade 1	0	2 (1.0)	0	0	0	0	2	(1.0)
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	1 (0.5)	0	0	0	0	1	(0.5)
	Grade 4	0	0	0	0	0	0	0	
	Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Aspartate Aminotransferase (U/L) - Aspartate Aminotransferase Increased

		Baseline Grade							
Worst Post-Baseline Grade		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	193 (96.5)	2 (1.0)	0	0	0	195	(97.5)
Grade 1		0	3 (1.5)	1 (0.5)	0	0	0	4	(2.0)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	197 (98.5)	3 (1.5)	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Bilirubin (umol/L) - Bilirubin Increased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0		0	197 (98.5)	0	0	0	0	197 (98.5)	
Grade 1		0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)	
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Creatinine (umol/L) - Creatinine Increased

		Baseline Grade							
Worst Grade	Post-Baseline	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
	UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
	Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)
	Grade 1	0	0	0	0	0	0	0	
	Grade 2	0	0	0	0	0	0	0	
	Grade 3	0	0	0	0	0	0	0	
	Grade 4	0	0	0	0	0	0	0	
	Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Chemistry: Urea Nitrogen (mmol/L) - Blood Urea Nitrogen Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0		0	185 (92.5)	0	0	0	0	185	(92.5)
Grade 1		0	10 (5.0)	0	0	0	0	10	(5.0)
Grade 2		0	4 (2.0)	0	0	0	0	4	(2.0)
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Coagulation: Activated Partial Thromboplastin Time (sec) - Activated Partial Thromboplastin Time Increased

		Baseline Grade							
Worst Grade	Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	6 (3.0)	0	0	0	0	6	(3.0)
Grade 0		0	164 (82.0)	5 (2.5)	0	0	0	169	(84.5)
Grade 1		0	19 (9.5)	0	1 (0.5)	0	0	20	(10.0)
Grade 2		0	3 (1.5)	1 (0.5)	0	0	0	4	(2.0)
Grade 3		0	0	1 (0.5)	0	0	0	1	(0.5)
Grade 4		0	0	0	0	0	0	0	
Total		0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200	(100)

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.2.3

Shift from Baseline to the Worst Post-Baseline Result in Hematology, Chemistry and Coagulation Lab Test Toxicity Grades for
Subjects in Cohort 2 in Vaccination Stage
Safety Set

Vaccination Group: mRNA-1273 Total (N=200)

Coagulation: Prothrombin Time (sec) - Prothrombin Time Increased

Worst Post-Baseline Grade		Baseline Grade							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
UNK		0	6 (3.0)	0	0	0	0	6 (3.0)	
Grade 0		0	157 (78.5)	1 (0.5)	0	0	0	158 (79.0)	
Grade 1		0	29 (14.5)	3 (1.5)	0	0	0	32 (16.0)	
Grade 2		0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	1 (0.5)	0	0	0	0	1 (0.5)	
Total		0	196 (98.0)	4 (2.0)	0	0	0	200 (100)	

UNK = unknown due to missing lab result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Baseline				
n	200	200	200	400
Mean (SD)	76.1 (8.27)	75.5 (7.63)	76.0 (7.62)	75.7 (7.62)
Median	76.0	76.0	76.0	76.0
Min, Max	48, 97	53, 90	53, 97	53, 97
Day 1 - 1 Hour				
Postdose				
Absolute				
Result				
n	200	200	199	399
Mean (SD)	77.2 (7.91)	77.2 (7.71)	77.3 (7.61)	77.3 (7.65)
Median	78.0	78.0	78.0	78.0
Min, Max	59, 97	49, 99	59, 97	49, 99
Change from				
Baseline				
n	200	200	199	399
Mean (SD)	1.1 (9.38)	1.8 (8.45)	1.3 (8.33)	1.5 (8.38)
Median	1.0	1.5	0.0	1.0
Min, Max	-26, 33	-37, 25	-24, 28	-37, 28

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030301.sas 19NOV2020 00:35 Database Lock Date: 05NOV2020

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 8				
Absolute				
Result				
n	196	200	198	398
Mean (SD)	76.8 (8.45)	75.1 (8.07)	75.5 (7.73)	75.3 (7.90)
Median	77.0	75.0	76.0	76.0
Min, Max	57, 99	52, 99	58, 95	52, 99
Change from				
Baseline				
n	196	200	198	398
Mean (SD)	0.8 (9.89)	-0.3 (8.14)	-0.5 (9.04)	-0.4 (8.59)
Median	1.0	-1.0	0.0	0.0
Min, Max	-27, 26	-24, 17	-25, 25	-25, 25

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 15				
Absolute				
Result				
n	196	198	200	398
Mean (SD)	76.4 (7.74)	75.6 (7.87)	75.7 (7.70)	75.7 (7.78)
Median	77.0	75.0	76.0	75.5
Min, Max	54, 101	50, 94	50, 94	50, 94
Change from				
Baseline				
n	196	198	200	398
Mean (SD)	0.3 (9.58)	0.2 (8.17)	-0.3 (9.31)	-0.1 (8.75)
Median	-0.5	1.0	-1.0	0.0
Min, Max	-21, 47	-20, 22	-23, 24	-23, 24

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 29 - Predose Absolute Result				
n	195	197	198	395
Mean (SD)	75.6 (7.53)	75.4 (8.51)	74.3 (7.67)	74.8 (8.11)
Median	76.0	76.0	75.0	76.0
Min, Max	50, 98	52, 95	54, 92	52, 95
Change from Baseline				
n	195	197	198	395
Mean (SD)	-0.4 (8.31)	0.0 (9.21)	-1.8 (8.67)	-0.9 (8.98)
Median	-1.0	0.0	-1.5	-1.0
Min, Max	-16, 26	-36, 22	-31, 26	-36, 26

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t14030301.sas 19NOV2020 00:35 Database Lock Date: 05NOV2020

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 29 - 1				
Hour Postdose				
Absolute				
Result				
n	192	195	197	392
Mean (SD)	76.9 (7.51)	77.4 (7.95)	76.0 (8.22)	76.7 (8.10)
Median	78.0	78.0	76.0	77.0
Min, Max	53, 98	57, 99	54, 98	54, 99
Change from				
Baseline				
n	192	195	197	392
Mean (SD)	0.9 (9.37)	1.9 (8.85)	0.0 (9.24)	0.9 (9.09)
Median	0.0	2.0	0.0	0.0
Min, Max	-20, 31	-23, 26	-26, 29	-26, 29

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 36				
Absolute				
Result				
n	193	195	198	393
Mean (SD)	76.2 (8.30)	75.4 (8.21)	75.3 (8.28)	75.3 (8.24)
Median	77.0	76.0	75.5	76.0
Min, Max	51, 97	55, 99	51, 103	51, 103
Change from				
Baseline				
n	193	195	198	393
Mean (SD)	0.2 (9.59)	-0.2 (8.28)	-0.9 (8.86)	-0.5 (8.57)
Median	0.0	0.0	0.0	0.0
Min, Max	-29, 31	-18, 24	-31, 31	-31, 31

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 43				
Absolute				
Result				
n	195	193	195	388
Mean (SD)	75.7 (7.58)	75.5 (8.19)	75.2 (7.86)	75.4 (8.01)
Median	75.0	76.0	76.0	76.0
Min, Max	53, 97	57, 95	53, 101	53, 101
Change from				
Baseline				
n	195	193	195	388
Mean (SD)	-0.2 (9.01)	0.0 (8.65)	-1.0 (8.32)	-0.5 (8.49)
Median	0.0	0.0	-1.0	0.0
Min, Max	-27, 28	-29, 29	-25, 31	-29, 31

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 57				
Absolute				
Result				
n	195	195	197	392
Mean (SD)	76.9 (7.92)	76.1 (8.33)	76.4 (7.61)	76.3 (7.97)
Median	78.0	77.0	77.0	77.0
Min, Max	50, 92	50, 96	58, 100	50, 100
Change from				
Baseline				
n	195	195	197	392
Mean (SD)	0.9 (9.33)	0.6 (8.82)	0.3 (8.44)	0.4 (8.63)
Median	0.0	1.0	1.0	1.0
Min, Max	-25, 26	-23, 23	-26, 20	-26, 23

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline								
n	100	100	100	200	100	100	100	200
Mean (SD)	75.3 (8.37)	74.6 (7.67)	75.3 (6.98)	75.0 (7.32)	76.9 (8.14)	76.3 (7.54)	76.8 (8.17)	76.5 (7.85)
Median	76.0	75.0	76.0	76.0	77.5	77.0	78.0	78.0
Min, Max	53, 97	55, 90	53, 92	53, 92	48, 91	53, 90	59, 97	53, 97
Day 1 - 1 Hour								
Postdose								
Absolute								
Result								
n	100	100	99	199	100	100	100	200
Mean (SD)	76.9 (8.26)	77.3 (7.65)	76.3 (7.48)	76.8 (7.56)	77.4 (7.58)	77.1 (7.81)	78.4 (7.63)	77.8 (7.73)
Median	76.5	78.0	76.0	77.0	78.0	78.0	79.5	78.0
Min, Max	59, 97	49, 94	59, 93	49, 94	60, 94	51, 99	60, 97	51, 99
Change from								
Baseline								
n	100	100	99	199	100	100	100	200
Mean (SD)	1.6 (8.90)	2.7 (7.59)	1.0 (8.53)	1.8 (8.09)	0.6 (9.85)	0.9 (9.18)	1.6 (8.16)	1.2 (8.67)
Median	1.0	2.0	0.0	1.0	1.0	1.0	2.0	1.0
Min, Max	-26, 23	-20, 19	-24, 28	-24, 28	-26, 33	-37, 25	-18, 21	-37, 25

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 8								
Absolute								
Result								
n	97	100	99	199	99	100	99	199
Mean (SD)	77.2 (8.81)	74.7 (7.95)	74.6 (7.80)	74.6 (7.85)	76.5 (8.10)	75.6 (8.21)	76.5 (7.58)	76.0 (7.90)
Median	78.0	74.0	75.0	74.0	76.0	75.0	78.0	76.0
Min, Max	57, 99	60, 94	58, 95	58, 95	60, 94	52, 99	60, 93	52, 99
Change from								
Baseline								
n	97	100	99	199	99	100	99	199
Mean (SD)	2.0 (8.75)	0.0 (7.98)	-0.7 (8.61)	-0.3 (8.29)	-0.3 (10.81)	-0.7 (8.32)	-0.3 (9.49)	-0.5 (8.90)
Median	2.0	-0.5	0.0	0.0	0.0	-1.5	0.0	-1.0
Min, Max	-18, 22	-24, 17	-25, 24	-25, 24	-27, 26	-24, 17	-22, 25	-24, 25

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 15								
Absolute								
Result								
n	97	99	100	199	99	99	100	199
Mean (SD)	76.4 (7.96)	75.8 (8.47)	74.6 (8.00)	75.2 (8.24)	76.3 (7.55)	75.4 (7.26)	76.8 (7.25)	76.1 (7.27)
Median	78.0	75.0	74.5	75.0	76.0	75.0	77.0	77.0
Min, Max	55, 95	50, 94	50, 89	50, 94	54, 101	60, 90	57, 94	57, 94
Change from								
Baseline								
n	97	99	100	199	99	99	100	199
Mean (SD)	1.1 (8.07)	1.2 (8.11)	-0.7 (9.68)	0.2 (8.96)	-0.4 (10.84)	-0.8 (8.14)	0.0 (8.96)	-0.4 (8.55)
Median	0.0	1.0	0.0	0.0	-2.0	0.0	-1.0	0.0
Min, Max	-21, 20	-18, 22	-23, 24	-23, 24	-21, 47	-20, 18	-18, 21	-20, 21

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 -								
Predose								
Absolute								
Result								
n	95	98	100	198	100	99	98	197
Mean (SD)	75.2 (7.91)	75.8 (8.56)	73.9 (7.58)	74.9 (8.12)	75.9 (7.18)	75.0 (8.47)	74.6 (7.79)	74.8 (8.12)
Median	75.0	76.5	74.5	76.0	76.0	75.0	75.5	75.0
Min, Max	52, 98	53, 95	54, 88	53, 95	50, 92	52, 94	59, 92	52, 94
Change from								
Baseline								
n	95	98	100	198	100	99	98	197
Mean (SD)	0.2 (7.65)	1.3 (8.55)	-1.3 (8.19)	0.0 (8.46)	-1.0 (8.90)	-1.2 (9.69)	-2.3 (9.15)	-1.8 (9.42)
Median	0.0	2.0	-1.5	0.0	-2.5	-2.0	-1.5	-2.0
Min, Max	-16, 14	-18, 22	-28, 26	-28, 26	-16, 26	-36, 22	-31, 15	-36, 22

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 - 1								
Hour Postdose								
Absolute								
Result								
n	93	97	99	196	99	98	98	196
Mean (SD)	76.8 (7.20)	77.8 (8.43)	75.0 (8.51)	76.4 (8.57)	77.1 (7.82)	77.0 (7.46)	77.1 (7.82)	77.0 (7.62)
Median	77.0	78.0	75.0	77.0	78.0	78.0	77.5	78.0
Min, Max	60, 96	57, 99	54, 98	54, 99	53, 98	58, 94	56, 97	56, 97
Change from								
Baseline								
n	93	97	99	196	99	98	98	196
Mean (SD)	1.8 (8.52)	3.2 (8.79)	-0.3 (9.47)	1.5 (9.29)	0.2 (10.09)	0.7 (8.76)	0.2 (9.04)	0.4 (8.88)
Median	2.0	4.0	-1.0	1.0	0.0	0.0	0.5	0.0
Min, Max	-19, 24	-20, 26	-26, 29	-26, 29	-20, 31	-23, 24	-21, 23	-23, 24

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 36								
Absolute								
Result								
n	93	96	100	196	100	99	98	197
Mean (SD)	75.8 (8.56)	74.9 (8.81)	74.3 (8.76)	74.6 (8.77)	76.5 (8.09)	75.8 (7.61)	76.4 (7.66)	76.1 (7.62)
Median	77.0	75.0	74.0	75.0	76.0	76.0	76.0	76.0
Min, Max	54, 96	58, 99	51, 103	51, 103	51, 97	55, 90	58, 95	55, 95
Change from								
Baseline								
n	93	96	100	196	100	99	98	197
Mean (SD)	0.9 (8.78)	0.1 (8.47)	-1.0 (8.52)	-0.5 (8.49)	-0.3 (10.30)	-0.5 (8.12)	-0.7 (9.23)	-0.6 (8.67)
Median	0.0	2.0	-0.5	1.0	-0.5	-1.0	0.0	-1.0
Min, Max	-22, 20	-18, 24	-28, 16	-28, 24	-29, 31	-17, 22	-31, 31	-31, 31

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 43								
Absolute								
Result								
n	95	95	99	194	100	98	96	194
Mean (SD)	75.9 (7.98)	75.2 (8.57)	74.3 (8.45)	74.8 (8.50)	75.6 (7.22)	75.8 (7.83)	76.2 (7.12)	76.0 (7.47)
Median	75.0	74.0	74.0	74.0	75.5	76.0	76.0	76.0
Min, Max	57, 92	59, 95	53, 101	53, 101	53, 97	57, 94	55, 91	55, 94
Change from								
Baseline								
n	95	95	99	194	100	98	96	194
Mean (SD)	0.9 (8.36)	0.6 (8.51)	-1.0 (8.83)	-0.2 (8.69)	-1.3 (9.52)	-0.6 (8.79)	-1.1 (7.81)	-0.8 (8.30)
Median	2.0	2.0	-3.0	0.0	-4.0	0.0	0.0	0.0
Min, Max	-27, 20	-22, 22	-25, 31	-25, 31	-20, 28	-29, 29	-20, 18	-29, 29

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 57								
Absolute								
Result								
n	95	96	98	194	100	99	99	198
Mean (SD)	76.3 (8.51)	75.9 (8.01)	75.7 (8.01)	75.8 (7.99)	77.4 (7.32)	76.3 (8.67)	77.2 (7.15)	76.7 (7.94)
Median	77.0	75.0	76.0	76.0	78.5	77.0	78.0	77.5
Min, Max	50, 92	53, 92	58, 100	53, 100	61, 89	50, 96	58, 93	50, 96
Change from								
Baseline								
n	95	96	98	194	100	99	99	198
Mean (SD)	1.2 (8.80)	1.3 (8.66)	0.3 (8.23)	0.8 (8.44)	0.6 (9.83)	0.0 (8.97)	0.2 (8.70)	0.1 (8.82)
Median	0.0	2.0	1.0	1.0	-0.5	0.0	1.0	1.0
Min, Max	-20, 22	-18, 20	-18, 20	-18, 20	-25, 26	-23, 23	-26, 18	-26, 23

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Baseline				
n	200	200	200	400
Mean (SD)	69.8 (10.10)	72.0 (9.91)	70.6 (10.04)	71.3 (9.99)
Median	68.0	71.0	70.0	71.0
Min, Max	42, 97	47, 100	52, 102	47, 102
Day 1 - 1 Hour				
Postdose				
Absolute				
Result				
n	200	200	199	399
Mean (SD)	64.6 (9.77)	65.2 (9.34)	65.8 (9.30)	65.5 (9.32)
Median	64.0	65.0	65.0	65.0
Min, Max	42, 102	41, 93	47, 94	41, 94
Change from				
Baseline				
n	200	200	199	399
Mean (SD)	-5.1 (9.51)	-6.8 (8.32)	-4.8 (9.47)	-5.8 (8.95)
Median	-6.0	-6.5	-6.0	-6.0
Min, Max	-28, 33	-39, 12	-29, 27	-39, 27

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 8				
Absolute				
Result				
n	196	199	198	397
Mean (SD)	69.3 (10.49)	70.3 (9.67)	70.4 (9.54)	70.4 (9.60)
Median	70.0	70.0	70.0	70.0
Min, Max	35, 98	42, 101	45, 98	42, 101
Change from				
Baseline				
n	196	199	198	397
Mean (SD)	-0.5 (9.42)	-1.8 (9.27)	-0.2 (9.46)	-1.0 (9.39)
Median	-1.0	-1.0	0.0	-1.0
Min, Max	-30, 33	-31, 27	-24, 42	-31, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 15				
Absolute				
Result				
n	196	198	200	398
Mean (SD)	68.8 (10.33)	70.8 (10.05)	70.1 (9.59)	70.4 (9.82)
Median	68.0	71.0	70.0	70.0
Min, Max	32, 102	44, 104	47, 97	44, 104
Change from				
Baseline				
n	196	198	200	398
Mean (SD)	-1.0 (9.51)	-1.2 (10.21)	-0.5 (10.71)	-0.9 (10.46)
Median	-1.5	-2.0	-1.0	-1.0
Min, Max	-29, 34	-41, 37	-34, 29	-41, 37

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 29 -				
Predose				
Absolute				
Result				
n	195	197	198	395
Mean (SD)	68.7 (10.32)	70.3 (10.26)	70.2 (9.26)	70.2 (9.76)
Median	68.0	69.0	69.0	69.0
Min, Max	37, 99	49, 99	48, 100	48, 100
Change from				
Baseline				
n	195	197	198	395
Mean (SD)	-1.0 (10.52)	-1.6 (9.57)	-0.4 (10.20)	-1.0 (9.90)
Median	-1.0	-2.0	0.0	-1.0
Min, Max	-37, 35	-31, 19	-32, 28	-32, 28

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 29 - 1 Hour Postdose Absolute Result				
n	192	195	197	392
Mean (SD)	64.9 (10.18)	65.1 (8.98)	64.8 (8.73)	65.0 (8.84)
Median	64.0	64.0	64.0	64.0
Min, Max	32, 100	44, 93	40, 93	40, 93
Change from Baseline				
n	192	195	197	392
Mean (SD)	-4.6 (10.26)	-6.6 (10.27)	-5.8 (10.76)	-6.2 (10.52)
Median	-4.5	-7.0	-6.0	-6.0
Min, Max	-29, 26	-41, 42	-37, 25	-41, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 36				
Absolute				
Result				
n	193	195	198	393
Mean (SD)	69.2 (10.39)	70.8 (9.60)	70.3 (9.77)	70.5 (9.68)
Median	68.0	70.0	69.0	70.0
Min, Max	42, 112	48, 101	49, 105	48, 105
Change from				
Baseline				
n	193	195	198	393
Mean (SD)	-0.5 (9.49)	-1.0 (10.08)	-0.4 (10.46)	-0.7 (10.27)
Median	-1.0	-1.0	-1.0	-1.0
Min, Max	-27, 24	-30, 44	-31, 44	-31, 44

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 43				
Absolute				
Result				
n	195	193	194	387
Mean (SD)	69.1 (10.34)	70.7 (9.82)	70.9 (10.04)	70.8 (9.92)
Median	69.0	70.0	69.0	70.0
Min, Max	36, 99	48, 107	48, 100	48, 107
Change from				
Baseline				
n	195	193	194	387
Mean (SD)	-0.5 (11.02)	-1.0 (9.61)	0.2 (10.85)	-0.4 (10.25)
Median	-2.0	-1.0	0.0	0.0
Min, Max	-37, 29	-24, 23	-30, 33	-30, 33

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 57				
Absolute				
Result				
n	195	195	197	392
Mean (SD)	69.3 (10.43)	71.0 (9.72)	69.7 (10.06)	70.3 (9.90)
Median	69.0	71.0	69.0	70.0
Min, Max	41, 99	45, 100	47, 99	45, 100
Change from				
Baseline				
n	195	195	197	392
Mean (SD)	-0.3 (9.63)	-0.7 (10.43)	-0.9 (11.00)	-0.8 (10.71)
Median	0.0	-1.0	-2.0	-1.0
Min, Max	-31, 25	-37, 31	-27, 32	-37, 32

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline								
n	100	100	100	200	100	100	100	200
Mean (SD)	69.3 (10.95)	73.1 (10.53)	71.1 (9.45)	72.1 (10.03)	70.2 (9.19)	70.9 (9.17)	70.1 (10.61)	70.5 (9.90)
Median	68.0	72.0	71.0	72.0	68.5	68.0	69.0	68.5
Min, Max	42, 94	47, 100	52, 102	47, 102	51, 97	50, 94	52, 95	50, 95
Day 1 - 1 Hour								
Postdose								
Absolute								
Result								
n	100	100	99	199	100	100	100	200
Mean (SD)	65.0 (10.30)	66.3 (10.26)	66.4 (8.83)	66.4 (9.55)	64.2 (9.24)	64.0 (8.22)	65.2 (9.75)	64.6 (9.02)
Median	65.0	65.0	65.0	65.0	64.0	64.5	64.0	64.0
Min, Max	42, 102	41, 93	48, 88	41, 93	42, 91	44, 85	47, 94	44, 94
Change from								
Baseline								
n	100	100	99	199	100	100	100	200
Mean (SD)	-4.2 (10.71)	-6.8 (9.38)	-4.8 (8.97)	-5.8 (9.20)	-6.0 (8.09)	-6.9 (7.15)	-4.8 (9.98)	-5.9 (8.72)
Median	-6.5	-7.0	-4.0	-6.0	-6.0	-6.0	-6.0	-6.0
Min, Max	-27, 33	-39, 12	-25, 19	-39, 19	-28, 16	-29, 6	-29, 27	-29, 27

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 8								
Absolute								
Result								
n	97	99	99	198	99	100	99	199
Mean (SD)	69.0 (11.55)	70.9 (10.47)	71.2 (10.21)	71.1 (10.31)	69.5 (9.40)	69.7 (8.82)	69.7 (8.81)	69.7 (8.79)
Median	71.0	70.0	71.0	71.0	70.0	69.0	69.0	69.0
Min, Max	35, 98	42, 101	45, 97	42, 101	50, 88	50, 90	48, 98	48, 98
Change from								
Baseline								
n	97	99	99	198	99	100	99	199
Mean (SD)	-0.3 (9.95)	-2.3 (10.00)	0.1 (9.08)	-1.1 (9.60)	-0.7 (8.91)	-1.3 (8.51)	-0.5 (9.86)	-0.9 (9.19)
Median	0.0	-1.0	0.0	-0.5	-1.0	-0.5	-1.0	-1.0
Min, Max	-30, 33	-31, 27	-24, 35	-31, 35	-28, 31	-29, 15	-20, 42	-29, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 15								
Absolute								
Result								
n	97	99	100	199	99	99	100	199
Mean (SD)	68.4 (11.79)	72.7 (10.89)	70.4 (10.10)	71.5 (10.54)	69.1 (8.71)	68.9 (8.79)	69.8 (9.10)	69.4 (8.94)
Median	67.0	73.0	69.0	72.0	68.0	68.0	70.0	69.0
Min, Max	32, 102	44, 104	47, 97	44, 104	48, 100	52, 101	48, 95	48, 101
Change from								
Baseline								
n	97	99	100	199	99	99	100	199
Mean (SD)	-1.0 (9.98)	-0.4 (11.29)	-0.8 (10.55)	-0.6 (10.89)	-1.1 (9.09)	-2.0 (8.99)	-0.3 (10.92)	-1.2 (10.02)
Median	-2.0	-1.0	-1.0	-1.0	-1.0	-2.0	0.0	-1.0
Min, Max	-29, 34	-41, 27	-25, 27	-41, 27	-29, 32	-20, 37	-34, 29	-34, 37

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 -								
Predose								
Absolute								
Result								
n	95	98	100	198	100	99	98	197
Mean (SD)	69.1 (11.42)	71.6 (11.39)	70.6 (9.11)	71.1 (10.29)	68.2 (9.19)	69.0 (8.87)	69.8 (9.44)	69.4 (9.14)
Median	68.0	72.0	70.0	71.0	68.0	68.0	68.0	68.0
Min, Max	37, 99	49, 95	52, 96	49, 96	49, 90	53, 99	48, 100	48, 100
Change from								
Baseline								
n	95	98	100	198	100	99	98	197
Mean (SD)	0.2 (10.72)	-1.2 (9.72)	-0.5 (9.43)	-0.8 (9.55)	-2.1 (10.26)	-2.0 (9.45)	-0.3 (10.99)	-1.2 (10.25)
Median	-1.0	-1.5	0.0	-1.0	-0.5	-2.0	0.0	-1.0
Min, Max	-25, 35	-31, 19	-21, 27	-31, 27	-37, 18	-30, 18	-32, 28	-32, 28

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 - 1								
Hour Postdose								
Absolute								
Result								
n	93	97	99	196	99	98	98	196
Mean (SD)	65.0 (10.95)	65.0 (9.21)	64.8 (9.13)	64.9 (9.15)	64.9 (9.46)	65.2 (8.79)	64.8 (8.35)	65.0 (8.55)
Median	65.0	64.0	64.0	64.0	64.0	64.0	63.5	64.0
Min, Max	32, 100	44, 89	40, 89	40, 89	49, 88	50, 93	50, 93	50, 93
Change from								
Baseline								
n	93	97	99	196	99	98	98	196
Mean (SD)	-4.0 (10.00)	-7.6 (10.61)	-6.3 (10.18)	-6.9 (10.39)	-5.2 (10.51)	-5.7 (9.90)	-5.4 (11.36)	-5.5 (10.63)
Median	-4.0	-7.0	-7.0	-7.0	-6.0	-5.0	-4.0	-5.0
Min, Max	-29, 26	-41, 42	-32, 25	-41, 42	-29, 19	-34, 26	-37, 24	-37, 26

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 36								
Absolute								
Result								
n	93	96	100	196	100	99	98	197
Mean (SD)	68.7 (11.16)	71.5 (10.85)	71.1 (10.46)	71.3 (10.63)	69.6 (9.65)	70.1 (8.21)	69.4 (8.99)	69.8 (8.59)
Median	68.0	70.0	70.0	70.0	68.0	69.0	68.0	69.0
Min, Max	42, 92	48, 101	49, 105	48, 105	49, 112	53, 90	50, 91	50, 91
Change from								
Baseline								
n	93	96	100	196	100	99	98	197
Mean (SD)	-0.3 (10.15)	-1.3 (11.42)	-0.1 (10.31)	-0.7 (10.86)	-0.7 (8.87)	-0.8 (8.64)	-0.7 (10.66)	-0.7 (9.67)
Median	0.0	-1.0	-1.0	-1.0	-1.0	0.0	-1.5	-1.0
Min, Max	-24, 24	-30, 44	-27, 44	-30, 44	-27, 20	-24, 19	-31, 32	-31, 32

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 43								
Absolute								
Result								
n	95	95	99	194	100	98	95	193
Mean (SD)	69.5 (11.54)	72.2 (10.84)	71.4 (10.50)	71.8 (10.65)	68.8 (9.11)	69.1 (8.50)	70.3 (9.55)	69.7 (9.03)
Median	71.0	72.0	70.0	71.0	68.0	69.0	68.0	69.0
Min, Max	36, 99	48, 107	48, 99	48, 107	45, 94	51, 93	52, 100	51, 100
Change from								
Baseline								
n	95	95	99	194	100	98	95	193
Mean (SD)	0.5 (10.87)	-0.3 (10.44)	0.4 (10.73)	0.0 (10.57)	-1.5 (11.13)	-1.6 (8.74)	0.1 (11.03)	-0.8 (9.94)
Median	0.0	0.0	0.0	0.0	-2.0	-2.0	1.0	-1.0
Min, Max	-37, 29	-22, 23	-20, 32	-22, 32	-37, 26	-24, 16	-30, 33	-30, 33

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 57								
Absolute								
Result								
n	95	96	98	194	100	99	99	198
Mean (SD)	68.9 (10.97)	72.3 (9.78)	69.9 (9.60)	71.1 (9.74)	69.7 (9.93)	69.7 (9.52)	69.5 (10.54)	69.6 (10.02)
Median	69.0	72.5	69.0	71.0	68.0	69.0	68.0	69.0
Min, Max	41, 93	45, 96	47, 98	45, 98	47, 99	49, 100	49, 99	49, 100
Change from								
Baseline								
n	95	96	98	194	100	99	99	198
Mean (SD)	0.1 (9.89)	-0.3 (10.78)	-1.2 (10.66)	-0.7 (10.70)	-0.6 (9.43)	-1.1 (10.12)	-0.7 (11.38)	-0.9 (10.74)
Median	0.0	-1.0	-2.0	-1.5	0.0	-1.0	-2.0	-1.0
Min, Max	-31, 23	-37, 28	-23, 26	-37, 28	-25, 25	-24, 31	-27, 32	-27, 32

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Baseline				
n	200	200	200	400
Mean (SD)	15.1 (1.62)	14.9 (1.56)	15.0 (1.74)	15.0 (1.65)
Median	15.0	15.0	15.0	15.0
Min, Max	10, 19	12, 21	10, 19	10, 21
Day 1 - 1 Hour				
Postdose				
Absolute				
Result				
n	200	200	199	399
Mean (SD)	14.9 (1.52)	14.8 (1.37)	15.0 (1.57)	14.9 (1.48)
Median	15.0	15.0	15.0	15.0
Min, Max	10, 18	12, 18	12, 20	12, 20
Change from				
Baseline				
n	200	200	199	399
Mean (SD)	-0.1 (1.41)	-0.1 (1.42)	0.0 (1.45)	0.0 (1.43)
Median	0.0	0.0	0.0	0.0
Min, Max	-6, 4	-4, 4	-4, 4	-4, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 8				
Absolute				
Result				
n	196	199	198	397
Mean (SD)	14.6 (1.73)	14.5 (1.62)	14.9 (1.52)	14.7 (1.58)
Median	14.0	14.0	15.0	14.0
Min, Max	10, 20	10, 20	12, 20	10, 20
Change from				
Baseline				
n	196	199	198	397
Mean (SD)	-0.5 (1.93)	-0.4 (1.92)	-0.1 (1.67)	-0.3 (1.80)
Median	0.0	0.0	0.0	0.0
Min, Max	-8, 4	-7, 4	-6, 4	-7, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 15				
Absolute				
Result				
n	196	198	200	398
Mean (SD)	14.9 (1.57)	14.8 (1.55)	14.9 (1.61)	14.8 (1.58)
Median	15.0	15.0	15.0	15.0
Min, Max	12, 20	12, 19	10, 20	10, 20
Change from				
Baseline				
n	196	198	200	398
Mean (SD)	-0.1 (1.59)	-0.2 (1.67)	-0.1 (1.81)	-0.1 (1.74)
Median	0.0	0.0	0.0	0.0
Min, Max	-4, 4	-5, 4	-6, 5	-6, 5

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 29 -				
Predose				
Absolute				
Result				
n	195	197	198	395
Mean (SD)	15.0 (1.55)	14.9 (1.57)	15.0 (1.59)	14.9 (1.57)
Median	15.0	15.0	15.0	15.0
Min, Max	12, 19	12, 20	12, 20	12, 20
Change from				
Baseline				
n	195	197	198	395
Mean (SD)	0.0 (1.79)	0.0 (1.73)	0.0 (1.55)	0.0 (1.64)
Median	0.0	0.0	0.0	0.0
Min, Max	-5, 6	-4, 8	-4, 4	-4, 8

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 29 - 1				
Hour Postdose				
Absolute				
Result				
n	192	195	197	392
Mean (SD)	14.7 (1.54)	14.8 (1.38)	14.7 (1.56)	14.7 (1.47)
Median	14.0	15.0	15.0	15.0
Min, Max	12, 18	12, 18	12, 18	12, 18
Change from				
Baseline				
n	192	195	197	392
Mean (SD)	-0.4 (1.74)	-0.1 (1.76)	-0.3 (1.82)	-0.2 (1.79)
Median	0.0	0.0	0.0	0.0
Min, Max	-6, 4	-6, 6	-7, 4	-7, 6

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 36				
Absolute				
Result				
n	193	195	198	393
Mean (SD)	14.7 (1.70)	14.7 (1.39)	14.9 (1.55)	14.8 (1.48)
Median	15.0	14.0	15.0	14.0
Min, Max	10, 20	12, 20	12, 20	12, 20
Change from				
Baseline				
n	193	195	198	393
Mean (SD)	-0.3 (2.06)	-0.2 (1.85)	-0.2 (1.96)	-0.2 (1.90)
Median	0.0	0.0	0.0	0.0
Min, Max	-7, 6	-6, 6	-7, 4	-7, 6

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 43				
Absolute				
Result				
n	195	193	195	388
Mean (SD)	14.9 (1.53)	14.8 (1.54)	14.8 (1.48)	14.8 (1.51)
Median	15.0	15.0	15.0	15.0
Min, Max	12, 18	10, 20	12, 18	10, 20
Change from				
Baseline				
n	195	193	195	388
Mean (SD)	-0.2 (1.97)	-0.1 (1.76)	-0.2 (1.85)	-0.2 (1.81)
Median	0.0	0.0	0.0	0.0
Min, Max	-7, 6	-7, 4	-7, 4	-7, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 57				
Absolute				
Result				
n	195	195	197	392
Mean (SD)	14.8 (1.68)	14.6 (1.44)	14.7 (1.58)	14.7 (1.51)
Median	15.0	14.0	14.0	14.0
Min, Max	12, 22	12, 18	12, 19	12, 19
Change from				
Baseline				
n	195	195	197	392
Mean (SD)	-0.3 (2.03)	-0.3 (1.74)	-0.4 (1.84)	-0.3 (1.79)
Median	0.0	0.0	0.0	0.0
Min, Max	-6, 8	-7, 4	-6, 5	-7, 5

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline								
n	100	100	100	200	100	100	100	200
Mean (SD)	14.8 (1.56)	14.8 (1.44)	15.1 (1.70)	14.9 (1.58)	15.4 (1.64)	15.0 (1.68)	15.0 (1.78)	15.0 (1.72)
Median	15.0	15.0	15.0	15.0	16.0	15.0	15.0	15.0
Min, Max	10, 18	12, 19	10, 19	10, 19	10, 19	12, 21	11, 19	11, 21
Day 1 - 1 Hour								
Postdose								
Absolute								
Result								
n	100	100	99	199	100	100	100	200
Mean (SD)	14.8 (1.50)	14.7 (1.26)	15.0 (1.47)	14.9 (1.38)	15.1 (1.54)	14.9 (1.47)	15.1 (1.67)	15.0 (1.57)
Median	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
Min, Max	10, 18	12, 17	12, 18	12, 18	12, 18	12, 18	12, 20	12, 20
Change from								
Baseline								
n	100	100	99	199	100	100	100	200
Mean (SD)	0.0 (1.26)	-0.1 (1.24)	-0.1 (1.51)	-0.1 (1.38)	-0.3 (1.54)	-0.1 (1.59)	0.1 (1.38)	0.0 (1.49)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-3, 4	-3, 4	-4, 4	-4, 4	-6, 4	-4, 4	-4, 4	-4, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 8								
Absolute								
Result								
n	97	99	99	198	99	100	99	199
Mean (SD)	14.6 (1.70)	14.4 (1.65)	14.8 (1.50)	14.6 (1.59)	14.6 (1.76)	14.6 (1.59)	15.0 (1.54)	14.8 (1.58)
Median	15.0	14.0	15.0	14.0	14.0	14.0	15.0	15.0
Min, Max	10, 19	12, 18	12, 20	12, 20	10, 20	10, 20	12, 18	10, 20
Change from								
Baseline								
n	97	99	99	198	99	100	99	199
Mean (SD)	-0.2 (1.69)	-0.3 (1.60)	-0.2 (1.68)	-0.3 (1.64)	-0.7 (2.12)	-0.5 (2.20)	0.0 (1.66)	-0.2 (1.96)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 4	-4, 4	-6, 4	-6, 4	-8, 4	-7, 4	-5, 4	-7, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 15								
Absolute								
Result								
n	97	99	100	199	99	99	100	199
Mean (SD)	14.8 (1.52)	14.5 (1.61)	14.7 (1.58)	14.6 (1.59)	15.1 (1.62)	15.0 (1.45)	15.1 (1.61)	15.1 (1.53)
Median	15.0	14.0	15.0	15.0	15.0	15.0	15.0	15.0
Min, Max	12, 18	12, 17	12, 18	12, 18	12, 20	12, 19	10, 20	10, 20
Change from								
Baseline								
n	97	99	100	199	99	99	100	199
Mean (SD)	0.0 (1.53)	-0.3 (1.66)	-0.4 (1.80)	-0.3 (1.73)	-0.3 (1.65)	0.0 (1.68)	0.1 (1.80)	0.0 (1.74)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-3, 4	-4, 4	-6, 5	-6, 5	-4, 4	-5, 4	-5, 4	-5, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 -								
Predose								
Absolute								
Result								
n	95	98	100	198	100	99	98	197
Mean (SD)	15.0 (1.50)	14.9 (1.45)	15.1 (1.60)	15.0 (1.52)	15.1 (1.59)	14.8 (1.68)	14.9 (1.58)	14.9 (1.63)
Median	15.0	15.0	15.0	15.0	15.5	14.0	14.0	14.0
Min, Max	12, 19	12, 20	12, 20	12, 20	12, 18	12, 20	12, 18	12, 20
Change from								
Baseline								
n	95	98	100	198	100	99	98	197
Mean (SD)	0.2 (1.88)	0.2 (1.52)	0.0 (1.50)	0.1 (1.51)	-0.3 (1.67)	-0.2 (1.89)	-0.1 (1.60)	-0.2 (1.75)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 6	-4, 5	-4, 4	-4, 5	-5, 4	-4, 8	-4, 4	-4, 8

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 - 1								
Hour Postdose								
Absolute								
Result								
n	93	97	99	196	99	98	98	196
Mean (SD)	14.5 (1.56)	14.6 (1.46)	14.7 (1.52)	14.7 (1.49)	14.9 (1.49)	14.9 (1.29)	14.7 (1.60)	14.8 (1.45)
Median	14.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
Min, Max	12, 18	12, 18	12, 18	12, 18	12, 18	12, 18	12, 18	12, 18
Change from								
Baseline								
n	93	97	99	196	99	98	98	196
Mean (SD)	-0.3 (1.71)	-0.1 (1.84)	-0.4 (1.94)	-0.3 (1.89)	-0.4 (1.78)	-0.1 (1.69)	-0.3 (1.69)	-0.2 (1.69)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 4	-6, 6	-7, 4	-7, 6	-6, 4	-4, 4	-5, 4	-5, 4

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 36								
Absolute								
Result								
n	93	96	100	196	100	99	98	197
Mean (SD)	14.8 (1.70)	14.8 (1.41)	15.0 (1.52)	14.9 (1.47)	14.7 (1.72)	14.5 (1.37)	14.7 (1.58)	14.6 (1.48)
Median	15.0	14.5	15.5	15.0	15.0	14.0	14.0	14.0
Min, Max	10, 20	12, 20	12, 20	12, 20	10, 20	12, 18	12, 18	12, 18
Change from								
Baseline								
n	93	96	100	196	100	99	98	197
Mean (SD)	0.0 (2.08)	0.0 (1.86)	0.0 (2.13)	0.0 (2.00)	-0.7 (2.00)	-0.5 (1.80)	-0.3 (1.76)	-0.4 (1.78)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-7, 6	-6, 6	-7, 4	-7, 6	-7, 2	-6, 4	-5, 4	-6, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 43								
Absolute								
Result								
n	95	95	99	194	100	98	96	194
Mean (SD)	15.0 (1.45)	14.9 (1.44)	14.9 (1.39)	14.9 (1.41)	14.8 (1.62)	14.7 (1.64)	14.8 (1.56)	14.8 (1.60)
Median	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0
Min, Max	12, 18	10, 18	12, 17	10, 18	12, 18	12, 20	12, 18	12, 20
Change from								
Baseline								
n	95	95	99	194	100	98	96	194
Mean (SD)	0.2 (1.76)	0.1 (1.65)	-0.2 (1.72)	-0.1 (1.69)	-0.5 (2.11)	-0.3 (1.86)	-0.2 (1.99)	-0.3 (1.92)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 6	-4, 4	-4, 4	-4, 4	-7, 6	-7, 4	-7, 4	-7, 4

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 57								
Absolute								
Result								
n	95	96	98	194	100	99	99	198
Mean (SD)	14.9 (1.42)	14.6 (1.45)	14.6 (1.57)	14.6 (1.51)	14.7 (1.89)	14.6 (1.44)	14.8 (1.59)	14.7 (1.51)
Median	15.0	14.0	14.0	14.0	14.0	14.0	14.0	14.0
Min, Max	12, 17	12, 18	12, 18	12, 18	12, 22	12, 18	12, 19	12, 19
Change from								
Baseline								
n	95	96	98	194	100	99	99	198
Mean (SD)	0.1 (1.62)	-0.2 (1.67)	-0.5 (1.75)	-0.4 (1.72)	-0.7 (2.31)	-0.4 (1.81)	-0.2 (1.91)	-0.3 (1.86)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 6	-5, 4	-6, 4	-6, 4	-6, 8	-7, 4	-5, 5	-7, 5

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Baseline				
n	200	200	200	400
Mean (SD)	121.9 (11.65)	121.0 (12.66)	121.9 (11.92)	121.5 (12.29)
Median	121.0	122.0	120.0	122.0
Min, Max	88, 148	85, 156	96, 149	85, 156
Day 1 - 1 Hour				
Postdose				
Absolute				
Result				
n	200	200	199	399
Mean (SD)	124.8 (12.67)	123.1 (12.82)	124.2 (12.63)	123.6 (12.72)
Median	124.0	124.0	124.0	124.0
Min, Max	88, 158	94, 159	99, 159	94, 159
Change from				
Baseline				
n	200	200	199	399
Mean (SD)	2.8 (11.59)	2.1 (11.15)	2.3 (11.91)	2.2 (11.52)
Median	3.0	1.0	1.0	1.0
Min, Max	-30, 36	-36, 38	-34, 44	-36, 44

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 8				
Absolute				
Result				
n	196	200	198	398
Mean (SD)	120.4 (11.30)	119.9 (12.47)	120.3 (12.38)	120.1 (12.41)
Median	120.0	121.0	120.0	120.0
Min, Max	86, 148	89, 153	90, 160	89, 160
Change from				
Baseline				
n	196	200	198	398
Mean (SD)	-1.4 (12.69)	-1.1 (11.55)	-1.6 (12.74)	-1.3 (12.14)
Median	-1.0	-2.0	-2.0	-2.0
Min, Max	-35, 42	-26, 39	-34, 42	-34, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 15				
Absolute				
Result				
n	196	198	200	398
Mean (SD)	121.2 (11.80)	119.9 (12.33)	120.3 (11.67)	120.1 (11.99)
Median	122.0	119.5	120.0	120.0
Min, Max	86, 154	87, 145	92, 150	87, 150
Change from				
Baseline				
n	196	198	200	398
Mean (SD)	-0.6 (11.48)	-1.2 (11.31)	-1.7 (11.85)	-1.4 (11.57)
Median	-1.0	-1.0	-2.0	-2.0
Min, Max	-40, 34	-29, 35	-30, 50	-30, 50

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 29 -				
Predose				
Absolute				
Result				
n	195	197	198	395
Mean (SD)	120.1 (12.09)	119.9 (12.38)	118.9 (12.13)	119.4 (12.24)
Median	120.0	120.0	119.0	119.0
Min, Max	91, 157	91, 159	85, 158	85, 159
Change from				
Baseline				
n	195	197	198	395
Mean (SD)	-1.8 (12.62)	-1.1 (11.79)	-3.1 (12.47)	-2.1 (12.16)
Median	-2.0	-1.0	-2.0	-2.0
Min, Max	-34, 32	-36, 40	-34, 28	-36, 40

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 29 - 1 Hour Postdose Absolute Result				
n	192	195	197	392
Mean (SD)	122.2 (11.69)	122.7 (12.47)	121.9 (12.08)	122.3 (12.27)
Median	122.0	124.0	121.0	122.0
Min, Max	89, 153	92, 151	91, 168	91, 168
Change from Baseline				
n	192	195	197	392
Mean (SD)	0.3 (12.24)	1.7 (12.88)	-0.1 (12.99)	0.8 (12.95)
Median	0.0	0.0	0.0	0.0
Min, Max	-32, 36	-31, 41	-34, 41	-34, 41

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 36				
Absolute				
Result				
n	193	195	198	393
Mean (SD)	121.7 (12.80)	119.4 (12.50)	119.6 (11.38)	119.5 (11.93)
Median	122.0	119.0	119.0	119.0
Min, Max	89, 154	92, 151	94, 151	92, 151
Change from				
Baseline				
n	193	195	198	393
Mean (SD)	-0.2 (12.95)	-1.7 (11.66)	-2.5 (13.31)	-2.1 (12.51)
Median	0.0	-2.0	-2.0	-2.0
Min, Max	-42, 37	-30, 42	-43, 32	-43, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 43				
Absolute				
Result				
n	195	193	195	388
Mean (SD)	120.3 (11.94)	120.3 (13.68)	119.5 (11.70)	119.9 (12.71)
Median	120.0	120.0	120.0	120.0
Min, Max	90, 178	90, 169	90, 150	90, 169
Change from				
Baseline				
n	195	193	195	388
Mean (SD)	-1.6 (13.22)	-0.7 (12.51)	-2.7 (13.10)	-1.7 (12.83)
Median	-2.0	-2.0	-3.0	-3.0
Min, Max	-35, 54	-30, 55	-42, 34	-42, 55

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 57				
Absolute				
Result				
n	195	195	197	392
Mean (SD)	121.7 (12.63)	121.5 (13.31)	121.2 (11.43)	121.3 (12.39)
Median	122.0	122.0	121.0	121.0
Min, Max	91, 152	92, 172	95, 155	92, 172
Change from				
Baseline				
n	195	195	197	392
Mean (SD)	-0.2 (13.02)	0.4 (13.29)	-1.0 (12.64)	-0.3 (12.97)
Median	-1.0	0.0	-2.0	-1.0
Min, Max	-36, 36	-45, 36	-40, 42	-45, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline								
n	100	100	100	200	100	100	100	200
Mean (SD)	119.3 (11.50)	118.1 (12.14)	119.3 (10.63)	118.7 (11.39)	124.6 (11.24)	123.9 (12.55)	124.5 (12.60)	124.2 (12.54)
Median	119.0	118.0	118.5	118.0	125.5	124.0	123.0	124.0
Min, Max	88, 146	85, 146	98, 145	85, 146	95, 148	93, 156	96, 149	93, 156
Day 1 - 1 Hour								
Postdose								
Absolute								
Result								
n	100	100	99	199	100	100	100	200
Mean (SD)	120.5 (12.40)	119.7 (11.86)	120.9 (12.45)	120.3 (12.14)	129.0 (11.51)	126.4 (12.91)	127.4 (12.03)	126.9 (12.46)
Median	120.0	120.0	119.0	119.0	129.0	126.0	129.0	128.0
Min, Max	88, 154	94, 147	99, 155	94, 155	101, 158	97, 159	102, 159	97, 159
Change from								
Baseline								
n	100	100	99	199	100	100	100	200
Mean (SD)	1.2 (11.00)	1.6 (9.35)	1.7 (11.54)	1.7 (10.47)	4.5 (11.99)	2.5 (12.74)	2.8 (12.30)	2.7 (12.49)
Median	1.5	1.5	1.0	1.0	4.0	1.0	1.0	1.0
Min, Max	-24, 32	-26, 30	-21, 31	-26, 31	-30, 36	-36, 38	-34, 44	-36, 44

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 8								
Absolute								
Result								
n	97	100	99	199	99	100	99	199
Mean (SD)	119.3 (11.07)	117.9 (12.80)	118.2 (12.01)	118.0 (12.38)	121.4 (11.49)	121.9 (11.86)	122.5 (12.44)	122.2 (12.12)
Median	120.0	119.5	120.0	120.0	121.0	123.5	123.0	123.0
Min, Max	86, 147	89, 148	90, 148	89, 148	95, 148	95, 153	95, 160	95, 160
Change from								
Baseline								
n	97	100	99	199	99	100	99	199
Mean (SD)	0.2 (10.35)	-0.2 (11.06)	-1.0 (10.94)	-0.6 (10.98)	-3.1 (14.49)	-2.0 (12.00)	-2.1 (14.35)	-2.1 (13.19)
Median	0.0	0.0	-1.0	-1.0	-4.0	-3.0	-3.0	-3.0
Min, Max	-32, 25	-26, 39	-30, 20	-30, 39	-35, 42	-26, 35	-34, 42	-34, 42

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 15								
Absolute								
Result								
n	97	99	100	199	99	99	100	199
Mean (SD)	118.8 (11.45)	117.6 (12.17)	117.1 (10.35)	117.3 (11.27)	123.6 (11.71)	122.2 (12.11)	123.4 (12.10)	122.8 (12.09)
Median	118.0	117.0	116.5	117.0	124.0	123.0	123.0	123.0
Min, Max	86, 149	87, 145	92, 141	87, 145	99, 154	96, 144	96, 150	96, 150
Change from								
Baseline								
n	97	99	100	199	99	99	100	199
Mean (SD)	-0.4 (10.18)	-0.6 (10.09)	-2.2 (10.63)	-1.4 (10.37)	-0.9 (12.68)	-1.8 (12.44)	-1.1 (12.98)	-1.4 (12.69)
Median	-1.0	-1.0	-2.5	-2.0	0.0	-2.0	-1.0	-1.0
Min, Max	-21, 31	-24, 23	-30, 25	-30, 25	-40, 34	-29, 35	-26, 50	-29, 50

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 -								
Predose								
Absolute								
Result								
n	95	98	100	198	100	99	98	197
Mean (SD)	117.5 (11.82)	117.3 (12.16)	116.4 (11.25)	116.9 (11.69)	122.5 (11.88)	122.4 (12.13)	121.4 (12.52)	121.9 (12.31)
Median	118.0	118.0	115.5	118.0	122.0	122.0	121.0	121.0
Min, Max	92, 145	91, 148	85, 140	85, 148	91, 157	92, 159	89, 158	89, 159
Change from								
Baseline								
n	95	98	100	198	100	99	98	197
Mean (SD)	-1.5 (11.65)	-0.7 (10.32)	-2.9 (11.56)	-1.8 (10.99)	-2.1 (13.52)	-1.6 (13.13)	-3.3 (13.39)	-2.5 (13.26)
Median	-1.0	-1.0	-2.0	-1.0	-2.5	-3.0	-2.5	-3.0
Min, Max	-34, 31	-27, 26	-33, 27	-33, 27	-34, 32	-36, 40	-34, 28	-36, 40

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 - 1								
Hour Postdose								
Absolute								
Result								
n	93	97	99	196	99	98	98	196
Mean (SD)	119.0 (11.56)	120.6 (12.88)	118.6 (10.84)	119.6 (11.91)	125.2 (11.05)	124.9 (11.72)	125.3 (12.38)	125.1 (12.02)
Median	118.0	120.0	119.0	120.0	125.0	126.0	124.0	125.0
Min, Max	89, 144	93, 151	91, 153	91, 153	94, 153	92, 150	96, 168	92, 168
Change from								
Baseline								
n	93	97	99	196	99	98	98	196
Mean (SD)	0.1 (11.89)	2.5 (10.74)	-0.8 (11.74)	0.8 (11.34)	0.6 (12.62)	0.9 (14.71)	0.5 (14.18)	0.7 (14.41)
Median	1.0	1.0	0.0	0.0	0.0	-1.5	0.0	0.0
Min, Max	-26, 28	-15, 37	-27, 30	-27, 37	-32, 36	-31, 41	-34, 41	-34, 41

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 36								
Absolute								
Result								
n	93	96	100	196	100	99	98	197
Mean (SD)	119.0 (12.40)	115.9 (11.96)	116.6 (10.24)	116.3 (11.09)	124.1 (12.72)	122.8 (12.12)	122.6 (11.74)	122.7 (11.90)
Median	119.0	116.0	116.0	116.0	125.0	122.0	122.0	122.0
Min, Max	89, 146	92, 148	95, 142	92, 148	96, 154	92, 151	94, 151	92, 151
Change from								
Baseline								
n	93	96	100	196	100	99	98	197
Mean (SD)	0.1 (11.80)	-2.4 (10.21)	-2.7 (12.77)	-2.5 (11.56)	-0.4 (13.99)	-1.0 (12.92)	-2.3 (13.91)	-1.6 (13.40)
Median	0.0	-3.0	-1.5	-2.5	-2.0	-1.0	-2.0	-2.0
Min, Max	-38, 28	-28, 28	-35, 28	-35, 28	-42, 37	-30, 42	-43, 32	-43, 42

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 43								
Absolute								
Result								
n	95	95	99	194	100	98	96	194
Mean (SD)	119.4 (12.53)	117.5 (12.64)	117.1 (10.57)	117.3 (11.60)	121.1 (11.36)	123.0 (14.18)	122.0 (12.32)	122.5 (13.27)
Median	120.0	118.0	118.0	118.0	121.0	122.0	122.0	122.0
Min, Max	90, 178	90, 165	93, 149	90, 165	96, 150	94, 169	90, 150	90, 169
Change from								
Baseline								
n	95	95	99	194	100	98	96	194
Mean (SD)	0.5 (12.57)	-0.8 (10.95)	-2.4 (11.45)	-1.6 (11.21)	-3.5 (13.59)	-0.7 (13.91)	-3.1 (14.66)	-1.9 (14.30)
Median	0.0	-2.0	-3.0	-2.0	-4.0	-2.5	-3.0	-3.0
Min, Max	-35, 54	-23, 35	-27, 26	-27, 35	-35, 24	-30, 55	-42, 34	-42, 55

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 57								
Absolute								
Result								
n	95	96	98	194	100	99	99	198
Mean (SD)	119.9 (13.76)	119.5 (12.78)	118.7 (10.93)	119.1 (11.86)	123.3 (11.26)	123.4 (13.59)	123.7 (11.43)	123.6 (12.53)
Median	119.0	119.0	118.0	118.0	123.0	123.0	123.0	123.0
Min, Max	91, 152	92, 145	95, 145	92, 145	97, 147	93, 172	99, 155	93, 172
Change from								
Baseline								
n	95	96	98	194	100	99	99	198
Mean (SD)	0.9 (13.36)	1.2 (11.70)	-0.8 (10.47)	0.2 (11.11)	-1.3 (12.67)	-0.4 (14.68)	-1.1 (14.53)	-0.7 (14.57)
Median	0.0	2.0	-2.0	0.0	-1.0	-4.0	-2.0	-2.0
Min, Max	-31, 36	-34, 29	-24, 22	-34, 29	-36, 25	-45, 36	-40, 42	-45, 42

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Baseline				
n	200	200	200	400
Mean (SD)	36.78 (0.256)	36.77 (0.276)	36.78 (0.295)	36.78 (0.286)
Median	36.80	36.80	36.80	36.80
Min, Max	35.7, 37.4	35.6, 37.7	34.8, 37.6	34.8, 37.7
Day 1 - 1 Hour				
Postdose				
Absolute				
Result				
n	200	200	199	399
Mean (SD)	36.65 (0.302)	36.65 (0.311)	36.63 (0.326)	36.64 (0.319)
Median	36.70	36.70	36.70	36.70
Min, Max	35.5, 37.3	35.7, 37.5	35.6, 37.3	35.6, 37.5
Change from				
Baseline				
n	200	200	199	399
Mean (SD)	-0.13 (0.358)	-0.12 (0.332)	-0.15 (0.378)	-0.13 (0.356)
Median	-0.10	-0.10	-0.10	-0.10
Min, Max	-1.4, 1.2	-1.2, 0.7	-1.5, 1.9	-1.5, 1.9

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 8				
Absolute				
Result				
n	196	200	198	398
Mean (SD)	36.77 (0.246)	36.77 (0.262)	36.73 (0.293)	36.75 (0.278)
Median	36.80	36.80	36.70	36.80
Min, Max	35.9, 37.5	35.8, 37.6	35.1, 37.4	35.1, 37.6
Change from				
Baseline				
n	196	200	198	398
Mean (SD)	-0.01 (0.314)	0.00 (0.334)	-0.04 (0.381)	-0.02 (0.358)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.8, 1.2	-1.2, 1.3	-1.5, 1.9	-1.5, 1.9

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 15				
Absolute				
Result				
n	196	198	200	398
Mean (SD)	36.75 (0.255)	36.75 (0.272)	36.76 (0.299)	36.76 (0.286)
Median	36.70	36.80	36.80	36.80
Min, Max	35.9, 37.7	35.7, 37.3	35.7, 38.0	35.7, 38.0
Change from				
Baseline				
n	196	198	200	398
Mean (SD)	-0.03 (0.330)	-0.02 (0.333)	-0.02 (0.375)	-0.02 (0.355)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.0, 1.5	-1.1, 1.3	-1.1, 1.7	-1.1, 1.7

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 29 -				
Predose				
Absolute				
Result				
n	195	197	198	395
Mean (SD)	36.76 (0.237)	36.77 (0.296)	36.74 (0.281)	36.75 (0.289)
Median	36.80	36.80	36.80	36.80
Min, Max	36.2, 37.7	35.6, 37.6	35.2, 37.4	35.2, 37.6
Change from				
Baseline				
n	195	197	198	395
Mean (SD)	-0.02 (0.334)	-0.01 (0.317)	-0.05 (0.377)	-0.03 (0.348)
Median	0.00	0.00	0.00	0.00
Min, Max	-0.9, 1.4	-1.1, 1.0	-1.6, 1.6	-1.6, 1.6

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	50 µg (N=200)	mRNA-1273 100 µg (N=200)	Total (N=400)
Day 29 - 1				
Hour Postdose				
Absolute				
Result				
n	192	195	197	392
Mean (SD)	36.71 (0.237)	36.71 (0.294)	36.66 (0.305)	36.69 (0.300)
Median	36.70	36.70	36.70	36.70
Min, Max	35.9, 37.3	35.6, 37.6	35.0, 37.4	35.0, 37.6
Change from				
Baseline				
n	192	195	197	392
Mean (SD)	-0.08 (0.294)	-0.06 (0.355)	-0.12 (0.383)	-0.09 (0.370)
Median	-0.10	0.00	-0.10	-0.10
Min, Max	-1.0, 1.1	-1.2, 1.3	-1.6, 2.0	-1.6, 2.0

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 36				
Absolute				
Result				
n	193	195	198	393
Mean (SD)	36.76 (0.290)	36.76 (0.247)	36.77 (0.302)	36.76 (0.276)
Median	36.80	36.80	36.75	36.80
Min, Max	35.8, 37.6	36.1, 37.4	36.1, 38.6	36.1, 38.6
Change from				
Baseline				
n	193	195	198	393
Mean (SD)	-0.02 (0.342)	-0.02 (0.337)	-0.01 (0.370)	-0.01 (0.354)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.3, 1.1	-1.0, 1.5	-1.2, 1.7	-1.2, 1.7

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 43				
Absolute				
Result				
n	195	193	195	388
Mean (SD)	36.77 (0.275)	36.70 (0.304)	36.73 (0.321)	36.72 (0.313)
Median	36.70	36.70	36.80	36.80
Min, Max	35.3, 37.6	35.6, 37.7	35.3, 37.4	35.3, 37.7
Change from				
Baseline				
n	195	193	195	388
Mean (SD)	-0.02 (0.343)	-0.08 (0.367)	-0.04 (0.384)	-0.06 (0.376)
Median	0.00	-0.10	0.00	-0.10
Min, Max	-1.3, 1.1	-1.5, 1.4	-1.6, 1.6	-1.6, 1.6

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
	Placebo (N=200)	mRNA-1273		
		50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 57				
Absolute				
Result				
n	195	194	197	391
Mean (SD)	36.79 (0.268)	36.78 (0.274)	36.75 (0.264)	36.76 (0.269)
Median	36.80	36.80	36.80	36.80
Min, Max	35.7, 37.5	35.9, 37.5	35.8, 37.6	35.8, 37.6
Change from				
Baseline				
n	195	194	197	391
Mean (SD)	0.01 (0.320)	0.00 (0.335)	-0.03 (0.367)	-0.01 (0.352)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.2, 1.1	-1.1, 1.0	-1.1, 1.7	-1.1, 1.7

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Baseline								
n	100	100	100	200	100	100	100	200
Mean (SD)	36.83 (0.264)	36.78 (0.325)	36.82 (0.261)	36.80 (0.295)	36.73 (0.239)	36.76 (0.219)	36.74 (0.322)	36.75 (0.275)
Median	36.80	36.80	36.90	36.80	36.80	36.70	36.70	36.70
Min, Max	35.7, 37.4	35.6, 37.7	35.9, 37.6	35.6, 37.7	36.1, 37.3	35.9, 37.2	34.8, 37.3	34.8, 37.3
Day 1 - 1 Hour								
Postdose								
Absolute								
Result								
n	100	100	99	199	100	100	100	200
Mean (SD)	36.71 (0.267)	36.71 (0.324)	36.69 (0.312)	36.70 (0.318)	36.60 (0.324)	36.60 (0.288)	36.57 (0.330)	36.58 (0.309)
Median	36.70	36.70	36.70	36.70	36.60	36.60	36.70	36.60
Min, Max	35.7, 37.3	35.7, 37.5	35.6, 37.3	35.6, 37.5	35.5, 37.3	35.7, 37.2	35.6, 37.2	35.6, 37.2
Change from								
Baseline								
n	100	100	99	199	100	100	100	200
Mean (SD)	-0.12 (0.342)	-0.07 (0.348)	-0.13 (0.350)	-0.10 (0.349)	-0.14 (0.375)	-0.17 (0.310)	-0.17 (0.405)	-0.17 (0.360)
Median	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10	-0.10
Min, Max	-1.2, 1.2	-1.2, 0.7	-1.5, 0.9	-1.5, 0.9	-1.4, 1.0	-1.1, 0.7	-1.1, 1.9	-1.1, 1.9

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	mRNA-1273				mRNA-1273			
	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)	Placebo (N=100)	50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 8								
Absolute								
Result								
n	97	100	99	199	99	100	99	199
Mean (SD)	36.75 (0.239)	36.80 (0.258)	36.77 (0.272)	36.78 (0.265)	36.79 (0.254)	36.75 (0.264)	36.70 (0.310)	36.72 (0.288)
Median	36.70	36.80	36.80	36.80	36.80	36.70	36.70	36.70
Min, Max	35.9, 37.5	36.1, 37.6	35.8, 37.3	35.8, 37.6	35.9, 37.4	35.8, 37.5	35.1, 37.4	35.1, 37.5
Change from								
Baseline								
n	97	100	99	199	99	100	99	199
Mean (SD)	-0.08 (0.317)	0.02 (0.346)	-0.05 (0.323)	-0.02 (0.336)	0.05 (0.300)	-0.02 (0.322)	-0.03 (0.433)	-0.03 (0.380)
Median	-0.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	-0.8, 1.2	-0.9, 1.3	-1.0, 0.6	-1.0, 1.3	-0.7, 1.0	-1.2, 0.8	-1.5, 1.9	-1.5, 1.9

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 15								
Absolute								
Result								
n	97	99	100	199	99	99	100	199
Mean (SD)	36.74 (0.266)	36.77 (0.268)	36.79 (0.321)	36.78 (0.295)	36.76 (0.245)	36.74 (0.277)	36.72 (0.272)	36.73 (0.274)
Median	36.70	36.80	36.80	36.80	36.80	36.70	36.70	36.70
Min, Max	35.9, 37.7	35.9, 37.3	35.8, 38.0	35.8, 38.0	36.0, 37.2	35.7, 37.3	35.7, 37.4	35.7, 37.4
Change from								
Baseline								
n	97	99	100	199	99	99	100	199
Mean (SD)	-0.09 (0.370)	-0.01 (0.332)	-0.03 (0.364)	-0.02 (0.348)	0.02 (0.277)	-0.03 (0.336)	-0.01 (0.388)	-0.02 (0.362)
Median	-0.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	-1.0, 1.5	-1.1, 0.7	-1.1, 1.3	-1.1, 1.3	-0.7, 0.8	-0.8, 1.3	-0.9, 1.7	-0.9, 1.7

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 -								
Predose								
Absolute								
Result								
n	95	98	100	198	100	99	98	197
Mean (SD)	36.75 (0.261)	36.76 (0.319)	36.77 (0.239)	36.76 (0.281)	36.78 (0.212)	36.78 (0.272)	36.71 (0.317)	36.74 (0.297)
Median	36.70	36.80	36.80	36.80	36.80	36.80	36.70	36.70
Min, Max	36.2, 37.7	35.7, 37.6	36.0, 37.4	35.7, 37.6	36.2, 37.2	35.6, 37.5	35.2, 37.4	35.2, 37.5
Change from								
Baseline								
n	95	98	100	198	100	99	98	197
Mean (SD)	-0.09 (0.370)	-0.02 (0.354)	-0.06 (0.320)	-0.04 (0.337)	0.04 (0.285)	0.01 (0.275)	-0.03 (0.429)	-0.01 (0.360)
Median	-0.10	0.00	-0.10	0.00	0.00	0.00	0.00	0.00
Min, Max	-0.9, 1.4	-1.1, 1.0	-0.9, 1.3	-1.1, 1.3	-0.7, 0.7	-0.7, 0.7	-1.6, 1.6	-1.6, 1.6

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 29 - 1								
Hour Postdose								
Absolute								
Result								
n	93	97	99	196	99	98	98	196
Mean (SD)	36.72 (0.226)	36.77 (0.305)	36.69 (0.321)	36.73 (0.315)	36.69 (0.248)	36.66 (0.274)	36.63 (0.286)	36.65 (0.280)
Median	36.70	36.80	36.70	36.80	36.70	36.70	36.60	36.70
Min, Max	36.1, 37.3	35.8, 37.4	35.0, 37.4	35.0, 37.4	35.9, 37.3	35.6, 37.6	35.6, 37.3	35.6, 37.6
Change from								
Baseline								
n	93	97	99	196	99	98	98	196
Mean (SD)	-0.11 (0.290)	-0.01 (0.363)	-0.13 (0.355)	-0.07 (0.362)	-0.05 (0.296)	-0.10 (0.343)	-0.11 (0.411)	-0.11 (0.378)
Median	-0.10	0.00	-0.10	-0.10	0.00	-0.10	-0.10	-0.10
Min, Max	-1.0, 1.0	-1.2, 0.9	-1.6, 0.7	-1.6, 0.9	-0.9, 1.1	-1.2, 1.3	-1.3, 2.0	-1.3, 2.0

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 36								
Absolute								
Result								
n	93	96	100	196	100	99	98	197
Mean (SD)	36.75 (0.305)	36.74 (0.223)	36.82 (0.300)	36.78 (0.267)	36.77 (0.277)	36.77 (0.269)	36.72 (0.297)	36.74 (0.284)
Median	36.80	36.80	36.80	36.80	36.80	36.80	36.70	36.70
Min, Max	35.8, 37.5	36.1, 37.1	36.2, 38.6	36.1, 38.6	35.9, 37.6	36.2, 37.4	36.1, 37.2	36.1, 37.4
Change from								
Baseline								
n	93	96	100	196	100	99	98	197
Mean (SD)	-0.08 (0.366)	-0.04 (0.331)	-0.01 (0.382)	-0.02 (0.357)	0.04 (0.310)	0.01 (0.344)	-0.02 (0.359)	-0.01 (0.351)
Median	-0.10	-0.05	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	-1.3, 1.1	-0.7, 1.5	-1.2, 1.7	-1.2, 1.7	-0.8, 0.7	-1.0, 1.5	-0.9, 1.4	-1.0, 1.5

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Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 43								
Absolute								
Result								
n	95	95	99	194	100	98	96	194
Mean (SD)	36.80 (0.269)	36.75 (0.292)	36.77 (0.286)	36.76 (0.289)	36.73 (0.277)	36.65 (0.307)	36.70 (0.351)	36.67 (0.330)
Median	36.80	36.80	36.80	36.80	36.70	36.70	36.80	36.70
Min, Max	36.1, 37.6	35.9, 37.6	36.0, 37.4	35.9, 37.6	35.3, 37.6	35.6, 37.7	35.3, 37.3	35.3, 37.7
Change from								
Baseline								
n	95	95	99	194	100	98	96	194
Mean (SD)	-0.03 (0.349)	-0.03 (0.388)	-0.06 (0.343)	-0.05 (0.365)	0.00 (0.339)	-0.12 (0.341)	-0.02 (0.423)	-0.07 (0.386)
Median	0.00	0.00	-0.10	-0.10	-0.05	-0.10	0.00	-0.10
Min, Max	-0.8, 1.0	-1.0, 1.4	-1.1, 0.9	-1.1, 1.4	-1.3, 1.1	-1.5, 1.3	-1.6, 1.6	-1.6, 1.6

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=100)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=100)	100 µg (N=100)	Total (N=200)		50 µg (N=100)	100 µg (N=100)	Total (N=200)
Day 57								
Absolute								
Result								
n	95	96	98	194	100	98	99	197
Mean (SD)	36.81 (0.254)	36.80 (0.268)	36.78 (0.257)	36.79 (0.262)	36.77 (0.280)	36.75 (0.280)	36.72 (0.270)	36.74 (0.275)
Median	36.80	36.80	36.80	36.80	36.80	36.80	36.80	36.80
Min, Max	36.2, 37.5	35.9, 37.5	36.1, 37.6	35.9, 37.6	35.7, 37.5	35.9, 37.4	35.8, 37.2	35.8, 37.4
Change from								
Baseline								
n	95	96	98	194	100	98	99	197
Mean (SD)	-0.02 (0.338)	0.02 (0.354)	-0.05 (0.336)	-0.02 (0.346)	0.03 (0.301)	-0.01 (0.316)	-0.02 (0.397)	-0.01 (0.358)
Median	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	-0.9, 1.1	-1.1, 1.0	-1.0, 0.9	-1.1, 1.0	-1.2, 0.8	-1.1, 0.8	-1.1, 1.7	-1.1, 1.7

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	0	0	0	0	0	0			
Grade 0	0	189 (94.5)	5 (2.5)	1 (0.5)	0	0	195 (97.5)			
Grade 1	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			
Day 8										
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)			
Grade 0	0	181 (90.5)	6 (3.0)	1 (0.5)	0	0	188 (94.0)			
Grade 1	0	6 (3.0)	0	0	0	0	6 (3.0)			
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)			
Grade 0	0	184 (92.0)	6 (3.0)	1 (0.5)	0	0	191 (95.5)			
Grade 1	0	4 (2.0)	0	0	0	0	4 (2.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			
Day 29 - Predose										
UNK	0	4 (2.0)	1 (0.5)	0	0	0	5 (2.5)			
Grade 0	0	186 (93.0)	5 (2.5)	1 (0.5)	0	0	192 (96.0)			
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	7 (3.5)	1 (0.5)	0	0	0	8 (4.0)			
Grade 0	0	184 (92.0)	5 (2.5)	1 (0.5)	0	0	190 (95.0)			
Grade 1	0	0	0	0	0	0	0			
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			
Day 36										
UNK	0	6 (3.0)	1 (0.5)	0	0	0	7 (3.5)			
Grade 0	0	183 (91.5)	5 (2.5)	0	0	0	188 (94.0)			
Grade 1	0	2 (1.0)	0	1 (0.5)	0	0	3 (1.5)			
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	4 (2.0)	1 (0.5)	0	0	0		5 (2.5)	
Grade 0	0	186 (93.0)	5 (2.5)	1 (0.5)	0	0		192 (96.0)	
Grade 1	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 2	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0		200 (100)	
Day 57									
UNK	0	4 (2.0)	1 (0.5)	0	0	0		5 (2.5)	
Grade 0	0	187 (93.5)	5 (2.5)	1 (0.5)	0	0		193 (96.5)	
Grade 1	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	173 (86.5)	5 (2.5)	0	0	0		178 (89.0)	
Grade 1	0	11 (5.5)	1 (0.5)	1 (0.5)	0	0		13 (6.5)	
Grade 2	0	8 (4.0)	0	0	0	0		8 (4.0)	
Grade 3	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	193 (96.5)	6 (3.0)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline										Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)						
Post-Baseline Grade												
Day 1 - 1 Hour Postdose												
UNK	0	0		0		0		0		0		0
Grade 0	0	169 (84.5)		3 (1.5)		0		0		0		172 (86.0)
Grade 1	0	17 (8.5)		1 (0.5)		1 (0.5)		0		0		19 (9.5)
Grade 2	0	4 (2.0)		1 (0.5)		0		1 (0.5)		0		6 (3.0)
Grade 3	0	2 (1.0)		0		1 (0.5)		0		0		3 (1.5)
Grade 4	0	0		0		0		0		0		0
Total	0	192 (96.0)		5 (2.5)		2 (1.0)		1 (0.5)		0		200 (100)
Day 8												
UNK	0	4 (2.0)		0		0		0		0		4 (2.0)
Grade 0	0	177 (88.5)		2 (1.0)		0		0		0		179 (89.5)
Grade 1	0	10 (5.0)		1 (0.5)		2 (1.0)		0		0		13 (6.5)
Grade 2	0	0		2 (1.0)		0		0		0		2 (1.0)
Grade 3	0	1 (0.5)		0		0		1 (0.5)		0		2 (1.0)
Grade 4	0	0		0		0		0		0		0
Total	0	192 (96.0)		5 (2.5)		2 (1.0)		1 (0.5)		0		200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline										
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	Total
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)	n (%)
Day 15											
UNK	0	3	(1.5)	1	(0.5)	0		0		0	4 (2.0)
Grade 0	0	181	(90.5)	3	(1.5)	0		0		0	184 (92.0)
Grade 1	0	7	(3.5)	0		0		0		0	7 (3.5)
Grade 2	0	1	(0.5)	1	(0.5)	2	(1.0)	0		0	4 (2.0)
Grade 3	0	0		0		0		1	(0.5)	0	1 (0.5)
Grade 4	0	0		0		0		0		0	0
Total	0	192	(96.0)	5	(2.5)	2	(1.0)	1	(0.5)	0	200 (100)
Day 29 - Predose											
UNK	0	5	(2.5)	0		0		0		0	5 (2.5)
Grade 0	0	176	(88.0)	5	(2.5)	1	(0.5)	0		0	182 (91.0)
Grade 1	0	10	(5.0)	0		0		0		0	10 (5.0)
Grade 2	0	1	(0.5)	0		0		0		0	1 (0.5)
Grade 3	0	0		0		1	(0.5)	1	(0.5)	0	2 (1.0)
Grade 4	0	0		0		0		0		0	0
Total	0	192	(96.0)	5	(2.5)	2	(1.0)	1	(0.5)	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	7 (3.5)	1 (0.5)	0	0	0	8 (4.0)			
Grade 0	0	162 (81.0)	2 (1.0)	0	0	0	164 (82.0)			
Grade 1	0	15 (7.5)	2 (1.0)	1 (0.5)	0	0	18 (9.0)			
Grade 2	0	7 (3.5)	0	0	0	0	7 (3.5)			
Grade 3	0	1 (0.5)	0	1 (0.5)	1 (0.5)	0	3 (1.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	200 (100)			
Day 36										
UNK	0	6 (3.0)	1 (0.5)	0	0	0	7 (3.5)			
Grade 0	0	178 (89.0)	2 (1.0)	0	0	0	180 (90.0)			
Grade 1	0	6 (3.0)	1 (0.5)	0	0	0	7 (3.5)			
Grade 2	0	1 (0.5)	1 (0.5)	2 (1.0)	1 (0.5)	0	5 (2.5)			
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	5 (2.5)	0	0	0	0		5	(2.5)
Grade 0	0	179 (89.5)	4 (2.0)	0	0	0		183	(91.5)
Grade 1	0	4 (2.0)	1 (0.5)	2 (1.0)	0	0		7	(3.5)
Grade 2	0	3 (1.5)	0	0	0	0		3	(1.5)
Grade 3	0	1 (0.5)	0	0	1 (0.5)	0		2	(1.0)
Grade 4	0	0	0	0	0	0		0	
Total	0	192 (96.0)	5 (2.5)	2 (1.0)	1 (0.5)	0		200	(100)
Day 57									
UNK	0	5 (2.5)	0	0	0	0		5	(2.5)
Grade 0	0	179 (89.5)	4 (2.0)	1 (0.5)	1 (0.5)	0		185	(92.5)
Grade 1	0	3 (1.5)	1 (0.5)	0	0	0		4	(2.0)
Grade 2	0	4 (2.0)	0	0	0	0		4	(2.0)
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0		2	(1.0)
Grade 4	0	0	0	0	0	0		0	
Total	0	192 (96.0)	5 (2.5)	2 (1.0)	1 (0.5)	0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	141 (70.5)	2 (1.0)	0	0	0	143 (71.5)
Grade 1	0	35 (17.5)	0	0	0	0	35 (17.5)
Grade 2	0	13 (6.5)	3 (1.5)	1 (0.5)	0	0	17 (8.5)
Grade 3	0	3 (1.5)	0	1 (0.5)	1 (0.5)	0	5 (2.5)
Grade 4	0	0	0	0	0	0	0
Total	0	192 (96.0)	5 (2.5)	2 (1.0)	1 (0.5)	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	199 (99.5)	0	0	0	0	0	199 (99.5)	
Grade 1	0	1 (0.5)	0	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200 (100)	
Day 8									
UNK	0	4 (2.0)	0	0	0	0	0	4 (2.0)	
Grade 0	0	196 (98.0)	0	0	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)		
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)		
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		
Day 29 - Predose									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (4.0)	0	0	0	0	8 (4.0)	
Grade 0	0	192 (96.0)	0	0	0	0	192 (96.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)	
Grade 0	0	192 (96.0)	0	0	0	0	192 (96.0)	
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 57								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	0
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	163 (81.5)	10 (5.0)	0	0	0	0	173 (86.5)	
Grade 1	0	6 (3.0)	21 (10.5)	0	0	0	0	27 (13.5)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	0	200 (100)	
Day 8									
UNK	0	4 (2.0)	0	0	0	0	0	4 (2.0)	
Grade 0	0	159 (79.5)	25 (12.5)	0	0	0	0	184 (92.0)	
Grade 1	0	6 (3.0)	6 (3.0)	0	0	0	0	12 (6.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline											
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)
Day 15												
UNK	0	3	(1.5)	1	(0.5)	0		0		0		4 (2.0)
Grade 0	0	159	(79.5)	13	(6.5)	0		0		0		172 (86.0)
Grade 1	0	7	(3.5)	17	(8.5)	0		0		0		24 (12.0)
Grade 2	0	0		0		0		0		0		0
Grade 3	0	0		0		0		0		0		0
Grade 4	0	0		0		0		0		0		0
Total	0	169	(84.5)	31	(15.5)	0		0		0		200 (100)
Day 29 - Predose												
UNK	0	5	(2.5)	0		0		0		0		5 (2.5)
Grade 0	0	159	(79.5)	9	(4.5)	0		0		0		168 (84.0)
Grade 1	0	5	(2.5)	22	(11.0)	0		0		0		27 (13.5)
Grade 2	0	0		0		0		0		0		0
Grade 3	0	0		0		0		0		0		0
Grade 4	0	0		0		0		0		0		0
Total	0	169	(84.5)	31	(15.5)	0		0		0		200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Post-Baseline Grade										
Day 29 - 1 Hour										
Postdose										
UNK	0	7 (3.5)	1 (0.5)	0	0	0	8 (4.0)			
Grade 0	0	157 (78.5)	16 (8.0)	0	0	0	173 (86.5)			
Grade 1	0	5 (2.5)	14 (7.0)	0	0	0	19 (9.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)			
Day 36										
UNK	0	6 (3.0)	1 (0.5)	0	0	0	7 (3.5)			
Grade 0	0	162 (81.0)	20 (10.0)	0	0	0	182 (91.0)			
Grade 1	0	1 (0.5)	10 (5.0)	0	0	0	11 (5.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	158 (79.0)	16 (8.0)	0	0	0	174 (87.0)		
Grade 1	0	6 (3.0)	15 (7.5)	0	0	0	21 (10.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)		
Day 57									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	160 (80.0)	19 (9.5)	0	0	0	179 (89.5)		
Grade 1	0	3 (1.5)	11 (5.5)	0	0	0	14 (7.0)		
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	145 (72.5)	3 (1.5)	0	0	0		148 (74.0)	
Grade 1	0	23 (11.5)	27 (13.5)	0	0	0		50 (25.0)	
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0		2 (1.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	169 (84.5)	31 (15.5)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	199 (99.5)	0	0	0	0	199 (99.5)		
Grade 1	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		
Day 8									
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)		
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195 (97.5)		
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	4 (2.0)	0	0	0	0	4	(2.0)	
Grade 0	0	194 (97.0)	0	0	0	0	194	(97.0)	
Grade 1	0	1 (0.5)	1 (0.5)	0	0	0	2	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195	(97.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (4.0)	0	0	0	0	8 (4.0)	
Grade 0	0	191 (95.5)	0	0	0	0	191 (95.5)	
Grade 1	0	0	1 (0.5)	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 36								
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)	
Grade 0	0	192 (96.0)	0	0	0	0	192 (96.0)	
Grade 1	0	0	1 (0.5)	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 57								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	1 (0.5)	1 (0.5)	0	0	0	2	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	177 (88.5)	4 (2.0)	0	0	0	181 (90.5)	
Grade 1	0	10 (5.0)	4 (2.0)	0	0	0	14 (7.0)	
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 3	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	8 (4.0)	0	0	0	200 (100)	
Day 8								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	181 (90.5)	7 (3.5)	0	0	0	188 (94.0)	
Grade 1	0	7 (3.5)	1 (0.5)	0	0	0	8 (4.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	8 (4.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	184 (92.0)	6 (3.0)	0	0	0	190 (95.0)	
Grade 1	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)	
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	8 (4.0)	0	0	0	200 (100)	
Day 29 - Predose								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	181 (90.5)	7 (3.5)	0	0	0	188 (94.0)	
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6 (3.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	8 (4.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour									
Postdose									
UNK	0	8 (4.0)	0	0	0	0	8	(4.0)	
Grade 0	0	177 (88.5)	6 (3.0)	0	0	0	183	(91.5)	
Grade 1	0	6 (3.0)	2 (1.0)	0	0	0	8	(4.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	192 (96.0)	8 (4.0)	0	0	0	200	(100)	
Day 36									
UNK	0	7 (3.5)	0	0	0	0	7	(3.5)	
Grade 0	0	176 (88.0)	6 (3.0)	0	0	0	182	(91.0)	
Grade 1	0	7 (3.5)	2 (1.0)	0	0	0	9	(4.5)	
Grade 2	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	192 (96.0)	8 (4.0)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43									
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)	
Grade 0	0	181 (90.5)	7 (3.5)	0	0	0	188	(94.0)	
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6	(3.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 4	0	0	0	0	0	0	0		
Total	0	192 (96.0)	8 (4.0)	0	0	0	200	(100)	
Day 57									
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)	
Grade 0	0	175 (87.5)	8 (4.0)	0	0	0	183	(91.5)	
Grade 1	0	11 (5.5)	0	0	0	0	11	(5.5)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	192 (96.0)	8 (4.0)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	155 (77.5)	1 (0.5)	0	0	0		156 (78.0)	
Grade 1	0	26 (13.0)	6 (3.0)	0	0	0		32 (16.0)	
Grade 2	0	6 (3.0)	1 (0.5)	0	0	0		7 (3.5)	
Grade 3	0	5 (2.5)	0	0	0	0		5 (2.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	192 (96.0)	8 (4.0)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	200 (100)	0	0	0	0	200 (100)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		
Day 8									
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)		
Grade 0	0	196 (98.0)	0	0	0	0	196 (98.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)		
Grade 0	0	196 (98.0)	0	0	0	0	196 (98.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		
Day 29 - Predose									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (4.0)	0	0	0	0	8 (4.0)	
Grade 0	0	192 (96.0)	0	0	0	0	192 (96.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)	
Grade 0	0	193 (96.5)	0	0	0	0	193 (96.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 57								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: Placebo (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	198 (99.0)	0	0	0	0		198 (99.0)	
Grade 1	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 2	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	200 (100)	0	0	0	0		200 (100)	
Day 8									
UNK	0	0	0	0	0	0		0	
Grade 0	0	193 (96.5)	0	0	0	0		193 (96.5)	
Grade 1	0	6 (3.0)	0	0	0	0		6 (3.0)	
Grade 2	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	200 (100)	0	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	193 (96.5)	0	0	0	0	193 (96.5)		
Grade 1	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	190 (95.0)	0	0	0	0	190 (95.0)		
Grade 1	0	7 (3.5)	0	0	0	0	7 (3.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	187 (93.5)	0	0	0	0	187	(93.5)
Grade 1	0	7 (3.5)	0	0	0	0	7	(3.5)
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 36								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	192 (96.0)	0	0	0	0	192	(96.0)
Grade 1	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	7 (3.5)	0	0	0	0	7	(3.5)	
Grade 0	0	189 (94.5)	0	0	0	0	189	(94.5)	
Grade 1	0	4 (2.0)	0	0	0	0	4	(2.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 57									
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)	
Grade 0	0	192 (96.0)	0	0	0	0	192	(96.0)	
Grade 1	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	173 (86.5)	0	0	0	0	0	173 (86.5)	
Grade 1	0	22 (11.0)	0	0	0	0	0	22 (11.0)	
Grade 2	0	5 (2.5)	0	0	0	0	0	5 (2.5)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	0	0	0	0	0	0			
Grade 0	0	174 (87.0)	2 (1.0)	0	0	0	176 (88.0)			
Grade 1	0	19 (9.5)	1 (0.5)	0	0	0	20 (10.0)			
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0	2 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)			
Day 8										
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 0	0	190 (95.0)	2 (1.0)	0	0	0	192 (96.0)			
Grade 1	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0	2 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	188 (94.0)	2 (1.0)	0	0	0	190 (95.0)		
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6 (3.0)		
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 3	0	0	0	1 (0.5)	0	0	1 (0.5)		
Grade 4	0	0	0	0	0	0	0		
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)		
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	185 (92.5)	2 (1.0)	0	0	0	187 (93.5)		
Grade 1	0	7 (3.5)	1 (0.5)	1 (0.5)	0	0	9 (4.5)		
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	172 (86.0)	2 (1.0)	1 (0.5)	0	0	175 (87.5)	
Grade 1	0	17 (8.5)	0	0	0	0	17 (8.5)	
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 3	0	0	1 (0.5)	0	0	0	1 (0.5)	
Grade 4	0	0	0	0	0	0	0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	1 (0.5)	0	0	0	5 (2.5)	
Grade 0	0	186 (93.0)	2 (1.0)	1 (0.5)	0	0	189 (94.5)	
Grade 1	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	7 (3.5)	0	0	0	0		7	(3.5)
Grade 0	0	180 (90.0)	3 (1.5)	0	0	0		183	(91.5)
Grade 1	0	9 (4.5)	0	0	0	0		9	(4.5)
Grade 2	0	0	0	1 (0.5)	0	0		1	(0.5)
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0		200	(100)
Day 57									
UNK	0	5 (2.5)	0	0	0	0		5	(2.5)
Grade 0	0	186 (93.0)	3 (1.5)	0	0	0		189	(94.5)
Grade 1	0	4 (2.0)	0	0	0	0		4	(2.0)
Grade 2	0	1 (0.5)	0	1 (0.5)	0	0		2	(1.0)
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	151 (75.5)	1 (0.5)	0	0	0		152 (76.0)	
Grade 1	0	37 (18.5)	1 (0.5)	0	0	0		38 (19.0)	
Grade 2	0	6 (3.0)	0	0	0	0		6 (3.0)	
Grade 3	0	2 (1.0)	1 (0.5)	1 (0.5)	0	0		4 (2.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)
Day 8									
UNK	0	1 (0.5)	0	0	0	0	0	1	(0.5)
Grade 0	0	198 (99.0)	0	0	0	0	0	198	(99.0)
Grade 1	0	1 (0.5)	0	0	0	0	0	1	(0.5)
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	2	(1.0)	0	0	0	0	2	(1.0)
Grade 0	0	196	(98.0)	0	0	0	0	196	(98.0)
Grade 1	0	2	(1.0)	0	0	0	0	2	(1.0)
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)
Day 29 - Predose									
UNK	0	3	(1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197	(98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	193 (96.5)	0	0	0	0	193 (96.5)	
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	7 (3.5)	0	0	0	0	0	7	(3.5)
Grade 0	0	192 (96.0)	0	0	0	0	0	192	(96.0)
Grade 1	0	1 (0.5)	0	0	0	0	0	1	(0.5)
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)
Day 57									
UNK	0	5 (2.5)	0	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	195 (97.5)	0	0	0	0	195	(97.5)
Grade 1	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline											
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)
Day 1 - 1 Hour Postdose												
UNK	0	0		0		0		0		0		0
Grade 0	0	178	(89.0)	6	(3.0)	0		0		0		184 (92.0)
Grade 1	0	4	(2.0)	11	(5.5)	1	(0.5)	0		0		16 (8.0)
Grade 2	0	0		0		0		0		0		0
Grade 3	0	0		0		0		0		0		0
Grade 4	0	0		0		0		0		0		0
Total	0	182	(91.0)	17	(8.5)	1	(0.5)	0		0		200 (100)
Day 8												
UNK	0	1	(0.5)	0		0		0		0		1 (0.5)
Grade 0	0	178	(89.0)	11	(5.5)	1	(0.5)	0		0		190 (95.0)
Grade 1	0	3	(1.5)	6	(3.0)	0		0		0		9 (4.5)
Grade 2	0	0		0		0		0		0		0
Grade 3	0	0		0		0		0		0		0
Grade 4	0	0		0		0		0		0		0
Total	0	182	(91.0)	17	(8.5)	1	(0.5)	0		0		200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 15													
UNK	0	2	(1.0)	0		0		0		0		2	(1.0)
Grade 0	0	175	(87.5)	4	(2.0)	0		0		0		179	(89.5)
Grade 1	0	5	(2.5)	13	(6.5)	1	(0.5)	0		0		19	(9.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	182	(91.0)	17	(8.5)	1	(0.5)	0		0		200	(100)
Day 29 - Predose													
UNK	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 0	0	173	(86.5)	3	(1.5)	0		0		0		176	(88.0)
Grade 1	0	6	(3.0)	14	(7.0)	1	(0.5)	0		0		21	(10.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	182	(91.0)	17	(8.5)	1	(0.5)	0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	4 (2.0)	1 (0.5)	0	0	0	5 (2.5)			
Grade 0	0	174 (87.0)	9 (4.5)	0	0	0	183 (91.5)			
Grade 1	0	4 (2.0)	7 (3.5)	1 (0.5)	0	0	12 (6.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	182 (91.0)	17 (8.5)	1 (0.5)	0	0	200 (100)			
Day 36										
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 0	0	173 (86.5)	14 (7.0)	1 (0.5)	0	0	188 (94.0)			
Grade 1	0	4 (2.0)	3 (1.5)	0	0	0	7 (3.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	182 (91.0)	17 (8.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	7 (3.5)	0	0	0	0		7	(3.5)
Grade 0	0	170 (85.0)	9 (4.5)	0	0	0		179	(89.5)
Grade 1	0	5 (2.5)	8 (4.0)	1 (0.5)	0	0		14	(7.0)
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	182 (91.0)	17 (8.5)	1 (0.5)	0	0		200	(100)
Day 57									
UNK	0	5 (2.5)	0	0	0	0		5	(2.5)
Grade 0	0	175 (87.5)	11 (5.5)	0	0	0		186	(93.0)
Grade 1	0	2 (1.0)	6 (3.0)	1 (0.5)	0	0		9	(4.5)
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	182 (91.0)	17 (8.5)	1 (0.5)	0	0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline						
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	159 (79.5)	0	0	0	0	159 (79.5)
Grade 1	0	23 (11.5)	17 (8.5)	1 (0.5)	0	0	41 (20.5)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	182 (91.0)	17 (8.5)	1 (0.5)	0	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	198 (99.0)	2 (1.0)	0	0	0		200	(100)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	198 (99.0)	2 (1.0)	0	0	0		200	(100)
Day 8									
UNK	0	0	0	0	0	0		0	
Grade 0	0	198 (99.0)	1 (0.5)	0	0	0		199	(99.5)
Grade 1	0	0	1 (0.5)	0	0	0		1	(0.5)
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	198 (99.0)	2 (1.0)	0	0	0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	194 (97.0)	2 (1.0)	0	0	0	196	(98.0)	
Grade 1	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	198 (99.0)	2 (1.0)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	195 (97.5)	2 (1.0)	0	0	0	197	(98.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	198 (99.0)	2 (1.0)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	193 (96.5)	2 (1.0)	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	
Day 36								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	193 (96.5)	2 (1.0)	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)	
Grade 0	0	191 (95.5)	2 (1.0)	0	0	0	193 (96.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	
Day 57								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	193 (96.5)	2 (1.0)	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	196 (98.0)	1 (0.5)	0	0	0		197 (98.5)	
Grade 1	0	2 (1.0)	1 (0.5)	0	0	0		3 (1.5)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	198 (99.0)	2 (1.0)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	0	0	0	0	0	0			
Grade 0	0	184 (92.0)	3 (1.5)	0	0	0	187 (93.5)			
Grade 1	0	6 (3.0)	4 (2.0)	1 (0.5)	0	0	11 (5.5)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	1 (0.5)	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			
Day 8										
UNK	0	0	0	0	0	0	0			
Grade 0	0	187 (93.5)	5 (2.5)	0	1 (0.5)	0	193 (96.5)			
Grade 1	0	3 (1.5)	1 (0.5)	1 (0.5)	0	0	5 (2.5)			
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 0	0	187 (93.5)	4 (2.0)	1 (0.5)	0	0	192 (96.0)			
Grade 1	0	2 (1.0)	3 (1.5)	0	1 (0.5)	0	6 (3.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			
Day 29 - Predose										
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)			
Grade 0	0	183 (91.5)	5 (2.5)	0	0	0	188 (94.0)			
Grade 1	0	5 (2.5)	2 (1.0)	0	1 (0.5)	0	8 (4.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	1 (0.5)	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 0	0	176 (88.0)	5 (2.5)	1 (0.5)	1 (0.5)	0	183 (91.5)			
Grade 1	0	9 (4.5)	2 (1.0)	0	0	0	11 (5.5)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			
Day 36										
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 0	0	181 (90.5)	5 (2.5)	0	1 (0.5)	0	187 (93.5)			
Grade 1	0	5 (2.5)	1 (0.5)	1 (0.5)	0	0	7 (3.5)			
Grade 2	0	0	1 (0.5)	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)			
Grade 0	0	176 (88.0)	6 (3.0)	0	1 (0.5)	0	183 (91.5)			
Grade 1	0	5 (2.5)	0	1 (0.5)	0	0	6 (3.0)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	2 (1.0)	1 (0.5)	0	0	0	3 (1.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			
Day 57										
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 0	0	174 (87.0)	6 (3.0)	1 (0.5)	1 (0.5)	0	182 (91.0)			
Grade 1	0	12 (6.0)	0	0	0	0	12 (6.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	1 (0.5)	0	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	153 (76.5)	1 (0.5)	0	0	0		154 (77.0)	
Grade 1	0	32 (16.0)	3 (1.5)	0	0	0		35 (17.5)	
Grade 2	0	4 (2.0)	2 (1.0)	0	0	0		6 (3.0)	
Grade 3	0	2 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	0		5 (2.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	191 (95.5)	7 (3.5)	1 (0.5)	1 (0.5)	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 8								
UNK	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 29 - Predose								
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 36								
UNK	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	7 (3.5)	0	0	0	0	0	7	(3.5)
Grade 0	0	193 (96.5)	0	0	0	0	0	193	(96.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)
Day 57									
UNK	0	6 (3.0)	0	0	0	0	0	6	(3.0)
Grade 0	0	194 (97.0)	0	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 0	0	187 (93.5)	4 (2.0)	1 (0.5)	0	0	192 (96.0)			
Grade 1	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0	200 (100)			
Day 8										
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 0	0	190 (95.0)	4 (2.0)	1 (0.5)	0	0	195 (97.5)			
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	193 (96.5)	4 (2.0)	1 (0.5)	0	0		198 (99.0)	
Grade 1	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0		200 (100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 0	0	192 (96.0)	4 (2.0)	1 (0.5)	0	0		197 (98.5)	
Grade 1	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 29 - 1 Hour									
Postdose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	185 (92.5)	4 (2.0)	1 (0.5)	0	0	190	(95.0)	
Grade 1	0	4 (2.0)	0	0	0	0	4	(2.0)	
Grade 2	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0	200	(100)	
Day 36									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	189 (94.5)	4 (2.0)	1 (0.5)	0	0	194	(97.0)	
Grade 1	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 4	0	0	0	0	0	0	0		
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	5	(2.5)	0		0		0		0		5	(2.5)
Grade 0	0	186	(93.0)	4	(2.0)	1	(0.5)	0		0		191	(95.5)
Grade 1	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 4	0	0		0		0		0		0		0	
Total	0	195	(97.5)	4	(2.0)	1	(0.5)	0		0		200	(100)
Day 57													
UNK	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 0	0	190	(95.0)	4	(2.0)	1	(0.5)	0		0		195	(97.5)
Grade 1	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 2	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	195	(97.5)	4	(2.0)	1	(0.5)	0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	174 (87.0)	4 (2.0)	1 (0.5)	0	0		179 (89.5)	
Grade 1	0	15 (7.5)	0	0	0	0		15 (7.5)	
Grade 2	0	5 (2.5)	0	0	0	0		5 (2.5)	
Grade 3	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	195 (97.5)	4 (2.0)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 1 - 1 Hour Postdose													
UNK	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 0	0	171	(85.5)	8	(4.0)	0		0		0		179	(89.5)
Grade 1	0	14	(7.0)	1	(0.5)	0		0		0		15	(7.5)
Grade 2	0	3	(1.5)	2	(1.0)	0		0		0		5	(2.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	189	(94.5)	11	(5.5)	0		0		0		200	(100)
Day 8													
UNK	0	2	(1.0)	0		0		0		0		2	(1.0)
Grade 0	0	181	(90.5)	8	(4.0)	0		0		0		189	(94.5)
Grade 1	0	3	(1.5)	3	(1.5)	0		0		0		6	(3.0)
Grade 2	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	189	(94.5)	11	(5.5)	0		0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	184 (92.0)	8 (4.0)	0	0	0		192 (96.0)	
Grade 1	0	4 (2.0)	2 (1.0)	0	0	0		6 (3.0)	
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0		2 (1.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	189 (94.5)	11 (5.5)	0	0	0		200 (100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 0	0	182 (91.0)	10 (5.0)	0	0	0		192 (96.0)	
Grade 1	0	4 (2.0)	1 (0.5)	0	0	0		5 (2.5)	
Grade 2	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	189 (94.5)	11 (5.5)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour									
Postdose									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	171 (85.5)	8 (4.0)	0	0	0	179 (89.5)		
Grade 1	0	13 (6.5)	2 (1.0)	0	0	0	15 (7.5)		
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)		
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 4	0	0	0	0	0	0	0		
Total	0	189 (94.5)	11 (5.5)	0	0	0	200 (100)		
Day 36									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	179 (89.5)	10 (5.0)	0	0	0	189 (94.5)		
Grade 1	0	8 (4.0)	0	0	0	0	8 (4.0)		
Grade 2	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	189 (94.5)	11 (5.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	180	(90.0)	10	(5.0)	0		0		0		190	(95.0)
Grade 1	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 2	0	0		1	(0.5)	0		0		0		1	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	189	(94.5)	11	(5.5)	0		0		0		200	(100)
Day 57													
UNK	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 0	0	179	(89.5)	8	(4.0)	0		0		0		187	(93.5)
Grade 1	0	4	(2.0)	3	(1.5)	0		0		0		7	(3.5)
Grade 2	0	3	(1.5)	0		0		0		0		3	(1.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	189	(94.5)	11	(5.5)	0		0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	150 (75.0)	6 (3.0)	0	0	0	156	(78.0)
Grade 1	0	31 (15.5)	1 (0.5)	0	0	0	32	(16.0)
Grade 2	0	7 (3.5)	4 (2.0)	0	0	0	11	(5.5)
Grade 3	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 4	0	0	0	0	0	0	0	
Total	0	189 (94.5)	11 (5.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0	0	198 (99.0)	1 (0.5)	0	0	0	199 (99.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 8								
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 0	0	197 (98.5)	1 (0.5)	0	0	0	198 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	199 (99.5)	1 (0.5)	0	0	0		200	(100)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	199 (99.5)	1 (0.5)	0	0	0		200	(100)
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0		2	(1.0)
Grade 0	0	197 (98.5)	1 (0.5)	0	0	0		198	(99.0)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	199 (99.5)	1 (0.5)	0	0	0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	196 (98.0)	1 (0.5)	0	0	0	197 (98.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 36								
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 0	0	196 (98.0)	1 (0.5)	0	0	0	197 (98.5)	
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	6 (3.0)	0	0	0	0	0	6	(3.0)
Grade 0	0	193 (96.5)	1 (0.5)	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	0	200	(100)
Day 57									
UNK	0	3 (1.5)	0	0	0	0	0	3	(1.5)
Grade 0	0	196 (98.0)	1 (0.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	198 (99.0)	1 (0.5)	0	0	0	199	(99.5)
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0	0	160 (80.0)	9 (4.5)	0	0	0	169	(84.5)
Grade 1	0	8 (4.0)	22 (11.0)	0	0	0	30	(15.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	200	(100)
Day 8								
UNK	0	0	2 (1.0)	0	0	0	2	(1.0)
Grade 0	0	162 (81.0)	17 (8.5)	0	0	0	179	(89.5)
Grade 1	0	7 (3.5)	12 (6.0)	0	0	0	19	(9.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 15									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	161 (80.5)	7 (3.5)	0	0	0	0	168 (84.0)	
Grade 1	0	8 (4.0)	24 (12.0)	0	0	0	0	32 (16.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	0	200 (100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	0	2 (1.0)	
Grade 0	0	158 (79.0)	8 (4.0)	0	0	0	0	166 (83.0)	
Grade 1	0	9 (4.5)	23 (11.5)	0	0	0	0	32 (16.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	163 (81.5)	15 (7.5)	0	0	0	178 (89.0)	
Grade 1	0	3 (1.5)	16 (8.0)	0	0	0	19 (9.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)	
Day 36								
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 0	0	160 (80.0)	20 (10.0)	0	0	0	180 (90.0)	
Grade 1	0	7 (3.5)	11 (5.5)	0	0	0	18 (9.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	162 (81.0)	14 (7.0)	0	0	0	176 (88.0)		
Grade 1	0	2 (1.0)	17 (8.5)	0	0	0	19 (9.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)		
Day 57									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	164 (82.0)	18 (9.0)	0	0	0	182 (91.0)		
Grade 1	0	2 (1.0)	13 (6.5)	0	0	0	15 (7.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	169 (84.5)	31 (15.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	140 (70.0)	2 (1.0)	0	0	0	142	(71.0)
Grade 1	0	29 (14.5)	29 (14.5)	0	0	0	58	(29.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	169 (84.5)	31 (15.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 8								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	0		0	0	0	0	0	
Grade 0	0	200	(100)	0	0	0	0	200	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)
Day 29 - Predose									
UNK	0	2	(1.0)	0	0	0	0	2	(1.0)
Grade 0	0	196	(98.0)	0	0	0	0	196	(98.0)
Grade 1	0	2	(1.0)	0	0	0	0	2	(1.0)
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 36								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	5 (2.5)	0	0	0	0	0	5	(2.5)
Grade 0	0	195 (97.5)	0	0	0	0	0	195	(97.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)
Day 57									
UNK	0	3 (1.5)	0	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 0	0	177 (88.5)	5 (2.5)	0	0	0	182 (91.0)		
Grade 1	0	11 (5.5)	2 (1.0)	0	0	0	13 (6.5)		
Grade 2	0	2 (1.0)	1 (0.5)	0	0	0	3 (1.5)		
Grade 3	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200 (100)		
Day 8									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	184 (92.0)	6 (3.0)	0	0	0	190 (95.0)		
Grade 1	0	4 (2.0)	2 (1.0)	0	0	0	6 (3.0)		
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 3	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	186 (93.0)	7 (3.5)	0	0	0		193 (96.5)	
Grade 1	0	5 (2.5)	2 (1.0)	0	0	0		7 (3.5)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	191 (95.5)	9 (4.5)	0	0	0		200 (100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 0	0	185 (92.5)	8 (4.0)	0	0	0		193 (96.5)	
Grade 1	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 2	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 3	0	0	1 (0.5)	0	0	0		1 (0.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	191 (95.5)	9 (4.5)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour									
Postdose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	181 (90.5)	8 (4.0)	0	0	0	189	(94.5)	
Grade 1	0	4 (2.0)	0	0	0	0	4	(2.0)	
Grade 2	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 3	0	1 (0.5)	1 (0.5)	0	0	0	2	(1.0)	
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200	(100)	
Day 36									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	184 (92.0)	7 (3.5)	0	0	0	191	(95.5)	
Grade 1	0	4 (2.0)	2 (1.0)	0	0	0	6	(3.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)		
Grade 0	0	179 (89.5)	8 (4.0)	0	0	0	187 (93.5)		
Grade 1	0	7 (3.5)	1 (0.5)	0	0	0	8 (4.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200 (100)		
Day 57									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	181 (90.5)	8 (4.0)	0	0	0	189 (94.5)		
Grade 1	0	7 (3.5)	0	0	0	0	7 (3.5)		
Grade 2	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	191 (95.5)	9 (4.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline						
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	158 (79.0)	5 (2.5)	0	0	0	163 (81.5)
Grade 1	0	26 (13.0)	1 (0.5)	0	0	0	27 (13.5)
Grade 2	0	6 (3.0)	1 (0.5)	0	0	0	7 (3.5)
Grade 3	0	1 (0.5)	2 (1.0)	0	0	0	3 (1.5)
Grade 4	0	0	0	0	0	0	0
Total	0	191 (95.5)	9 (4.5)	0	0	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 8								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 15									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	199 (99.5)	0	0	0	0	0	199 (99.5)	
Grade 1	0	1 (0.5)	0	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200 (100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	0	2 (1.0)	
Grade 0	0	198 (99.0)	0	0	0	0	0	198 (99.0)	
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 36								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 57								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	197 (98.5)	0	0	0	0	197 (98.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 0	0	385 (96.3)	4 (1.0)	1 (0.3)	0	0	390 (97.5)	
Grade 1	0	6 (1.5)	0	0	0	0	6 (1.5)	
Grade 2	0	3 (0.8)	0	0	0	0	3 (0.8)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	395 (98.8)	4 (1.0)	1 (0.3)	0	0	400 (100)	
Day 8								
UNK	0	2 (0.5)	0	0	0	0	2 (0.5)	
Grade 0	0	383 (95.8)	4 (1.0)	1 (0.3)	0	0	388 (97.0)	
Grade 1	0	8 (2.0)	0	0	0	0	8 (2.0)	
Grade 2	0	2 (0.5)	0	0	0	0	2 (0.5)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	395 (98.8)	4 (1.0)	1 (0.3)	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 15													
UNK	0	2	(0.5)	0		0		0		0		2	(0.5)
Grade 0	0	386	(96.5)	4	(1.0)	1	(0.3)	0		0		391	(97.8)
Grade 1	0	7	(1.8)	0		0		0		0		7	(1.8)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	395	(98.8)	4	(1.0)	1	(0.3)	0		0		400	(100)
Day 29 - Predose													
UNK	0	5	(1.3)	0		0		0		0		5	(1.3)
Grade 0	0	382	(95.5)	4	(1.0)	1	(0.3)	0		0		387	(96.8)
Grade 1	0	8	(2.0)	0		0		0		0		8	(2.0)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	395	(98.8)	4	(1.0)	1	(0.3)	0		0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)	
Grade 0	0	372 (93.0)	4 (1.0)	1 (0.3)	0	0	377 (94.3)	
Grade 1	0	11 (2.8)	0	0	0	0	11 (2.8)	
Grade 2	0	4 (1.0)	0	0	0	0	4 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	395 (98.8)	4 (1.0)	1 (0.3)	0	0	400 (100)	
Day 36								
UNK	0	7 (1.8)	0	0	0	0	7 (1.8)	
Grade 0	0	381 (95.3)	4 (1.0)	1 (0.3)	0	0	386 (96.5)	
Grade 1	0	5 (1.3)	0	0	0	0	5 (1.3)	
Grade 2	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 3	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 4	0	0	0	0	0	0	0	
Total	0	395 (98.8)	4 (1.0)	1 (0.3)	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	12	(3.0)	0		0		0		0		12	(3.0)
Grade 0	0	375	(93.8)	4	(1.0)	1	(0.3)	0		0		380	(95.0)
Grade 1	0	7	(1.8)	0		0		0		0		7	(1.8)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	1	(0.3)	0		0		0		0		1	(0.3)
Grade 4	0	0		0		0		0		0		0	
Total	0	395	(98.8)	4	(1.0)	1	(0.3)	0		0		400	(100)
Day 57													
UNK	0	8	(2.0)	0		0		0		0		8	(2.0)
Grade 0	0	382	(95.5)	4	(1.0)	1	(0.3)	0		0		387	(96.8)
Grade 1	0	3	(0.8)	0		0		0		0		3	(0.8)
Grade 2	0	2	(0.5)	0		0		0		0		2	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	395	(98.8)	4	(1.0)	1	(0.3)	0		0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	347 (86.8)	4 (1.0)	1 (0.3)	0	0	0	352 (88.0)	
Grade 1	0	37 (9.3)	0	0	0	0	0	37 (9.3)	
Grade 2	0	10 (2.5)	0	0	0	0	0	10 (2.5)	
Grade 3	0	1 (0.3)	0	0	0	0	0	1 (0.3)	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	395 (98.8)	4 (1.0)	1 (0.3)	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 1 - 1 Hour Postdose													
UNK	0	1	(0.3)	0		0		0		0		1	(0.3)
Grade 0	0	345	(86.3)	10	(2.5)	0		0		0		355	(88.8)
Grade 1	0	33	(8.3)	2	(0.5)	0		0		0		35	(8.8)
Grade 2	0	5	(1.3)	2	(0.5)	0		0		0		7	(1.8)
Grade 3	0	1	(0.3)	0		1	(0.3)	0		0		2	(0.5)
Grade 4	0	0		0		0		0		0		0	
Total	0	385	(96.3)	14	(3.5)	1	(0.3)	0		0		400	(100)
Day 8													
UNK	0	3	(0.8)	0		0		0		0		3	(0.8)
Grade 0	0	371	(92.8)	10	(2.5)	0		0		0		381	(95.3)
Grade 1	0	6	(1.5)	4	(1.0)	0		0		0		10	(2.5)
Grade 2	0	4	(1.0)	0		0		0		0		4	(1.0)
Grade 3	0	1	(0.3)	0		1	(0.3)	0		0		2	(0.5)
Grade 4	0	0		0		0		0		0		0	
Total	0	385	(96.3)	14	(3.5)	1	(0.3)	0		0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 15													
UNK	0	2	(0.5)	0		0		0		0		2	(0.5)
Grade 0	0	372	(93.0)	10	(2.5)	0		0		0		382	(95.5)
Grade 1	0	9	(2.3)	3	(0.8)	0		0		0		12	(3.0)
Grade 2	0	2	(0.5)	1	(0.3)	0		0		0		3	(0.8)
Grade 3	0	0		0		1	(0.3)	0		0		1	(0.3)
Grade 4	0	0		0		0		0		0		0	
Total	0	385	(96.3)	14	(3.5)	1	(0.3)	0		0		400	(100)
Day 29 - Predose													
UNK	0	5	(1.3)	0		0		0		0		5	(1.3)
Grade 0	0	367	(91.8)	12	(3.0)	0		0		0		379	(94.8)
Grade 1	0	11	(2.8)	2	(0.5)	1	(0.3)	0		0		14	(3.5)
Grade 2	0	2	(0.5)	0		0		0		0		2	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	385	(96.3)	14	(3.5)	1	(0.3)	0		0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)			
Grade 0	0	343 (85.8)	10 (2.5)	1 (0.3)	0	0	354 (88.5)			
Grade 1	0	30 (7.5)	2 (0.5)	0	0	0	32 (8.0)			
Grade 2	0	3 (0.8)	1 (0.3)	0	0	0	4 (1.0)			
Grade 3	0	1 (0.3)	1 (0.3)	0	0	0	2 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	385 (96.3)	14 (3.5)	1 (0.3)	0	0	400 (100)			
Day 36										
UNK	0	6 (1.5)	1 (0.3)	0	0	0	7 (1.8)			
Grade 0	0	365 (91.3)	12 (3.0)	1 (0.3)	0	0	378 (94.5)			
Grade 1	0	13 (3.3)	0	0	0	0	13 (3.3)			
Grade 2	0	1 (0.3)	1 (0.3)	0	0	0	2 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	385 (96.3)	14 (3.5)	1 (0.3)	0	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	13 (3.3)	0	0	0	0		13	(3.3)
Grade 0	0	360 (90.0)	13 (3.3)	0	0	0		373	(93.3)
Grade 1	0	12 (3.0)	0	0	0	0		12	(3.0)
Grade 2	0	0	1 (0.3)	1 (0.3)	0	0		2	(0.5)
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	385 (96.3)	14 (3.5)	1 (0.3)	0	0		400	(100)
Day 57									
UNK	0	8 (2.0)	0	0	0	0		8	(2.0)
Grade 0	0	365 (91.3)	11 (2.8)	0	0	0		376	(94.0)
Grade 1	0	8 (2.0)	3 (0.8)	0	0	0		11	(2.8)
Grade 2	0	4 (1.0)	0	1 (0.3)	0	0		5	(1.3)
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	385 (96.3)	14 (3.5)	1 (0.3)	0	0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	301 (75.3)	7 (1.8)	0	0	0	308 (77.0)
Grade 1	0	68 (17.0)	2 (0.5)	0	0	0	70 (17.5)
Grade 2	0	13 (3.3)	4 (1.0)	0	0	0	17 (4.3)
Grade 3	0	3 (0.8)	1 (0.3)	1 (0.3)	0	0	5 (1.3)
Grade 4	0	0	0	0	0	0	0
Total	0	385 (96.3)	14 (3.5)	1 (0.3)	0	0	400 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 0	0	398 (99.5)	1 (0.3)	0	0	0	399 (99.8)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	399 (99.8)	1 (0.3)	0	0	0	400 (100)	
Day 8								
UNK	0	3 (0.8)	0	0	0	0	3 (0.8)	
Grade 0	0	395 (98.8)	1 (0.3)	0	0	0	396 (99.0)	
Grade 1	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	399 (99.8)	1 (0.3)	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 0	0	395 (98.8)	1 (0.3)	0	0	0	396	(99.0)	
Grade 1	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	399 (99.8)	1 (0.3)	0	0	0	400	(100)	
Day 29 - Predose									
UNK	0	5 (1.3)	0	0	0	0	5	(1.3)	
Grade 0	0	394 (98.5)	1 (0.3)	0	0	0	395	(98.8)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	399 (99.8)	1 (0.3)	0	0	0	400	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)	
Grade 0	0	391 (97.8)	1 (0.3)	0	0	0	392 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	399 (99.8)	1 (0.3)	0	0	0	400 (100)	
Day 36								
UNK	0	7 (1.8)	0	0	0	0	7 (1.8)	
Grade 0	0	389 (97.3)	1 (0.3)	0	0	0	390 (97.5)	
Grade 1	0	3 (0.8)	0	0	0	0	3 (0.8)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	399 (99.8)	1 (0.3)	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	13 (3.3)	0	0	0	0		13	(3.3)
Grade 0	0	385 (96.3)	1 (0.3)	0	0	0		386	(96.5)
Grade 1	0	1 (0.3)	0	0	0	0		1	(0.3)
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	399 (99.8)	1 (0.3)	0	0	0		400	(100)
Day 57									
UNK	0	8 (2.0)	0	0	0	0		8	(2.0)
Grade 0	0	391 (97.8)	1 (0.3)	0	0	0		392	(98.0)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	399 (99.8)	1 (0.3)	0	0	0		400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	393 (98.3)	1 (0.3)	0	0	0	394	(98.5)
Grade 1	0	6 (1.5)	0	0	0	0	6	(1.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	399 (99.8)	1 (0.3)	0	0	0	400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	1 (0.3)	0	0	0	0	1 (0.3)			
Grade 0	0	338 (84.5)	15 (3.8)	0	0	0	353 (88.3)			
Grade 1	0	12 (3.0)	33 (8.3)	1 (0.3)	0	0	46 (11.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			
Day 8										
UNK	0	1 (0.3)	2 (0.5)	0	0	0	3 (0.8)			
Grade 0	0	340 (85.0)	28 (7.0)	1 (0.3)	0	0	369 (92.3)			
Grade 1	0	10 (2.5)	18 (4.5)	0	0	0	28 (7.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	2 (0.5)	0	0	0	0	2 (0.5)			
Grade 0	0	336 (84.0)	11 (2.8)	0	0	0	347 (86.8)			
Grade 1	0	13 (3.3)	37 (9.3)	1 (0.3)	0	0	51 (12.8)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			
Day 29 - Predose										
UNK	0	5 (1.3)	0	0	0	0	5 (1.3)			
Grade 0	0	331 (82.8)	11 (2.8)	0	0	0	342 (85.5)			
Grade 1	0	15 (3.8)	37 (9.3)	1 (0.3)	0	0	53 (13.3)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	7 (1.8)	1 (0.3)	0	0	0	8 (2.0)			
Grade 0	0	337 (84.3)	24 (6.0)	0	0	0	361 (90.3)			
Grade 1	0	7 (1.8)	23 (5.8)	1 (0.3)	0	0	31 (7.8)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			
Day 36										
UNK	0	7 (1.8)	0	0	0	0	7 (1.8)			
Grade 0	0	333 (83.3)	34 (8.5)	1 (0.3)	0	0	368 (92.0)			
Grade 1	0	11 (2.8)	14 (3.5)	0	0	0	25 (6.3)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	12 (3.0)	0	0	0	0	12 (3.0)			
Grade 0	0	332 (83.0)	23 (5.8)	0	0	0	355 (88.8)			
Grade 1	0	7 (1.8)	25 (6.3)	1 (0.3)	0	0	33 (8.3)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			
Day 57										
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)			
Grade 0	0	339 (84.8)	29 (7.3)	0	0	0	368 (92.0)			
Grade 1	0	4 (1.0)	19 (4.8)	1 (0.3)	0	0	24 (6.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	299 (74.8)	2 (0.5)	0	0	0	301 (75.3)
Grade 1	0	52 (13.0)	46 (11.5)	1 (0.3)	0	0	99 (24.8)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.3)	0	0	0	0	1	(0.3)
Grade 0	0	397 (99.3)	2 (0.5)	0	0	0	399	(99.8)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400	(100)
Day 8								
UNK	0	2 (0.5)	0	0	0	0	2	(0.5)
Grade 0	0	396 (99.0)	1 (0.3)	0	0	0	397	(99.3)
Grade 1	0	0	1 (0.3)	0	0	0	1	(0.3)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 0	0	394 (98.5)	2 (0.5)	0	0	0	396	(99.0)	
Grade 1	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	398 (99.5)	2 (0.5)	0	0	0	400	(100)	
Day 29 - Predose									
UNK	0	5 (1.3)	0	0	0	0	5	(1.3)	
Grade 0	0	391 (97.8)	2 (0.5)	0	0	0	393	(98.3)	
Grade 1	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	398 (99.5)	2 (0.5)	0	0	0	400	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)	
Grade 0	0	390 (97.5)	2 (0.5)	0	0	0	392 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400 (100)	
Day 36								
UNK	0	7 (1.8)	0	0	0	0	7 (1.8)	
Grade 0	0	391 (97.8)	2 (0.5)	0	0	0	393 (98.3)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	12 (3.0)	0	0	0	0	12 (3.0)	
Grade 0	0	386 (96.5)	2 (0.5)	0	0	0	388 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400 (100)	
Day 57								
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)	
Grade 0	0	390 (97.5)	2 (0.5)	0	0	0	392 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	398 (99.5)	2 (0.5)	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	394 (98.5)	1 (0.3)	0	0	0		395 (98.8)	
Grade 1	0	4 (1.0)	1 (0.3)	0	0	0		5 (1.3)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	398 (99.5)	2 (0.5)	0	0	0		400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	1 (0.3)	0	0	0	0	1 (0.3)			
Grade 0	0	361 (90.3)	8 (2.0)	0	0	0	369 (92.3)			
Grade 1	0	17 (4.3)	6 (1.5)	1 (0.3)	0	0	24 (6.0)			
Grade 2	0	3 (0.8)	1 (0.3)	0	0	0	4 (1.0)			
Grade 3	0	0	1 (0.3)	0	1 (0.3)	0	2 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			
Day 8										
UNK	0	2 (0.5)	0	0	0	0	2 (0.5)			
Grade 0	0	371 (92.8)	11 (2.8)	0	1 (0.3)	0	383 (95.8)			
Grade 1	0	7 (1.8)	3 (0.8)	1 (0.3)	0	0	11 (2.8)			
Grade 2	0	2 (0.5)	1 (0.3)	0	0	0	3 (0.8)			
Grade 3	0	0	1 (0.3)	0	0	0	1 (0.3)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	2 (0.5)	0	0	0	0	2 (0.5)			
Grade 0	0	373 (93.3)	11 (2.8)	1 (0.3)	0	0	385 (96.3)			
Grade 1	0	7 (1.8)	5 (1.3)	0	1 (0.3)	0	13 (3.3)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			
Day 29 - Predose										
UNK	0	5 (1.3)	0	0	0	0	5 (1.3)			
Grade 0	0	368 (92.0)	13 (3.3)	0	0	0	381 (95.3)			
Grade 1	0	7 (1.8)	2 (0.5)	0	1 (0.3)	0	10 (2.5)			
Grade 2	0	2 (0.5)	0	0	0	0	2 (0.5)			
Grade 3	0	0	1 (0.3)	1 (0.3)	0	0	2 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)			
Grade 0	0	357 (89.3)	13 (3.3)	1 (0.3)	1 (0.3)	0	372 (93.0)			
Grade 1	0	13 (3.3)	2 (0.5)	0	0	0	15 (3.8)			
Grade 2	0	3 (0.8)	0	0	0	0	3 (0.8)			
Grade 3	0	1 (0.3)	1 (0.3)	0	0	0	2 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			
Day 36										
UNK	0	7 (1.8)	0	0	0	0	7 (1.8)			
Grade 0	0	365 (91.3)	12 (3.0)	0	1 (0.3)	0	378 (94.5)			
Grade 1	0	9 (2.3)	3 (0.8)	1 (0.3)	0	0	13 (3.3)			
Grade 2	0	1 (0.3)	1 (0.3)	0	0	0	2 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	12 (3.0)	0	0	0	0	12 (3.0)			
Grade 0	0	355 (88.8)	14 (3.5)	0	1 (0.3)	0	370 (92.5)			
Grade 1	0	12 (3.0)	1 (0.3)	1 (0.3)	0	0	14 (3.5)			
Grade 2	0	1 (0.3)	0	0	0	0	1 (0.3)			
Grade 3	0	2 (0.5)	1 (0.3)	0	0	0	3 (0.8)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			
Day 57										
UNK	0	8 (2.0)	0	0	0	0	8 (2.0)			
Grade 0	0	355 (88.8)	14 (3.5)	1 (0.3)	1 (0.3)	0	371 (92.8)			
Grade 1	0	19 (4.8)	0	0	0	0	19 (4.8)			
Grade 2	0	0	1 (0.3)	0	0	0	1 (0.3)			
Grade 3	0	0	1 (0.3)	0	0	0	1 (0.3)			
Grade 4	0	0	0	0	0	0	0			
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0	400 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	311 (77.8)	6 (1.5)	0	0	0		317 (79.3)	
Grade 1	0	58 (14.5)	4 (1.0)	0	0	0		62 (15.5)	
Grade 2	0	10 (2.5)	3 (0.8)	0	0	0		13 (3.3)	
Grade 3	0	3 (0.8)	3 (0.8)	1 (0.3)	1 (0.3)	0		8 (2.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	382 (95.5)	16 (4.0)	1 (0.3)	1 (0.3)	0		400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.3)	0	0	0	0	1 (0.3)	
Grade 0	0	399 (99.8)	0	0	0	0	399 (99.8)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400 (100)	
Day 8								
UNK	0	2 (0.5)	0	0	0	0	2 (0.5)	
Grade 0	0	398 (99.5)	0	0	0	0	398 (99.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	2 (0.5)	0	0	0	0	2	(0.5)	
Grade 0	0	397 (99.3)	0	0	0	0	397	(99.3)	
Grade 1	0	1 (0.3)	0	0	0	0	1	(0.3)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	400 (100)	0	0	0	0	400	(100)	
Day 29 - Predose									
UNK	0	5 (1.3)	0	0	0	0	5	(1.3)	
Grade 0	0	395 (98.8)	0	0	0	0	395	(98.8)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	400 (100)	0	0	0	0	400	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	8 (2.0)	0	0	0	0	8	(2.0)
Grade 0	0	392 (98.0)	0	0	0	0	392	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400	(100)
Day 36								
UNK	0	7 (1.8)	0	0	0	0	7	(1.8)
Grade 0	0	392 (98.0)	0	0	0	0	392	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	1 (0.3)	0	0	0	0	1	(0.3)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	12 (3.0)	0	0	0	0	12 (3.0)	
Grade 0	0	388 (97.0)	0	0	0	0	388 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400 (100)	
Day 57								
UNK	0	9 (2.3)	0	0	0	0	9 (2.3)	
Grade 0	0	391 (97.8)	0	0	0	0	391 (97.8)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort Overall; Vaccination Group: mRNA-1273 Total (N=400)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	398 (99.5)	0	0	0	0	398	(99.5)
Grade 1	0	1 (0.3)	0	0	0	0	1	(0.3)
Grade 2	0	1 (0.3)	0	0	0	0	1	(0.3)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	400 (100)	0	0	0	0	400	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	93 (93.0)	3 (3.0)	1 (1.0)	0	0		97 (97.0)	
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0		2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0		100 (100)	
Day 8									
UNK	0	3 (3.0)	0	0	0	0		3 (3.0)	
Grade 0	0	86 (86.0)	4 (4.0)	1 (1.0)	0	0		91 (91.0)	
Grade 1	0	4 (4.0)	0	0	0	0		4 (4.0)	
Grade 2	0	2 (2.0)	0	0	0	0		2 (2.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)			
Grade 0	0	90 (90.0)	4 (4.0)	1 (1.0)	0	0	95 (95.0)			
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			
Day 29 - Predose										
UNK	0	4 (4.0)	1 (1.0)	0	0	0	5 (5.0)			
Grade 0	0	89 (89.0)	3 (3.0)	1 (1.0)	0	0	93 (93.0)			
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)			
Grade 0	0	88 (88.0)	3 (3.0)	1 (1.0)	0	0	92 (92.0)			
Grade 1	0	0	0	0	0	0	0			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			
Day 36										
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)			
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91 (91.0)			
Grade 1	0	0	0	1 (1.0)	0	0	1 (1.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	4 (4.0)	1 (1.0)	0	0	0	5 (5.0)			
Grade 0	0	89 (89.0)	3 (3.0)	1 (1.0)	0	0	93 (93.0)			
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			
Day 57										
UNK	0	4 (4.0)	1 (1.0)	0	0	0	5 (5.0)			
Grade 0	0	89 (89.0)	3 (3.0)	1 (1.0)	0	0	93 (93.0)			
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	84 (84.0)	3 (3.0)	0	0	0	87	(87.0)
Grade 1	0	5 (5.0)	1 (1.0)	1 (1.0)	0	0	7	(7.0)
Grade 2	0	6 (6.0)	0	0	0	0	6	(6.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline										Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4						
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose												
UNK	0	0	0	0	0	0	0	0	0	0	0	
Grade 0	0	83 (83.0)	3 (3.0)	0	0	0	0	0	0	86 (86.0)		
Grade 1	0	7 (7.0)	0	1 (1.0)	0	1 (1.0)	0	0	0	8 (8.0)		
Grade 2	0	2 (2.0)	1 (1.0)	0	1 (1.0)	1 (1.0)	0	0	0	4 (4.0)		
Grade 3	0	1 (1.0)	0	1 (1.0)	1 (1.0)	0	0	0	0	2 (2.0)		
Grade 4	0	0	0	0	0	0	0	0	0	0		
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	2 (2.0)	1 (1.0)	0	0	0	100 (100)		
Day 8												
UNK	0	3 (3.0)	0	0	0	0	0	0	0	3 (3.0)		
Grade 0	0	86 (86.0)	2 (2.0)	0	0	0	0	0	0	88 (88.0)		
Grade 1	0	3 (3.0)	0	2 (2.0)	0	2 (2.0)	0	0	0	5 (5.0)		
Grade 2	0	0	2 (2.0)	0	0	0	0	0	0	2 (2.0)		
Grade 3	0	1 (1.0)	0	0	0	1 (1.0)	0	0	0	2 (2.0)		
Grade 4	0	0	0	0	0	0	0	0	0	0		
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	2 (2.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)			
Grade 0	0	85 (85.0)	3 (3.0)	0	0	0	88 (88.0)			
Grade 1	0	5 (5.0)	0	0	0	0	5 (5.0)			
Grade 2	0	1 (1.0)	0	2 (2.0)	0	0	3 (3.0)			
Grade 3	0	0	0	0	1 (1.0)	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100 (100)			
Day 29 - Predose										
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)			
Grade 0	0	85 (85.0)	4 (4.0)	1 (1.0)	0	0	90 (90.0)			
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	1 (1.0)	1 (1.0)	0	2 (2.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)

Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)			
Grade 0	0	77 (77.0)	1 (1.0)	0	0	0	78 (78.0)			
Grade 1	0	7 (7.0)	2 (2.0)	1 (1.0)	0	0	10 (10.0)			
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 3	0	1 (1.0)	0	1 (1.0)	1 (1.0)	0	3 (3.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100 (100)			
Day 36										
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)			
Grade 0	0	84 (84.0)	2 (2.0)	0	0	0	86 (86.0)			
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 2	0	0	1 (1.0)	2 (2.0)	1 (1.0)	0	4 (4.0)			
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	83 (83.0)	4 (4.0)	0	0	0	87	(87.0)
Grade 1	0	2 (2.0)	0	2 (2.0)	0	0	4	(4.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	1 (1.0)	0	2	(2.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100	(100)
Day 57								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	83 (83.0)	3 (3.0)	1 (1.0)	1 (1.0)	0	88	(88.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)
Grade 2	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 3	0	1 (1.0)	0	1 (1.0)	0	0	2	(2.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	69 (69.0)	2 (2.0)	0	0	0		71 (71.0)	
Grade 1	0	16 (16.0)	0	0	0	0		16 (16.0)	
Grade 2	0	6 (6.0)	2 (2.0)	1 (1.0)	0	0		9 (9.0)	
Grade 3	0	2 (2.0)	0	1 (1.0)	1 (1.0)	0		4 (4.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	99 (99.0)	0	0	0	0	0	99 (99.0)	99 (99.0)
Grade 1	0	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (1.0)
Grade 2	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0
Total	0	100 (100)	0	0	0	0	0	100 (100)	100 (100)
Day 8									
UNK	0	3 (3.0)	0	0	0	0	0	3 (3.0)	3 (3.0)
Grade 0	0	97 (97.0)	0	0	0	0	0	97 (97.0)	97 (97.0)
Grade 1	0	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0	0
Total	0	100 (100)	0	0	0	0	0	100 (100)	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)	
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	7 (7.0)	0	0	0	0	7	(7.0)
Grade 0	0	93 (93.0)	0	0	0	0	93	(93.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	7 (7.0)	0	0	0	0	7	(7.0)
Grade 0	0	93 (93.0)	0	0	0	0	93	(93.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	87 (87.0)	3 (3.0)	0	0	0	90 (90.0)		
Grade 1	0	4 (4.0)	6 (6.0)	0	0	0	10 (10.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)		
Day 8									
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)		
Grade 0	0	85 (85.0)	6 (6.0)	0	0	0	91 (91.0)		
Grade 1	0	3 (3.0)	3 (3.0)	0	0	0	6 (6.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 0	0	83 (83.0)	6 (6.0)	0	0	0	89 (89.0)	
Grade 1	0	6 (6.0)	2 (2.0)	0	0	0	8 (8.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	82 (82.0)	1 (1.0)	0	0	0	83 (83.0)	
Grade 1	0	4 (4.0)	8 (8.0)	0	0	0	12 (12.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)	
Grade 0	0	83 (83.0)	3 (3.0)	0	0	0	86 (86.0)	
Grade 1	0	2 (2.0)	5 (5.0)	0	0	0	7 (7.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	
Day 36								
UNK	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)	
Grade 0	0	84 (84.0)	5 (5.0)	0	0	0	89 (89.0)	
Grade 1	0	1 (1.0)	3 (3.0)	0	0	0	4 (4.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	82 (82.0)	3 (3.0)	0	0	0	85 (85.0)	
Grade 1	0	4 (4.0)	6 (6.0)	0	0	0	10 (10.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	
Day 57								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	83 (83.0)	4 (4.0)	0	0	0	87 (87.0)	
Grade 1	0	3 (3.0)	5 (5.0)	0	0	0	8 (8.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	78 (78.0)	1 (1.0)	0	0	0	79	(79.0)
Grade 1	0	13 (13.0)	8 (8.0)	0	0	0	21	(21.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	91 (91.0)	9 (9.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 8								
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 0	0	95 (95.0)	1 (1.0)	0	0	0	96 (96.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)	
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95	(95.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	7 (7.0)	0	0	0	0	7 (7.0)	
Grade 0	0	92 (92.0)	0	0	0	0	92 (92.0)	
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 36								
UNK	0	7 (7.0)	0	0	0	0	7 (7.0)	
Grade 0	0	92 (92.0)	0	0	0	0	92 (92.0)	
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 57								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	0
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline						
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose							
UNK	0	0	0	0	0	0	0
Grade 0	0	93 (93.0)	2 (2.0)	0	0	0	95 (95.0)
Grade 1	0	3 (3.0)	1 (1.0)	0	0	0	4 (4.0)
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)
Day 8							
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)
Grade 0	0	93 (93.0)	2 (2.0)	0	0	0	95 (95.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 0	0	93 (93.0)	3 (3.0)	0	0	0	96 (96.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	90 (90.0)	2 (2.0)	0	0	0	92 (92.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	7 (7.0)	0	0	0	0	7	(7.0)
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91	(91.0)
Grade 1	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	3 (3.0)	0	0	0	100	(100)
Day 36								
UNK	0	7 (7.0)	0	0	0	0	7	(7.0)
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91	(91.0)
Grade 1	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	3 (3.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)			
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91 (91.0)			
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)			
Day 57										
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)			
Grade 0	0	85 (85.0)	3 (3.0)	0	0	0	88 (88.0)			
Grade 1	0	6 (6.0)	0	0	0	0	6 (6.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	3 (3.0)	0	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	82 (82.0)	1 (1.0)	0	0	0	83	(83.0)
Grade 1	0	12 (12.0)	2 (2.0)	0	0	0	14	(14.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	3 (3.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	3	(3.0)	0	0	0	0	3	(3.0)
Grade 0	0	97	(97.0)	0	0	0	0	97	(97.0)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)		
Grade 0	0	97 (97.0)	0	0	0	0	97 (97.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)		
Grade 0	0	95 (95.0)	0	0	0	0	95 (95.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	7 (7.0)	0	0	0	0	7 (7.0)	
Grade 0	0	93 (93.0)	0	0	0	0	93 (93.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	7 (7.0)	0	0	0	0	7 (7.0)	
Grade 0	0	93 (93.0)	0	0	0	0	93 (93.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)		
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 8									
UNK	0	0	0	0	0	0	0		
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)		
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	94 (94.0)	0	0	0	0	94	(94.0)
Grade 1	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 0	0	93 (93.0)	0	0	0	0	93 (93.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	93 (93.0)	0	0	0	0	93 (93.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	92 (92.0)	0	0	0	0	92	(92.0)
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	84 (84.0)	0	0	0	0	84	(84.0)
Grade 1	0	14 (14.0)	0	0	0	0	14	(14.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	86 (86.0)	2 (2.0)	0	0	0		88 (88.0)	
Grade 1	0	10 (10.0)	0	0	0	0		10 (10.0)	
Grade 2	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 3	0	0	0	1 (1.0)	0	0		1 (1.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0		100 (100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 0	0	93 (93.0)	1 (1.0)	0	0	0		94 (94.0)	
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0		2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 3	0	1 (1.0)	0	1 (1.0)	0	0		2 (2.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	92 (92.0)	2 (2.0)	0	0	0	94 (94.0)			
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	1 (1.0)	0	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			
Day 29 - Predose										
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 0	0	89 (89.0)	2 (2.0)	0	0	0	91 (91.0)			
Grade 1	0	5 (5.0)	0	1 (1.0)	0	0	6 (6.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)

Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)			
Grade 0	0	84 (84.0)	1 (1.0)	1 (1.0)	0	0	86 (86.0)			
Grade 1	0	8 (8.0)	0	0	0	0	8 (8.0)			
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 3	0	0	1 (1.0)	0	0	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			
Day 36										
UNK	0	3 (3.0)	1 (1.0)	0	0	0	4 (4.0)			
Grade 0	0	89 (89.0)	1 (1.0)	1 (1.0)	0	0	91 (91.0)			
Grade 1	0	4 (4.0)	0	0	0	0	4 (4.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)			
Grade 0	0	88 (88.0)	2 (2.0)	0	0	0	90 (90.0)			
Grade 1	0	4 (4.0)	0	0	0	0	4 (4.0)			
Grade 2	0	0	0	1 (1.0)	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			
Day 57										
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)			
Grade 0	0	92 (92.0)	2 (2.0)	0	0	0	94 (94.0)			
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 2	0	0	0	1 (1.0)	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	78 (78.0)	1 (1.0)	0	0	0	79	(79.0)
Grade 1	0	14 (14.0)	0	0	0	0	14	(14.0)
Grade 2	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 3	0	1 (1.0)	1 (1.0)	1 (1.0)	0	0	3	(3.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 0	0	98	(98.0)	0	0	0	0	98	(98.0)
Grade 1	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 0	0	97 (97.0)	0	0	0	0	97 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	94 (94.0)	0	0	0	0	94 (94.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	94 (94.0)	0	0	0	0	94	(94.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)
Grade 1	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)	
Grade 1	0	1 (1.0)	4 (4.0)	0	0	0	5 (5.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)	
Grade 1	0	0	4 (4.0)	0	0	0	4 (4.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	91 (91.0)	0	0	0	0	91	(91.0)	
Grade 1	0	3 (3.0)	5 (5.0)	0	0	0	8	(8.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 0	0	89 (89.0)	0	0	0	0	89	(89.0)	
Grade 1	0	4 (4.0)	5 (5.0)	0	0	0	9	(9.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 0	0	89 (89.0)	4 (4.0)	0	0	0	93	(93.0)
Grade 1	0	3 (3.0)	1 (1.0)	0	0	0	4	(4.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)
Day 36								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	88 (88.0)	4 (4.0)	0	0	0	92	(92.0)
Grade 1	0	3 (3.0)	1 (1.0)	0	0	0	4	(4.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	87 (87.0)	0	0	0	0	87 (87.0)	
Grade 1	0	3 (3.0)	5 (5.0)	0	0	0	8 (8.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	90 (90.0)	2 (2.0)	0	0	0	92 (92.0)	
Grade 1	0	1 (1.0)	3 (3.0)	0	0	0	4 (4.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	83 (83.0)	0	0	0	0	83	(83.0)
Grade 1	0	12 (12.0)	5 (5.0)	0	0	0	17	(17.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 8								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	95 (95.0)	2 (2.0)	0	0	0	97 (97.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	96 (96.0)	2 (2.0)	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 0	0	95 (95.0)	2 (2.0)	0	0	0	97 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 36								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	94 (94.0)	2 (2.0)	0	0	0	96 (96.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	93 (93.0)	2 (2.0)	0	0	0	95 (95.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	94 (94.0)	2 (2.0)	0	0	0	96 (96.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97	(97.0)
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3	(3.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	97 (97.0)	1 (1.0)	0	0	0	98 (98.0)		
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)		
Day 8									
UNK	0	0	0	0	0	0	0		
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97 (97.0)		
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97	(97.0)
Grade 1	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	95 (95.0)	2 (2.0)	0	0	0	97	(97.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour									
Postdose									
UNK	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 0	0	90 (90.0)	1 (1.0)	0	0	0	91	(91.0)	
Grade 1	0	4 (4.0)	1 (1.0)	0	0	0	5	(5.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)	
Day 36									
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)	
Grade 0	0	93 (93.0)	2 (2.0)	0	0	0	95	(95.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	92 (92.0)	2 (2.0)	0	0	0	94 (94.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	91 (91.0)	2 (2.0)	0	0	0	93 (93.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	87 (87.0)	0	0	0	0	87	(87.0)
Grade 1	0	9 (9.0)	2 (2.0)	0	0	0	11	(11.0)
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 29 - 1 Hour								
Postdose								
UNK	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 0	0	97 (97.0)	0	0	0	0	97	(97.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	95 (95.0)	0	0	0	0	95 (95.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 57								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	96 (96.0)	0	0	0	0	96 (96.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	95 (95.0)	1 (1.0)	0	0	0	96	(96.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97	(97.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 15								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	95 (95.0)	1 (1.0)	0	0	0	96 (96.0)		
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Day 57									
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97 (97.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	89 (89.0)	1 (1.0)	0	0	0	0	90	(90.0)
Grade 1	0	7 (7.0)	0	0	0	0	0	7	(7.0)
Grade 2	0	2 (2.0)	0	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	87 (87.0)	3 (3.0)	0	0	0	90 (90.0)		
Grade 1	0	5 (5.0)	1 (1.0)	0	0	0	6 (6.0)		
Grade 2	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		
Day 8									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	89 (89.0)	3 (3.0)	0	0	0	92 (92.0)		
Grade 1	0	3 (3.0)	2 (2.0)	0	0	0	5 (5.0)		
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	0	0	0	0	0	0		
Grade 0	0	94 (94.0)	2 (2.0)	0	0	0	96	(96.0)	
Grade 1	0	1 (1.0)	2 (2.0)	0	0	0	3	(3.0)	
Grade 2	0	0	1 (1.0)	0	0	0	1	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	93 (93.0)	4 (4.0)	0	0	0	97	(97.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3	(3.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)

Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	83 (83.0)	3 (3.0)	0	0	0	86	(86.0)
Grade 1	0	9 (9.0)	1 (1.0)	0	0	0	10	(10.0)
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	89 (89.0)	4 (4.0)	0	0	0	93	(93.0)
Grade 1	0	6 (6.0)	0	0	0	0	6	(6.0)
Grade 2	0	0	1 (1.0)	0	0	0	1	(1.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	92 (92.0)	4 (4.0)	0	0	0	96 (96.0)		
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 2	0	0	1 (1.0)	0	0	0	1 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		
Day 57									
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 0	0	90 (90.0)	3 (3.0)	0	0	0	93 (93.0)		
Grade 1	0	2 (2.0)	2 (2.0)	0	0	0	4 (4.0)		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	73 (73.0)	2 (2.0)	0	0	0	75	(75.0)
Grade 1	0	17 (17.0)	0	0	0	0	17	(17.0)
Grade 2	0	4 (4.0)	3 (3.0)	0	0	0	7	(7.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 15								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 57								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	97 (97.0)	1 (1.0)	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99	(99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	80 (80.0)	3 (3.0)	0	0	0	83	(83.0)
Grade 1	0	7 (7.0)	9 (9.0)	0	0	0	16	(16.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	88 (88.0)	12 (12.0)	0	0	0	100	(100)
Day 8								
UNK	0	0	1 (1.0)	0	0	0	1	(1.0)
Grade 0	0	84 (84.0)	7 (7.0)	0	0	0	91	(91.0)
Grade 1	0	4 (4.0)	4 (4.0)	0	0	0	8	(8.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	88 (88.0)	12 (12.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline						
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 15							
UNK	0	0	0	0	0	0	0
Grade 0	0	84 (84.0)	5 (5.0)	0	0	0	89 (89.0)
Grade 1	0	4 (4.0)	7 (7.0)	0	0	0	11 (11.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	88 (88.0)	12 (12.0)	0	0	0	100 (100)
Day 29 - Predose							
UNK	0	0	0	0	0	0	0
Grade 0	0	84 (84.0)	3 (3.0)	0	0	0	87 (87.0)
Grade 1	0	4 (4.0)	9 (9.0)	0	0	0	13 (13.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	88 (88.0)	12 (12.0)	0	0	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	86 (86.0)	6 (6.0)	0	0	0	92 (92.0)	
Grade 1	0	1 (1.0)	6 (6.0)	0	0	0	7 (7.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	88 (88.0)	12 (12.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	8 (8.0)	0	0	0	93 (93.0)	
Grade 1	0	3 (3.0)	4 (4.0)	0	0	0	7 (7.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	88 (88.0)	12 (12.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade		Baseline							
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)	
Day 43									
UNK		0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0		0	86 (86.0)	4 (4.0)	0	0	0	90	(90.0)
Grade 1		0	1 (1.0)	8 (8.0)	0	0	0	9	(9.0)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	88 (88.0)	12 (12.0)	0	0	0	100	(100)
Day 57									
UNK		0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0		0	85 (85.0)	8 (8.0)	0	0	0	93	(93.0)
Grade 1		0	1 (1.0)	4 (4.0)	0	0	0	5	(5.0)
Grade 2		0	0	0	0	0	0	0	
Grade 3		0	0	0	0	0	0	0	
Grade 4		0	0	0	0	0	0	0	
Total		0	88 (88.0)	12 (12.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	70 (70.0)	2 (2.0)	0	0	0	72	(72.0)
Grade 1	0	18 (18.0)	10 (10.0)	0	0	0	28	(28.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	88 (88.0)	12 (12.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 15								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	92 (92.0)	0	0	0	0	92	(92.0)	
Grade 1	0	5 (5.0)	1 (1.0)	0	0	0	6	(6.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3	(3.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	0	0	0	0	0	0		
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)		
Grade 1	0	0	1 (1.0)	0	0	0	1 (1.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	96 (96.0)	1 (1.0)	0	0	0	97	(97.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	1 (1.0)	0	0	0	99	(99.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	97 (97.0)	1 (1.0)	0	0	0	98	(98.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	
Day 57									
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95	(95.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	90 (90.0)	0	0	0	0	90	(90.0)
Grade 1	0	7 (7.0)	1 (1.0)	0	0	0	8	(8.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							Total
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	0	99 (99.0)
Grade 1	0	1 (1.0)	0	0	0	0	0	1 (1.0)
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Total	0	100 (100)	0	0	0	0	0	100 (100)
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	0
Grade 0	0	100 (100)	0	0	0	0	0	100 (100)
Grade 1	0	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0	0
Total	0	100 (100)	0	0	0	0	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 57								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195	(97.5)	
Grade 1	0	4 (2.0)	0	0	0	0	4	(2.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	
Day 8									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195	(97.5)	
Grade 1	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	193 (96.5)	1 (0.5)	0	0	0	194	(97.0)	
Grade 1	0	5 (2.5)	0	0	0	0	5	(2.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195	(97.5)	
Grade 1	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	187 (93.5)	1 (0.5)	0	0	0	188 (94.0)	
Grade 1	0	5 (2.5)	0	0	0	0	5 (2.5)	
Grade 2	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	191 (95.5)	1 (0.5)	0	0	0	192 (96.0)	
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	187	(93.5)	1	(0.5)	0		0		0		188	(94.0)
Grade 1	0	5	(2.5)	0		0		0		0		5	(2.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 4	0	0		0		0		0		0		0	
Total	0	199	(99.5)	1	(0.5)	0		0		0		200	(100)
Day 57													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	191	(95.5)	1	(0.5)	0		0		0		192	(96.0)
Grade 1	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 2	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	199	(99.5)	1	(0.5)	0		0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline						
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	173 (86.5)	1 (0.5)	0	0	0	174 (87.0)
Grade 1	0	21 (10.5)	0	0	0	0	21 (10.5)
Grade 2	0	4 (2.0)	0	0	0	0	4 (2.0)
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)
Grade 4	0	0	0	0	0	0	0
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 0	0	173 (86.5)	5 (2.5)	0	0	0	178 (89.0)			
Grade 1	0	15 (7.5)	1 (0.5)	0	0	0	16 (8.0)			
Grade 2	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)			
Grade 3	0	0	0	1 (0.5)	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			
Day 8										
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 0	0	182 (91.0)	4 (2.0)	0	0	0	186 (93.0)			
Grade 1	0	4 (2.0)	3 (1.5)	0	0	0	7 (3.5)			
Grade 2	0	3 (1.5)	0	0	0	0	3 (1.5)			
Grade 3	0	1 (0.5)	0	1 (0.5)	0	0	2 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 0	0	186 (93.0)	4 (2.0)	0	0	0	190 (95.0)			
Grade 1	0	4 (2.0)	2 (1.0)	0	0	0	6 (3.0)			
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)			
Grade 3	0	0	0	1 (0.5)	0	0	1 (0.5)			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			
Day 29 - Predose										
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 0	0	182 (91.0)	6 (3.0)	0	0	0	188 (94.0)			
Grade 1	0	7 (3.5)	1 (0.5)	1 (0.5)	0	0	9 (4.5)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	167 (83.5)	4 (2.0)	1 (0.5)	0	0	172 (86.0)	
Grade 1	0	17 (8.5)	1 (0.5)	0	0	0	18 (9.0)	
Grade 2	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)	
Grade 3	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)	
Day 36								
UNK	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)	
Grade 0	0	178 (89.0)	5 (2.5)	1 (0.5)	0	0	184 (92.0)	
Grade 1	0	10 (5.0)	0	0	0	0	10 (5.0)	
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)			
Grade 0	0	180 (90.0)	6 (3.0)	0	0	0	186 (93.0)			
Grade 1	0	6 (3.0)	0	0	0	0	6 (3.0)			
Grade 2	0	0	1 (0.5)	1 (0.5)	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			
Day 57										
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)			
Grade 0	0	182 (91.0)	5 (2.5)	0	0	0	187 (93.5)			
Grade 1	0	3 (1.5)	2 (1.0)	0	0	0	5 (2.5)			
Grade 2	0	1 (0.5)	0	1 (0.5)	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	151 (75.5)	3 (1.5)	0	0	0	154 (77.0)
Grade 1	0	31 (15.5)	0	0	0	0	31 (15.5)
Grade 2	0	8 (4.0)	3 (1.5)	0	0	0	11 (5.5)
Grade 3	0	2 (1.0)	1 (0.5)	1 (0.5)	0	0	4 (2.0)
Grade 4	0	0	0	0	0	0	0
Total	0	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0	0	198 (99.0)	1 (0.5)	0	0	0	199 (99.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 8								
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 0	0	196 (98.0)	1 (0.5)	0	0	0	197 (98.5)	
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 0	0	197 (98.5)	1 (0.5)	0	0	0	198 (99.0)		
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	197 (98.5)	1 (0.5)	0	0	0	198 (99.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	195 (97.5)	1 (0.5)	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	192 (96.0)	1 (0.5)	0	0	0	193 (96.5)	
Grade 1	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 0	0	192 (96.0)	1 (0.5)	0	0	0	193 (96.5)		
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		
Day 57									
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 0	0	193 (96.5)	1 (0.5)	0	0	0	194 (97.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	199 (99.5)	1 (0.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	194 (97.0)	1 (0.5)	0	0	0	195	(97.5)
Grade 1	0	5 (2.5)	0	0	0	0	5	(2.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	199 (99.5)	1 (0.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0	0	174 (87.0)	4 (2.0)	0	0	0	178 (89.0)	
Grade 1	0	8 (4.0)	13 (6.5)	0	0	0	21 (10.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	183 (91.5)	17 (8.5)	0	0	0	200 (100)	
Day 8								
UNK	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)	
Grade 0	0	178 (89.0)	8 (4.0)	0	0	0	186 (93.0)	
Grade 1	0	4 (2.0)	8 (4.0)	0	0	0	12 (6.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	183 (91.5)	17 (8.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	175 (87.5)	5 (2.5)	0	0	0	180	(90.0)	
Grade 1	0	7 (3.5)	12 (6.0)	0	0	0	19	(9.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	183 (91.5)	17 (8.5)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	173 (86.5)	3 (1.5)	0	0	0	176	(88.0)	
Grade 1	0	8 (4.0)	14 (7.0)	0	0	0	22	(11.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	183 (91.5)	17 (8.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	175 (87.5)	10 (5.0)	0	0	0	185 (92.5)	
Grade 1	0	4 (2.0)	7 (3.5)	0	0	0	11 (5.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	183 (91.5)	17 (8.5)	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	173 (86.5)	12 (6.0)	0	0	0	185 (92.5)	
Grade 1	0	6 (3.0)	5 (2.5)	0	0	0	11 (5.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	183 (91.5)	17 (8.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	173	(86.5)	4	(2.0)	0		0		0		177	(88.5)
Grade 1	0	4	(2.0)	13	(6.5)	0		0		0		17	(8.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	183	(91.5)	17	(8.5)	0		0		0		200	(100)
Day 57													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	175	(87.5)	10	(5.0)	0		0		0		185	(92.5)
Grade 1	0	2	(1.0)	7	(3.5)	0		0		0		9	(4.5)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	183	(91.5)	17	(8.5)	0		0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	153 (76.5)	2 (1.0)	0	0	0	155	(77.5)
Grade 1	0	30 (15.0)	15 (7.5)	0	0	0	45	(22.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	183 (91.5)	17 (8.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 0	0	197 (98.5)	2 (1.0)	0	0	0	199 (99.5)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)		
Day 8									
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 0	0	197 (98.5)	1 (0.5)	0	0	0	198 (99.0)		
Grade 1	0	0	1 (0.5)	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 0	0	195 (97.5)	2 (1.0)	0	0	0	197 (98.5)	
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	
Day 29 - Predose								
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 0	0	195 (97.5)	2 (1.0)	0	0	0	197 (98.5)	
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	194 (97.0)	2 (1.0)	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	194 (97.0)	2 (1.0)	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)	
Grade 0	0	192 (96.0)	2 (1.0)	0	0	0	194 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	
Day 57								
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)	
Grade 0	0	192 (96.0)	2 (1.0)	0	0	0	194 (97.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	195 (97.5)	1 (0.5)	0	0	0	0	196 (98.0)	
Grade 1	0	3 (1.5)	1 (0.5)	0	0	0	0	4 (2.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	198 (99.0)	2 (1.0)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0	0	189 (94.5)	1 (0.5)	0	0	0	190	(95.0)
Grade 1	0	6 (3.0)	2 (1.0)	0	0	0	8	(4.0)
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	197 (98.5)	3 (1.5)	0	0	0	200	(100)
Day 8								
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 0	0	192 (96.0)	1 (0.5)	0	0	0	193	(96.5)
Grade 1	0	4 (2.0)	2 (1.0)	0	0	0	6	(3.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	197 (98.5)	3 (1.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	195 (97.5)	1 (0.5)	0	0	0	196	(98.0)	
Grade 1	0	1 (0.5)	2 (1.0)	0	0	0	3	(1.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	197 (98.5)	3 (1.5)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	194 (97.0)	3 (1.5)	0	0	0	197	(98.5)	
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	197 (98.5)	3 (1.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	186 (93.0)	2 (1.0)	0	0	0	188 (94.0)	
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6 (3.0)	
Grade 2	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	197 (98.5)	3 (1.5)	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	191 (95.5)	3 (1.5)	0	0	0	194 (97.0)	
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	197 (98.5)	3 (1.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 0	0	189 (94.5)	3 (1.5)	0	0	0	192 (96.0)		
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 4	0	0	0	0	0	0	0		
Total	0	197 (98.5)	3 (1.5)	0	0	0	200 (100)		
Day 57									
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 0	0	185 (92.5)	3 (1.5)	0	0	0	188 (94.0)		
Grade 1	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	197 (98.5)	3 (1.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	177 (88.5)	0	0	0	0		177 (88.5)	
Grade 1	0	16 (8.0)	3 (1.5)	0	0	0		19 (9.5)	
Grade 2	0	3 (1.5)	0	0	0	0		3 (1.5)	
Grade 3	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	197 (98.5)	3 (1.5)	0	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 8									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)	
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	196 (98.0)	0	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	195 (97.5)	0	0	0	0	195 (97.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)

Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	6 (3.0)	0	0	0	0	6	(3.0)
Grade 0	0	194 (97.0)	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 57								
UNK	0	6 (3.0)	0	0	0	0	6	(3.0)
Grade 0	0	194 (97.0)	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	96 (96.0)	2 (2.0)	0	0	0	0	98 (98.0)	
Grade 1	0	2 (2.0)	0	0	0	0	0	2 (2.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	0	100 (100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 0	0	95 (95.0)	2 (2.0)	0	0	0	0	97 (97.0)	
Grade 1	0	2 (2.0)	0	0	0	0	0	2 (2.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	94 (94.0)	2 (2.0)	0	0	0	96	(96.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	97 (97.0)	2 (2.0)	0	0	0	99	(99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	96 (96.0)	2 (2.0)	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	95 (95.0)	2 (2.0)	0	0	0	97 (97.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 43							
UNK	0	0	0	0	0	0	0
Grade 0	0	97 (97.0)	2 (2.0)	0	0	0	99 (99.0)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)
Day 57							
UNK	0	0	0	0	0	0	0
Grade 0	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)
Grade 1	0	0	0	0	0	0	0
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	0	0	0	0	0
Grade 4	0	0	0	0	0	0	0
Total	0	98 (98.0)	2 (2.0)	0	0	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	89 (89.0)	2 (2.0)	0	0	0	91	(91.0)
Grade 1	0	6 (6.0)	0	0	0	0	6	(6.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	98 (98.0)	2 (2.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	86 (86.0)	0	0	0	0	0	86	(86.0)
Grade 1	0	10 (10.0)	1 (1.0)	0	0	0	0	11	(11.0)
Grade 2	0	2 (2.0)	0	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	0	100	(100)
Day 8									
UNK	0	1 (1.0)	0	0	0	0	0	1	(1.0)
Grade 0	0	91 (91.0)	0	0	0	0	0	91	(91.0)
Grade 1	0	7 (7.0)	1 (1.0)	0	0	0	0	8	(8.0)
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	96 (96.0)	0	0	0	0	96 (96.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	91 (91.0)	1 (1.0)	0	0	0	92 (92.0)	
Grade 1	0	7 (7.0)	0	0	0	0	7 (7.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	85 (85.0)	1 (1.0)	0	0	0	86 (86.0)	
Grade 1	0	8 (8.0)	0	0	0	0	8 (8.0)	
Grade 2	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	94 (94.0)	0	0	0	0	94 (94.0)	
Grade 1	0	4 (4.0)	1 (1.0)	0	0	0	5 (5.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade		Baseline						
		UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43								
UNK		0	0	0	0	0	0	0
Grade 0		0	96 (96.0)	0	0	0	0	96 (96.0)
Grade 1		0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)
Grade 2		0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 3		0	0	0	0	0	0	0
Grade 4		0	0	0	0	0	0	0
Total		0	99 (99.0)	1 (1.0)	0	0	0	100 (100)
Day 57								
UNK		0	0	0	0	0	0	0
Grade 0		0	96 (96.0)	1 (1.0)	0	0	0	97 (97.0)
Grade 1		0	2 (2.0)	0	0	0	0	2 (2.0)
Grade 2		0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 3		0	0	0	0	0	0	0
Grade 4		0	0	0	0	0	0	0
Total		0	99 (99.0)	1 (1.0)	0	0	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	72 (72.0)	0	0	0	0	72	(72.0)
Grade 1	0	19 (19.0)	0	0	0	0	19	(19.0)
Grade 2	0	7 (7.0)	1 (1.0)	0	0	0	8	(8.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99	(99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	100 (100)	0	0	0	0	100 (100)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 43								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	76 (76.0)	7 (7.0)	0	0	0	0	83 (83.0)	
Grade 1	0	2 (2.0)	15 (15.0)	0	0	0	0	17 (17.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	0	100 (100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 0	0	74 (74.0)	19 (19.0)	0	0	0	0	93 (93.0)	
Grade 1	0	3 (3.0)	3 (3.0)	0	0	0	0	6 (6.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	76 (76.0)	7 (7.0)	0	0	0	83 (83.0)	
Grade 1	0	1 (1.0)	15 (15.0)	0	0	0	16 (16.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	77 (77.0)	8 (8.0)	0	0	0	85 (85.0)	
Grade 1	0	1 (1.0)	14 (14.0)	0	0	0	15 (15.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	74 (74.0)	13 (13.0)	0	0	0	87	(87.0)
Grade 1	0	3 (3.0)	9 (9.0)	0	0	0	12	(12.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	100	(100)
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	78 (78.0)	15 (15.0)	0	0	0	93	(93.0)
Grade 1	0	0	7 (7.0)	0	0	0	7	(7.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	76 (76.0)	13 (13.0)	0	0	0	0	89 (89.0)	
Grade 1	0	2 (2.0)	9 (9.0)	0	0	0	0	11 (11.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	0	100 (100)	
Day 57									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	77 (77.0)	15 (15.0)	0	0	0	0	92 (92.0)	
Grade 1	0	0	6 (6.0)	0	0	0	0	6 (6.0)	
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	78 (78.0)	22 (22.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	67 (67.0)	2 (2.0)	0	0	0		69 (69.0)	
Grade 1	0	10 (10.0)	19 (19.0)	0	0	0		29 (29.0)	
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0		2 (2.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	78 (78.0)	22 (22.0)	0	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99	(99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 43								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	84 (84.0)	2 (2.0)	0	0	0	86 (86.0)		
Grade 1	0	7 (7.0)	3 (3.0)	0	0	0	10 (10.0)		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	3 (3.0)	0	0	0	0	3 (3.0)		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		
Day 8									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	88 (88.0)	5 (5.0)	0	0	0	93 (93.0)		
Grade 1	0	6 (6.0)	0	0	0	0	6 (6.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	91 (91.0)	3 (3.0)	0	0	0	94 (94.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	91 (91.0)	5 (5.0)	0	0	0	96 (96.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	89 (89.0)	3 (3.0)	0	0	0	92 (92.0)	
Grade 1	0	4 (4.0)	2 (2.0)	0	0	0	6 (6.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91 (91.0)	
Grade 1	0	5 (5.0)	2 (2.0)	0	0	0	7 (7.0)	
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 43									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	93 (93.0)	4 (4.0)	0	0	0	0	97 (97.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	0	3 (3.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	0	100 (100)	
Day 57									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	90 (90.0)	5 (5.0)	0	0	0	0	95 (95.0)	
Grade 1	0	5 (5.0)	0	0	0	0	0	5 (5.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	73 (73.0)	0	0	0	0	73	(73.0)
Grade 1	0	14 (14.0)	4 (4.0)	0	0	0	18	(18.0)
Grade 2	0	4 (4.0)	1 (1.0)	0	0	0	5	(5.0)
Grade 3	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	95 (95.0)	5 (5.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	0	100	(100)
Day 8									
UNK	0	1 (1.0)	0	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 43								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: Placebo (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	0	100 (100)	
Day 8									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	95 (95.0)	0	0	0	0	0	95 (95.0)	
Grade 1	0	4 (4.0)	0	0	0	0	0	4 (4.0)	
Grade 2	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 29 - Predose								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	94 (94.0)	0	0	0	0	94	(94.0)
Grade 1	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 0	0	97 (97.0)	0	0	0	0	97 (97.0)		
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 57									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	97 (97.0)	0	0	0	0	97 (97.0)		
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	89 (89.0)	0	0	0	0	89	(89.0)
Grade 1	0	8 (8.0)	0	0	0	0	8	(8.0)
Grade 2	0	3 (3.0)	0	0	0	0	3	(3.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0		
Grade 0	0	88 (88.0)	0	0	0	0	88 (88.0)		
Grade 1	0	9 (9.0)	1 (1.0)	0	0	0	10 (10.0)		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Day 8									
UNK	0	0	0	0	0	0	0		
Grade 0	0	97 (97.0)	1 (1.0)	0	0	0	98 (98.0)		
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	96 (96.0)	0	0	0	0	96 (96.0)		
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	96 (96.0)	0	0	0	0	96 (96.0)		
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	88 (88.0)	1 (1.0)	0	0	0	89 (89.0)	
Grade 1	0	9 (9.0)	0	0	0	0	9 (9.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	
Day 36								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	97 (97.0)	1 (1.0)	0	0	0	98 (98.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 0	0	92 (92.0)	1 (1.0)	0	0	0	93 (93.0)		
Grade 1	0	5 (5.0)	0	0	0	0	5 (5.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		
Day 57									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	94 (94.0)	1 (1.0)	0	0	0	95 (95.0)		
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)		
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	99 (99.0)	1 (1.0)	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	73 (73.0)	0	0	0	0	73	(73.0)
Grade 1	0	23 (23.0)	1 (1.0)	0	0	0	24	(24.0)
Grade 2	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 3	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	99 (99.0)	1 (1.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 8								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100 (100)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							Total
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	84 (84.0)	5 (5.0)	0	0	0	89 (89.0)	
Grade 1	0	3 (3.0)	7 (7.0)	1 (1.0)	0	0	11 (11.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)	
Day 8								
UNK	0	0	0	0	0	0	0	
Grade 0	0	84 (84.0)	10 (10.0)	1 (1.0)	0	0	95 (95.0)	
Grade 1	0	3 (3.0)	2 (2.0)	0	0	0	5 (5.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	84 (84.0)	4 (4.0)	0	0	0	88 (88.0)	
Grade 1	0	2 (2.0)	8 (8.0)	1 (1.0)	0	0	11 (11.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)	
Day 29 - Predose								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	84 (84.0)	3 (3.0)	0	0	0	87 (87.0)	
Grade 1	0	2 (2.0)	9 (9.0)	1 (1.0)	0	0	12 (12.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)			
Grade 0	0	85 (85.0)	5 (5.0)	0	0	0	90 (90.0)			
Grade 1	0	1 (1.0)	6 (6.0)	1 (1.0)	0	0	8 (8.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)			
Day 36										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	85 (85.0)	10 (10.0)	1 (1.0)	0	0	96 (96.0)			
Grade 1	0	1 (1.0)	2 (2.0)	0	0	0	3 (3.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 0	0	83 (83.0)	9 (9.0)	0	0	0	92 (92.0)			
Grade 1	0	2 (2.0)	3 (3.0)	1 (1.0)	0	0	6 (6.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)			
Day 57										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	85 (85.0)	9 (9.0)	0	0	0	94 (94.0)			
Grade 1	0	1 (1.0)	3 (3.0)	1 (1.0)	0	0	5 (5.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	76 (76.0)	0	0	0	0	76	(76.0)
Grade 1	0	11 (11.0)	12 (12.0)	1 (1.0)	0	0	24	(24.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	
Day 29 - Predose									
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 1 - 1 Hour Postdose										
UNK	0	0	0	0	0	0	0			
Grade 0	0	87 (87.0)	2 (2.0)	0	0	0	89 (89.0)			
Grade 1	0	5 (5.0)	3 (3.0)	1 (1.0)	0	0	9 (9.0)			
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	1 (1.0)	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			
Day 8										
UNK	0	0	0	0	0	0	0			
Grade 0	0	91 (91.0)	4 (4.0)	0	1 (1.0)	0	96 (96.0)			
Grade 1	0	1 (1.0)	0	1 (1.0)	0	0	2 (2.0)			
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	91 (91.0)	3 (3.0)	1 (1.0)	0	0	95 (95.0)			
Grade 1	0	1 (1.0)	2 (2.0)	0	1 (1.0)	0	4 (4.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			
Day 29 - Predose										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	88 (88.0)	3 (3.0)	0	0	0	91 (91.0)			
Grade 1	0	4 (4.0)	2 (2.0)	0	1 (1.0)	0	7 (7.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	1 (1.0)	0	0	1 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 0	0	86 (86.0)	4 (4.0)	1 (1.0)	1 (1.0)	0	92 (92.0)			
Grade 1	0	5 (5.0)	1 (1.0)	0	0	0	6 (6.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			
Day 36										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	88 (88.0)	3 (3.0)	0	1 (1.0)	0	92 (92.0)			
Grade 1	0	4 (4.0)	1 (1.0)	1 (1.0)	0	0	6 (6.0)			
Grade 2	0	0	1 (1.0)	0	0	0	1 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Day 43							
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)
Grade 0	0	84 (84.0)	4 (4.0)	0	1 (1.0)	0	89 (89.0)
Grade 1	0	5 (5.0)	0	1 (1.0)	0	0	6 (6.0)
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 3	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)
Grade 4	0	0	0	0	0	0	0
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)
Day 57							
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 0	0	83 (83.0)	4 (4.0)	1 (1.0)	1 (1.0)	0	89 (89.0)
Grade 1	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	0	1 (1.0)	0	0	0	1 (1.0)
Grade 4	0	0	0	0	0	0	0
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	66 (66.0)	1 (1.0)	0	0	0	67	(67.0)
Grade 1	0	23 (23.0)	1 (1.0)	0	0	0	24	(24.0)
Grade 2	0	3 (3.0)	2 (2.0)	0	0	0	5	(5.0)
Grade 3	0	1 (1.0)	1 (1.0)	1 (1.0)	1 (1.0)	0	4	(4.0)
Grade 4	0	0	0	0	0	0	0	
Total	0	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)		
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 57								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 50 µg (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	92 (92.0)	3 (3.0)	1 (1.0)	0	0		96 (96.0)	
Grade 1	0	2 (2.0)	0	0	0	0		2 (2.0)	
Grade 2	0	2 (2.0)	0	0	0	0		2 (2.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0		100 (100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 0	0	94 (94.0)	3 (3.0)	1 (1.0)	0	0		98 (98.0)	
Grade 1	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	0	0	0	0	0	0			
Grade 0	0	94 (94.0)	3 (3.0)	1 (1.0)	0	0	98 (98.0)			
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)			
Day 29 - Predose										
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)			
Grade 0	0	93 (93.0)	3 (3.0)	1 (1.0)	0	0	97 (97.0)			
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	91 (91.0)	3 (3.0)	1 (1.0)	0	0	95 (95.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)	
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	91 (91.0)	3 (3.0)	1 (1.0)	0	0	95 (95.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3 (3.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)			
Grade 0	0	91 (91.0)	3 (3.0)	1 (1.0)	0	0	95 (95.0)			
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)			
Day 57										
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 0	0	94 (94.0)	3 (3.0)	1 (1.0)	0	0	98 (98.0)			
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	3 (3.0)	1 (1.0)	0	0	0	89 (89.0)	
Grade 1	0	8 (8.0)	0	0	0	0	0	8 (8.0)	
Grade 2	0	3 (3.0)	0	0	0	0	0	3 (3.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	96 (96.0)	3 (3.0)	1 (1.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							Total	
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	0
Grade 0	0	84 (84.0)	5 (5.0)	0	0	0	0	89 (89.0)	
Grade 1	0	9 (9.0)	0	0	0	0	0	9 (9.0)	
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	0	100 (100)	
Day 8									
UNK	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 0	0	92 (92.0)	5 (5.0)	0	0	0	0	97 (97.0)	
Grade 1	0	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	1 (1.0)	0	0	0	0	0	1 (1.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	90 (90.0)	6 (6.0)	0	0	0		96 (96.0)	
Grade 1	0	3 (3.0)	0	0	0	0		3 (3.0)	
Grade 2	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	94 (94.0)	6 (6.0)	0	0	0		100 (100)	
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0		2 (2.0)	
Grade 0	0	89 (89.0)	6 (6.0)	0	0	0		95 (95.0)	
Grade 1	0	2 (2.0)	0	0	0	0		2 (2.0)	
Grade 2	0	1 (1.0)	0	0	0	0		1 (1.0)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	94 (94.0)	6 (6.0)	0	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	88 (88.0)	5 (5.0)	0	0	0	93	(93.0)
Grade 1	0	4 (4.0)	1 (1.0)	0	0	0	5	(5.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100	(100)
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	90 (90.0)	6 (6.0)	0	0	0	96	(96.0)
Grade 1	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5 (5.0)	
Grade 0	0	88 (88.0)	6 (6.0)	0	0	0	94 (94.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100 (100)	
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	89 (89.0)	5 (5.0)	0	0	0	94 (94.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	77 (77.0)	4 (4.0)	0	0	0	81	(81.0)
Grade 1	0	14 (14.0)	1 (1.0)	0	0	0	15	(15.0)
Grade 2	0	3 (3.0)	1 (1.0)	0	0	0	4	(4.0)
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	94 (94.0)	6 (6.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 15									
UNK	0	0	0	0	0	0		0	
Grade 0	0	100 (100)	0	0	0	0		100	(100)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	100 (100)	0	0	0	0		100	(100)
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0		2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0		98	(98.0)
Grade 1	0	0	0	0	0	0		0	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	100 (100)	0	0	0	0		100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	5 (5.0)	0	0	0	0	5	(5.0)
Grade 0	0	95 (95.0)	0	0	0	0	95	(95.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	80 (80.0)	6 (6.0)	0	0	0	0	86 (86.0)	
Grade 1	0	1 (1.0)	13 (13.0)	0	0	0	0	14 (14.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	0	100 (100)	
Day 8									
UNK	0	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	78 (78.0)	10 (10.0)	0	0	0	0	88 (88.0)	
Grade 1	0	3 (3.0)	8 (8.0)	0	0	0	0	11 (11.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	77 (77.0)	2 (2.0)	0	0	0	0	79 (79.0)	
Grade 1	0	4 (4.0)	17 (17.0)	0	0	0	0	21 (21.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	0	100 (100)	
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0	0	2 (2.0)	
Grade 0	0	74 (74.0)	5 (5.0)	0	0	0	0	79 (79.0)	
Grade 1	0	5 (5.0)	14 (14.0)	0	0	0	0	19 (19.0)	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	77 (77.0)	9 (9.0)	0	0	0	86 (86.0)	
Grade 1	0	2 (2.0)	10 (10.0)	0	0	0	12 (12.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	100 (100)	
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	75 (75.0)	12 (12.0)	0	0	0	87 (87.0)	
Grade 1	0	4 (4.0)	7 (7.0)	0	0	0	11 (11.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)	
Grade 0	0	76 (76.0)	10 (10.0)	0	0	0	86 (86.0)	
Grade 1	0	1 (1.0)	9 (9.0)	0	0	0	10 (10.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	100 (100)	
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	79 (79.0)	10 (10.0)	0	0	0	89 (89.0)	
Grade 1	0	1 (1.0)	9 (9.0)	0	0	0	10 (10.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	70 (70.0)	0	0	0	0	70	(70.0)
Grade 1	0	11 (11.0)	19 (19.0)	0	0	0	30	(30.0)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	81 (81.0)	19 (19.0)	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99	(99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 29 - Predose									
UNK	0	2	(2.0)	0	0	0	0	2	(2.0)
Grade 0	0	97	(97.0)	0	0	0	0	97	(97.0)
Grade 1	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)
Grade 0	0	98 (98.0)	0	0	0	0	98	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	99 (99.0)	0	0	0	0	99 (99.0)	
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose								
UNK	0	0	0	0	0	0	0	
Grade 0	0	85 (85.0)	5 (5.0)	0	0	0	90 (90.0)	
Grade 1	0	6 (6.0)	1 (1.0)	0	0	0	7 (7.0)	
Grade 2	0	1 (1.0)	1 (1.0)	0	0	0	2 (2.0)	
Grade 3	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	100 (100)	
Day 8								
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 0	0	88 (88.0)	6 (6.0)	0	0	0	94 (94.0)	
Grade 1	0	2 (2.0)	1 (1.0)	0	0	0	3 (3.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1 (1.0)	
Grade 3	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Day 15								
UNK	0	0	0	0	0	0	0	
Grade 0	0	87 (87.0)	7 (7.0)	0	0	0	94 (94.0)	
Grade 1	0	5 (5.0)	1 (1.0)	0	0	0	6 (6.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	100 (100)	
Day 29 - Predose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	86 (86.0)	7 (7.0)	0	0	0	93 (93.0)	
Grade 1	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 2	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 3	0	0	1 (1.0)	0	0	0	1 (1.0)	
Grade 4	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour									
Postdose									
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 0	0	85 (85.0)	7 (7.0)	0	0	0	92	(92.0)	
Grade 1	0	3 (3.0)	0	0	0	0	3	(3.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 3	0	1 (1.0)	1 (1.0)	0	0	0	2	(2.0)	
Grade 4	0	0	0	0	0	0	0		
Total	0	92 (92.0)	8 (8.0)	0	0	0	100	(100)	
Day 36									
UNK	0	2 (2.0)	0	0	0	0	2	(2.0)	
Grade 0	0	86 (86.0)	6 (6.0)	0	0	0	92	(92.0)	
Grade 1	0	3 (3.0)	2 (2.0)	0	0	0	5	(5.0)	
Grade 2	0	1 (1.0)	0	0	0	0	1	(1.0)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	92 (92.0)	8 (8.0)	0	0	0	100	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	4 (4.0)	0	0	0	0	0	4	(4.0)
Grade 0	0	82 (82.0)	7 (7.0)	0	0	0	0	89	(89.0)
Grade 1	0	6 (6.0)	1 (1.0)	0	0	0	0	7	(7.0)
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	0	100	(100)
Day 57									
UNK	0	1 (1.0)	0	0	0	0	0	1	(1.0)
Grade 0	0	87 (87.0)	7 (7.0)	0	0	0	0	94	(94.0)
Grade 1	0	4 (4.0)	0	0	0	0	0	4	(4.0)
Grade 2	0	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	92 (92.0)	8 (8.0)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	68 (68.0)	5 (5.0)	0	0	0		73 (73.0)	
Grade 1	0	19 (19.0)	0	0	0	0		19 (19.0)	
Grade 2	0	4 (4.0)	1 (1.0)	0	0	0		5 (5.0)	
Grade 3	0	1 (1.0)	2 (2.0)	0	0	0		3 (3.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	92 (92.0)	8 (8.0)	0	0	0		100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	100	(100)	0	0	0	0	100	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)
Day 8									
UNK	0	1	(1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99	(99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	100	(100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	0	0	0	0	0	0		
Grade 0	0	100 (100)	0	0	0	0	100 (100)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		
Day 29 - Predose									
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)		
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)		
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	100 (100)	0	0	0	0	100 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	
Day 36								
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)	
Grade 0	0	98 (98.0)	0	0	0	0	98 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	4 (4.0)	0	0	0	0	4	(4.0)
Grade 0	0	96 (96.0)	0	0	0	0	96	(96.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)
Day 57								
UNK	0	1 (1.0)	0	0	0	0	1	(1.0)
Grade 0	0	99 (99.0)	0	0	0	0	99	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	100 (100)	0	0	0	0	100	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	100 (100)	0	0	0	0	100	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	191 (95.5)	3 (1.5)	1 (0.5)	0	0		195 (97.5)	
Grade 1	0	2 (1.0)	0	0	0	0		2 (1.0)	
Grade 2	0	3 (1.5)	0	0	0	0		3 (1.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0		200 (100)	
Day 8									
UNK	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 0	0	189 (94.5)	3 (1.5)	1 (0.5)	0	0		193 (96.5)	
Grade 1	0	5 (2.5)	0	0	0	0		5 (2.5)	
Grade 2	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 15										
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 0	0	193 (96.5)	3 (1.5)	1 (0.5)	0	0	197 (98.5)			
Grade 1	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)			
Day 29 - Predose										
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)			
Grade 0	0	188 (94.0)	3 (1.5)	1 (0.5)	0	0	192 (96.0)			
Grade 1	0	5 (2.5)	0	0	0	0	5 (2.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	185 (92.5)	3 (1.5)	1 (0.5)	0	0	189 (94.5)	
Grade 1	0	6 (3.0)	0	0	0	0	6 (3.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)	
Day 36								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	190 (95.0)	3 (1.5)	1 (0.5)	0	0	194 (97.0)	
Grade 1	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint	Baseline												
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)		n (%)	
Day 43													
UNK	0	6	(3.0)	0		0		0		0		6	(3.0)
Grade 0	0	188	(94.0)	3	(1.5)	1	(0.5)	0		0		192	(96.0)
Grade 1	0	2	(1.0)	0		0		0		0		2	(1.0)
Grade 2	0	0		0		0		0		0		0	
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	196	(98.0)	3	(1.5)	1	(0.5)	0		0		200	(100)
Day 57													
UNK	0	2	(1.0)	0		0		0		0		2	(1.0)
Grade 0	0	191	(95.5)	3	(1.5)	1	(0.5)	0		0		195	(97.5)
Grade 1	0	2	(1.0)	0		0		0		0		2	(1.0)
Grade 2	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	196	(98.0)	3	(1.5)	1	(0.5)	0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0	0	0	
Grade 0	0	174 (87.0)	3 (1.5)	1 (0.5)	0	0	0	178 (89.0)	
Grade 1	0	16 (8.0)	0	0	0	0	0	16 (8.0)	
Grade 2	0	6 (3.0)	0	0	0	0	0	6 (3.0)	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	196 (98.0)	3 (1.5)	1 (0.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline												
	UNK n (%)	Grade 0 n (%)		Grade 1 n (%)		Grade 2 n (%)		Grade 3 n (%)		Grade 4 n (%)		Total n (%)	
Day 1 - 1 Hour Postdose													
UNK	0	0		0		0		0		0		0	
Grade 0	0	172	(86.0)	5	(2.5)	0		0		0		177	(88.5)
Grade 1	0	18	(9.0)	1	(0.5)	0		0		0		19	(9.5)
Grade 2	0	2	(1.0)	1	(0.5)	0		0		0		3	(1.5)
Grade 3	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 4	0	0		0		0		0		0		0	
Total	0	193	(96.5)	7	(3.5)	0		0		0		200	(100)
Day 8													
UNK	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 0	0	189	(94.5)	6	(3.0)	0		0		0		195	(97.5)
Grade 1	0	2	(1.0)	1	(0.5)	0		0		0		3	(1.5)
Grade 2	0	1	(0.5)	0		0		0		0		1	(0.5)
Grade 3	0	0		0		0		0		0		0	
Grade 4	0	0		0		0		0		0		0	
Total	0	193	(96.5)	7	(3.5)	0		0		0		200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	186 (93.0)	6 (3.0)	0	0	0	192	(96.0)	
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6	(3.0)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	193 (96.5)	7 (3.5)	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	185 (92.5)	6 (3.0)	0	0	0	191	(95.5)	
Grade 1	0	4 (2.0)	1 (0.5)	0	0	0	5	(2.5)	
Grade 2	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	193 (96.5)	7 (3.5)	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	176 (88.0)	6 (3.0)	0	0	0	182 (91.0)	
Grade 1	0	13 (6.5)	1 (0.5)	0	0	0	14 (7.0)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	193 (96.5)	7 (3.5)	0	0	0	200 (100)	
Day 36								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	187 (93.5)	7 (3.5)	0	0	0	194 (97.0)	
Grade 1	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	193 (96.5)	7 (3.5)	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 43									
UNK	0	7 (3.5)	0	0	0	0	7 (3.5)		
Grade 0	0	180 (90.0)	7 (3.5)	0	0	0	187 (93.5)		
Grade 1	0	6 (3.0)	0	0	0	0	6 (3.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	193 (96.5)	7 (3.5)	0	0	0	200 (100)		
Day 57									
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)		
Grade 0	0	183 (91.5)	6 (3.0)	0	0	0	189 (94.5)		
Grade 1	0	5 (2.5)	1 (0.5)	0	0	0	6 (3.0)		
Grade 2	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	193 (96.5)	7 (3.5)	0	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Bradycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	150 (75.0)	4 (2.0)	0	0	0	154	(77.0)
Grade 1	0	37 (18.5)	2 (1.0)	0	0	0	39	(19.5)
Grade 2	0	5 (2.5)	1 (0.5)	0	0	0	6	(3.0)
Grade 3	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 4	0	0	0	0	0	0	0	
Total	0	193 (96.5)	7 (3.5)	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	200	(100)	0	0	0	0	200	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)
Day 8									
UNK	0	1	(0.5)	0	0	0	0	1	(0.5)
Grade 0	0	199	(99.5)	0	0	0	0	199	(99.5)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)	
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4	(2.0)
Grade 0	0	196 (98.0)	0	0	0	0	196	(98.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 36								
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline							Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Day 43									
UNK	0	7 (3.5)	0	0	0	0	0	7	(3.5)
Grade 0	0	193 (96.5)	0	0	0	0	0	193	(96.5)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)
Day 57									
UNK	0	2 (1.0)	0	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Pulse Rate (beats/min) - Tachycardia

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	199 (99.5)	0	0	0	0	199 (99.5)	
Grade 1	0	1 (0.5)	0	0	0	0	1 (0.5)	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	164 (82.0)	11 (5.5)	0	0	0		175 (87.5)	
Grade 1	0	4 (2.0)	20 (10.0)	1 (0.5)	0	0		25 (12.5)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0		200 (100)	
Day 8									
UNK	0	0	1 (0.5)	0	0	0		1 (0.5)	
Grade 0	0	162 (81.0)	20 (10.0)	1 (0.5)	0	0		183 (91.5)	
Grade 1	0	6 (3.0)	10 (5.0)	0	0	0		16 (8.0)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1 (0.5)		
Grade 0	0	161 (80.5)	6 (3.0)	0	0	0	167 (83.5)		
Grade 1	0	6 (3.0)	25 (12.5)	1 (0.5)	0	0	32 (16.0)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)		
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)		
Grade 0	0	158 (79.0)	8 (4.0)	0	0	0	166 (83.0)		
Grade 1	0	7 (3.5)	23 (11.5)	1 (0.5)	0	0	31 (15.5)		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)		

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	3 (1.5)	1 (0.5)	0	0	0	4 (2.0)			
Grade 0	0	162 (81.0)	14 (7.0)	0	0	0	176 (88.0)			
Grade 1	0	3 (1.5)	16 (8.0)	1 (0.5)	0	0	20 (10.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)			
Day 36										
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)			
Grade 0	0	160 (80.0)	22 (11.0)	1 (0.5)	0	0	183 (91.5)			
Grade 1	0	5 (2.5)	9 (4.5)	0	0	0	14 (7.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 43										
UNK	0	6 (3.0)	0	0	0	0	6 (3.0)			
Grade 0	0	159 (79.5)	19 (9.5)	0	0	0	178 (89.0)			
Grade 1	0	3 (1.5)	12 (6.0)	1 (0.5)	0	0	16 (8.0)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)			
Day 57										
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)			
Grade 0	0	164 (82.0)	19 (9.5)	0	0	0	183 (91.5)			
Grade 1	0	2 (1.0)	12 (6.0)	1 (0.5)	0	0	15 (7.5)			
Grade 2	0	0	0	0	0	0	0			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)			
Worst Post-Baseline									
UNK	0	0	0	0	0	0		0	
Grade 0	0	146 (73.0)	0	0	0	0		146 (73.0)	
Grade 1	0	22 (11.0)	31 (15.5)	1 (0.5)	0	0		54 (27.0)	
Grade 2	0	0	0	0	0	0		0	
Grade 3	0	0	0	0	0	0		0	
Grade 4	0	0	0	0	0	0		0	
Total	0	168 (84.0)	31 (15.5)	1 (0.5)	0	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	200	(100)	0	0	0	0	200	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)
Day 8									
UNK	0	1	(0.5)	0	0	0	0	1	(0.5)
Grade 0	0	199	(99.5)	0	0	0	0	199	(99.5)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	196 (98.0)	0	0	0	0	196	(98.0)	
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	196 (98.0)	0	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	197 (98.5)	0	0	0	0	197 (98.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	6 (3.0)	0	0	0	0	6	(3.0)
Grade 0	0	194 (97.0)	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 57								
UNK	0	2 (1.0)	0	0	0	0	2	(1.0)
Grade 0	0	198 (99.0)	0	0	0	0	198	(99.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Hypotension

Timepoint Post-Baseline Grade	Baseline						Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)
Grade 1	0	1 (0.5)	0	0	0	0	1	(0.5)
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline							Total	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0	0	0	0	0		0	
Grade 0	0	172 (86.0)	7 (3.5)	0	0	0		179 (89.5)	
Grade 1	0	11 (5.5)	4 (2.0)	1 (0.5)	0	0		16 (8.0)	
Grade 2	0	2 (1.0)	1 (0.5)	0	0	0		3 (1.5)	
Grade 3	0	0	1 (0.5)	0	1 (0.5)	0		2 (1.0)	
Grade 4	0	0	0	0	0	0		0	
Total	0	185 (92.5)	13 (6.5)	1 (0.5)	1 (0.5)	0		200 (100)	
Day 8									
UNK	0	1 (0.5)	0	0	0	0		1 (0.5)	
Grade 0	0	179 (89.5)	10 (5.0)	0	1 (0.5)	0		190 (95.0)	
Grade 1	0	3 (1.5)	1 (0.5)	1 (0.5)	0	0		5 (2.5)	
Grade 2	0	2 (1.0)	1 (0.5)	0	0	0		3 (1.5)	
Grade 3	0	0	1 (0.5)	0	0	0		1 (0.5)	
Grade 4	0	0	0	0	0	0		0	
Total	0	185 (92.5)	13 (6.5)	1 (0.5)	1 (0.5)	0		200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline										
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	Total
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)	n (%)
Day 15											
UNK	0	1	(0.5)	0		0		0		0	1 (0.5)
Grade 0	0	178	(89.0)	10	(5.0)	1	(0.5)	0		0	189 (94.5)
Grade 1	0	6	(3.0)	3	(1.5)	0		1	(0.5)	0	10 (5.0)
Grade 2	0	0		0		0		0		0	0
Grade 3	0	0		0		0		0		0	0
Grade 4	0	0		0		0		0		0	0
Total	0	185	(92.5)	13	(6.5)	1	(0.5)	1	(0.5)	0	200 (100)
Day 29 - Predose											
UNK	0	3	(1.5)	0		0		0		0	3 (1.5)
Grade 0	0	174	(87.0)	10	(5.0)	0		0		0	184 (92.0)
Grade 1	0	6	(3.0)	2	(1.0)	0		1	(0.5)	0	9 (4.5)
Grade 2	0	2	(1.0)	0		0		0		0	2 (1.0)
Grade 3	0	0		1	(0.5)	1	(0.5)	0		0	2 (1.0)
Grade 4	0	0		0		0		0		0	0
Total	0	185	(92.5)	13	(6.5)	1	(0.5)	1	(0.5)	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline									
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total			
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)			
Day 29 - 1 Hour										
Postdose										
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)			
Grade 0	0	171 (85.5)	11 (5.5)	1 (0.5)	1 (0.5)	0	184 (92.0)			
Grade 1	0	8 (4.0)	1 (0.5)	0	0	0	9 (4.5)			
Grade 2	0	1 (0.5)	0	0	0	0	1 (0.5)			
Grade 3	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)			
Grade 4	0	0	0	0	0	0	0			
Total	0	185 (92.5)	13 (6.5)	1 (0.5)	1 (0.5)	0	200 (100)			
Day 36										
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)			
Grade 0	0	174 (87.0)	9 (4.5)	0	1 (0.5)	0	184 (92.0)			
Grade 1	0	7 (3.5)	3 (1.5)	1 (0.5)	0	0	11 (5.5)			
Grade 2	0	1 (0.5)	1 (0.5)	0	0	0	2 (1.0)			
Grade 3	0	0	0	0	0	0	0			
Grade 4	0	0	0	0	0	0	0			
Total	0	185 (92.5)	13 (6.5)	1 (0.5)	1 (0.5)	0	200 (100)			

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint	Baseline											
	UNK	Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)		n (%)		n (%)		n (%)	n (%)	
Day 43												
UNK	0	6	(3.0)	0		0		0		0	6	(3.0)
Grade 0	0	166	(83.0)	11	(5.5)	0		1	(0.5)	0	178	(89.0)
Grade 1	0	11	(5.5)	1	(0.5)	1	(0.5)	0		0	13	(6.5)
Grade 2	0	1	(0.5)	0		0		0		0	1	(0.5)
Grade 3	0	1	(0.5)	1	(0.5)	0		0		0	2	(1.0)
Grade 4	0	0		0		0		0		0	0	
Total	0	185	(92.5)	13	(6.5)	1	(0.5)	1	(0.5)	0	200	(100)
Day 57												
UNK	0	2	(1.0)	0		0		0		0	2	(1.0)
Grade 0	0	170	(85.0)	11	(5.5)	1	(0.5)	1	(0.5)	0	183	(91.5)
Grade 1	0	13	(6.5)	0		0		0		0	13	(6.5)
Grade 2	0	0		1	(0.5)	0		0		0	1	(0.5)
Grade 3	0	0		1	(0.5)	0		0		0	1	(0.5)
Grade 4	0	0		0		0		0		0	0	
Total	0	185	(92.5)	13	(6.5)	1	(0.5)	1	(0.5)	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Systolic Blood Pressure (mmHg) - Systolic Hypertension

Timepoint Post-Baseline Grade	Baseline						Total n (%)
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	134 (67.0)	6 (3.0)	0	0	0	140 (70.0)
Grade 1	0	42 (21.0)	1 (0.5)	0	0	0	43 (21.5)
Grade 2	0	7 (3.5)	3 (1.5)	0	0	0	10 (5.0)
Grade 3	0	2 (1.0)	3 (1.5)	1 (0.5)	1 (0.5)	0	7 (3.5)
Grade 4	0	0	0	0	0	0	0
Total	0	185 (92.5)	13 (6.5)	1 (0.5)	1 (0.5)	0	200 (100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0		Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)		n (%)	n (%)	n (%)	n (%)	n (%)	
Day 1 - 1 Hour Postdose									
UNK	0	0		0	0	0	0	0	
Grade 0	0	200	(100)	0	0	0	0	200	(100)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)
Day 8									
UNK	0	1	(0.5)	0	0	0	0	1	(0.5)
Grade 0	0	199	(99.5)	0	0	0	0	199	(99.5)
Grade 1	0	0		0	0	0	0	0	
Grade 2	0	0		0	0	0	0	0	
Grade 3	0	0		0	0	0	0	0	
Grade 4	0	0		0	0	0	0	0	
Total	0	200	(100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline								
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total		
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)		
Day 15									
UNK	0	1 (0.5)	0	0	0	0	1	(0.5)	
Grade 0	0	199 (99.5)	0	0	0	0	199	(99.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	
Day 29 - Predose									
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)	
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)	
Grade 1	0	0	0	0	0	0	0		
Grade 2	0	0	0	0	0	0	0		
Grade 3	0	0	0	0	0	0	0		
Grade 4	0	0	0	0	0	0	0		
Total	0	200 (100)	0	0	0	0	200	(100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 29 - 1 Hour								
Postdose								
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)	
Grade 0	0	196 (98.0)	0	0	0	0	196 (98.0)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	
Day 36								
UNK	0	3 (1.5)	0	0	0	0	3 (1.5)	
Grade 0	0	197 (98.5)	0	0	0	0	197 (98.5)	
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200 (100)	

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint	Baseline							
	UNK	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4	Total	
Post-Baseline Grade	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	
Day 43								
UNK	0	6 (3.0)	0	0	0	0	6	(3.0)
Grade 0	0	194 (97.0)	0	0	0	0	194	(97.0)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)
Day 57								
UNK	0	3 (1.5)	0	0	0	0	3	(1.5)
Grade 0	0	197 (98.5)	0	0	0	0	197	(98.5)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.3.3.2
Shift from Baseline in Vital Signs Toxicity Grades by Visit
Safety Set

Cohort 2 (Age >= 55); Vaccination Group: mRNA-1273 Total (N=200)
Temperature (C) - Fever

Timepoint Post-Baseline Grade	Baseline						Total n (%)	
	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)		
Worst Post-Baseline								
UNK	0	0	0	0	0	0	0	
Grade 0	0	200 (100)	0	0	0	0	200	(100)
Grade 1	0	0	0	0	0	0	0	
Grade 2	0	0	0	0	0	0	0	
Grade 3	0	0	0	0	0	0	0	
Grade 4	0	0	0	0	0	0	0	
Total	0	200 (100)	0	0	0	0	200	(100)

UNK = unknown due to missing vital sign result.

Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.

Percentages are based on the number in the cell on the Total row and Total column.

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GM Level	10.82	10.52	10.50	10.51
95% CI [2]	9.61, 12.19	9.37, 11.81	9.37, 11.78	9.69, 11.40
Median	11.25	10.90	11.40	11.10
Min, Max	4.5, 57.7	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29				
n[3]	184	184	189	373
GM Level	10.50	10.12	9.91	10.01
95% CI [2]	9.30, 11.85	9.03, 11.34	8.84, 11.10	9.24, 10.85
Median	10.70	10.40	10.40	10.40
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.97	0.97	0.94	0.96
95% CI [2]	0.94, 1.01	0.94, 1.00	0.91, 0.98	0.93, 0.98
Day 43				
n[3]	180	175	181	356
GM Level	10.77	10.10	10.21	10.16
95% CI [2]	9.57, 12.12	8.98, 11.36	9.12, 11.44	9.36, 11.02
Median	11.15	10.80	10.50	10.55
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise	0.98	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.97	0.94, 1.01	0.93, 0.98

Notes are listed on last page.

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GM Level	10.60	9.86	10.22	10.04
95% CI [2]	9.36, 12.01	8.75, 11.10	9.11, 11.46	9.24, 10.89
Median	10.70	10.20	11.00	10.70
Min, Max	4.5, 59.5	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise	0.98	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.98

Notes are listed on last page.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t1402010101.sas 19NOV2020 00:15 Database Lock Date: 05NOV2020

Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Level	9.27	9.90	10.15	10.03	12.59	11.14	10.88	11.01
95% CI [2]	7.77, 11.07	8.46, 11.60	8.69, 11.85	8.99, 11.19	10.76, 14.73	9.40, 13.19	9.16, 12.92	9.77, 12.40
Median	4.50	10.40	11.50	10.90	14.00	12.10	11.00	11.70
Min, Max	4.5, 57.7	4.5, 55.6	4.5, 54.8	4.5, 55.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	90	89	95	184	94	95	94	189
GM Level	9.09	9.20	9.49	9.34	12.05	11.08	10.35	10.71
95% CI [2]	7.59, 10.88	7.86, 10.76	8.13, 11.07	8.38, 10.42	10.26, 14.16	9.39, 13.06	8.73, 12.28	9.52, 12.05
Median	4.50	9.30	10.10	9.65	13.85	11.40	10.50	11.10
Min, Max	4.5, 60.9	4.5, 53.7	4.5, 55.6	4.5, 55.6	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.99	0.94	0.93	0.94	0.96	0.99	0.95	0.97
95% CI [2]	0.93, 1.05	0.90, 0.99	0.88, 0.99	0.90, 0.97	0.91, 1.01	0.96, 1.03	0.91, 0.99	0.95, 1.00
Day 43								
n[3]	87	84	94	178	93	91	87	178
GM Level	9.36	9.22	10.00	9.63	12.27	10.98	10.44	10.72
95% CI [2]	7.83, 11.19	7.83, 10.85	8.61, 11.63	8.63, 10.74	10.51, 14.33	9.26, 13.02	8.77, 12.44	9.50, 12.09
Median	4.50	10.05	10.40	10.20	12.70	11.50	10.70	11.20
Min, Max	4.5, 55.7	4.5, 53.6	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise	0.99	0.94	0.98	0.96	0.97	0.95	0.96	0.95
95% CI [2]	0.91, 1.08	0.89, 0.98	0.92, 1.03	0.92, 0.99	0.94, 1.00	0.90, 1.00	0.92, 1.01	0.92, 0.99

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GM Level	9.28	9.20	9.68	9.44	12.00	10.50	10.76	10.63
95% CI [2]	7.67, 11.22	7.80, 10.84	8.24, 11.36	8.42, 10.57	10.20, 14.11	8.84, 12.48	9.12, 12.71	9.44, 11.97
Median	4.50	9.70	11.00	10.40	12.70	10.20	11.25	10.85
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 59.0	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise	1.02	0.95	0.98	0.97	0.94	0.94	0.97	0.95
95% CI [2]	0.94, 1.11	0.90, 1.00	0.92, 1.04	0.93, 1.00	0.90, 0.98	0.89, 0.99	0.91, 1.02	0.92, 0.99

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GM Level	5.952	6.078	5.875	5.975
95% CI [2]	5.592, 6.335	5.646, 6.543	5.485, 6.293	5.682, 6.282
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 106.00	1.95, 106.00
Day 29				
n[3]	184	184	189	373
GM Level	5.803	20.324	25.229	22.677
95% CI [2]	5.420, 6.213	18.601, 22.207	22.777, 27.944	21.179, 24.281
Median	5.900	20.200	25.600	22.000
Min, Max	1.95, 40.40	4.10, 106.50	4.30, 431.60	4.10, 431.60
GM Fold-Rise	0.98	3.36	4.29	3.80
95% CI [2]	0.95, 1.01	3.05, 3.69	3.87, 4.76	3.54, 4.08
Day 43				
n[3]	180	175	181	356
GM Level	5.735	169.460	198.134	183.478
95% CI [2]	5.361, 6.135	156.251, 183.786	182.865, 214.678	173.252, 194.309
Median	5.900	186.300	204.300	197.550
Min, Max	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise	0.97	27.46	33.51	30.38
95% CI [2]	0.95, 1.00	24.86, 30.33	30.37, 36.96	28.32, 32.59

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GM Level	5.861	123.892	147.415	135.176
95% CI [2]	5.461, 6.291	113.072, 135.748	134.466, 161.612	126.651, 144.275
Median	5.900	136.000	166.100	149.600
Min, Max	1.95, 62.50	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise	0.98	20.39	25.04	22.60
95% CI [2]	0.94, 1.03	18.31, 22.70	22.51, 27.86	20.94, 24.39

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Level	6.483	6.978	6.207	6.571	5.474	5.332	5.558	5.444
95% CI [2]	5.945, 7.070	6.266, 7.771	5.743, 6.709	6.153, 7.017	5.014, 5.976	4.845, 5.868	4.959, 6.230	5.056, 5.860
Median	6.450	6.650	6.500	6.500	5.600	5.500	5.850	5.800
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 16.30	1.95, 37.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	90	89	95	184	94	95	94	189
GM Level	6.319	25.291	32.678	28.868	5.349	16.561	19.424	17.928
95% CI [2]	5.737, 6.959	22.538, 28.379	28.761, 37.127	26.449, 31.509	4.862, 5.885	14.669, 18.696	16.826, 22.423	16.324, 19.689
Median	6.050	25.500	30.900	28.350	5.600	16.000	18.150	17.100
Min, Max	1.95, 40.40	7.30, 106.50	9.50, 285.00	7.30, 285.00	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise	0.98	3.65	5.26	4.41	0.98	3.11	3.49	3.29
95% CI [2]	0.94, 1.02	3.20, 4.16	4.57, 6.06	3.99, 4.87	0.94, 1.02	2.71, 3.57	3.03, 4.03	2.98, 3.64
Day 43								
n[3]	87	84	94	178	93	91	87	178
GM Level	6.188	188.765	239.140	213.881	5.341	153.397	161.693	157.397
95% CI [2]	5.644, 6.784	172.505, 206.557	221.120, 258.629	201.166, 227.400	4.844, 5.890	134.640, 174.768	141.614, 184.620	143.540, 172.593
Median	6.300	196.550	238.750	217.800	5.600	154.300	183.200	168.550
Min, Max	1.95, 14.80	46.70, 487.00	71.10, 487.00	46.70, 487.00	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise	0.97	26.82	38.47	32.45	0.98	28.05	28.86	28.44
95% CI [2]	0.94, 1.00	23.46, 30.67	34.54, 42.85	29.71, 35.45	0.94, 1.02	24.19, 32.53	24.49, 34.01	25.50, 31.73

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GM Level	6.536	145.710	181.147	162.776	5.300	106.837	120.792	113.524
95% CI [2]	5.914, 7.225	131.724, 161.182	164.168, 199.883	151.519, 174.869	4.811, 5.840	92.529, 123.357	104.603, 139.486	102.603, 125.607
Median	6.300	147.300	191.400	169.000	5.500	127.000	146.550	134.900
Min, Max	1.95, 62.50	36.70, 408.10	33.60, 487.00	33.60, 487.00	1.95, 14.00	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise	1.01	20.70	29.13	24.63	0.96	20.11	21.63	20.85
95% CI [2]	0.95, 1.08	17.92, 23.90	25.68, 33.03	22.33, 27.16	0.90, 1.01	17.12, 23.62	18.29, 25.59	18.58, 23.39

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Table 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Baseline				
n[1]	196	198	197	395
GM Level	11.09	10.75	10.40	10.57
95% CI [2]	9.87, 12.46	9.58, 12.06	9.30, 11.63	9.76, 11.45
Median	11.95	11.05	11.10	11.10
Min, Max	4.5, 57.7	4.5, 130.6	4.5, 90.1	4.5, 130.6
Day 29				
n[3]	194	196	195	391
GM Level	10.80	10.38	9.93	10.15
95% CI [2]	9.59, 12.16	9.28, 11.61	8.88, 11.11	9.38, 10.98
Median	11.25	10.65	10.40	10.60
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.97	0.97	0.95	0.96
95% CI [2]	0.94, 1.01	0.94, 1.01	0.92, 0.98	0.94, 0.98
Day 43				
n[3]	194	191	195	386
GM Level	10.79	10.40	10.13	10.27
95% CI [2]	9.63, 12.10	9.27, 11.67	9.09, 11.30	9.49, 11.11
Median	11.25	11.30	10.50	10.75
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise	0.97	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.98	0.94, 1.01	0.94, 0.98

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Day 57				
n[3]	196	194	197	391
GM Level	11.04	10.25	10.05	10.15
95% CI [2]	9.78, 12.48	9.14, 11.49	9.03, 11.20	9.39, 10.97
Median	11.05	10.35	11.00	11.00
Min, Max	4.5, 241.6	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise	1.00	0.94	0.97	0.95
95% CI [2]	0.94, 1.06	0.91, 0.98	0.93, 1.01	0.93, 0.98

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
Statistic	(N=96)	(N=98)	(N=99)	(N=197)	(N=100)	(N=100)	(N=98)	(N=198)
Baseline								
n[1]	96	98	99	197	100	100	98	198
GM Level	9.50	10.09	9.91	10.00	12.88	11.44	10.93	11.18
95% CI [2]	7.98, 11.30	8.59, 11.84	8.52, 11.52	8.96, 11.15	11.06, 15.01	9.69, 13.51	9.25, 12.91	9.95, 12.57
Median	4.50	10.40	11.10	10.60	14.30	12.10	11.40	11.90
Min, Max	4.5, 57.7	4.5, 130.6	4.5, 54.8	4.5, 130.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	94	97	98	195	100	99	97	196
GM Level	9.34	9.50	9.39	9.45	12.38	11.31	10.51	10.91
95% CI [2]	7.82, 11.15	8.12, 11.11	8.07, 10.93	8.48, 10.52	10.58, 14.49	9.63, 13.29	8.90, 12.41	9.73, 12.23
Median	4.50	9.80	9.80	9.80	14.00	11.60	10.60	11.35
Min, Max	4.5, 60.9	4.5, 72.0	4.5, 55.6	4.5, 72.0	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.98	0.95	0.94	0.95	0.96	1.00	0.95	0.97
95% CI [2]	0.93, 1.04	0.90, 1.01	0.89, 0.99	0.91, 0.98	0.92, 1.01	0.96, 1.03	0.92, 0.99	0.95, 1.00
Day 43								
n[3]	94	95	99	194	100	96	96	192
GM Level	9.31	9.66	9.72	9.69	12.41	11.20	10.58	10.88
95% CI [2]	7.85, 11.04	8.26, 11.29	8.40, 11.25	8.71, 10.77	10.67, 14.42	9.44, 13.28	8.97, 12.48	9.68, 12.24
Median	4.50	10.20	10.20	10.20	12.60	11.50	10.95	11.35
Min, Max	4.5, 55.7	4.5, 56.2	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise	0.99	0.93	0.98	0.96	0.96	0.96	0.97	0.96
95% CI [2]	0.91, 1.07	0.89, 0.98	0.93, 1.04	0.92, 0.99	0.93, 0.99	0.91, 1.01	0.93, 1.01	0.93, 0.99

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 57								
n[3]	96	95	99	194	100	99	98	197
GM Level	9.54	9.73	9.55	9.64	12.71	10.77	10.59	10.68
95% CI [2]	8.00, 11.37	8.31, 11.38	8.24, 11.08	8.66, 10.72	10.75, 15.04	9.10, 12.75	9.04, 12.40	9.52, 11.98
Median	4.50	10.40	11.00	10.75	13.10	10.30	11.25	11.00
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 241.6	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise	1.00	0.94	0.96	0.95	0.99	0.95	0.97	0.96
95% CI [2]	0.93, 1.08	0.89, 0.99	0.91, 1.02	0.92, 0.99	0.90, 1.08	0.90, 1.00	0.92, 1.02	0.92, 0.99

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Baseline				
n[1]	196	198	197	395
GM Level	5.963	6.140	5.877	6.008
95% CI [2]	5.617, 6.330	5.692, 6.625	5.501, 6.278	5.714, 6.317
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 108.70	1.95, 106.00	1.95, 108.70
Day 29				
n[3]	194	196	195	391
GM Level	5.924	20.381	25.264	22.686
95% CI [2]	5.530, 6.346	18.625, 22.303	22.825, 27.964	21.186, 24.291
Median	5.900	19.900	25.800	21.900
Min, Max	1.95, 40.40	4.10, 414.30	4.30, 431.60	4.10, 431.60
GM Fold-Rise	0.99	3.33	4.30	3.78
95% CI [2]	0.96, 1.03	3.04, 3.65	3.88, 4.77	3.53, 4.05
Day 43				
n[3]	194	191	195	386
GM Level	5.907	165.113	194.834	179.512
95% CI [2]	5.478, 6.369	151.574, 179.860	178.283, 212.920	168.729, 190.985
Median	5.900	185.700	205.700	197.600
Min, Max	1.95, 313.10	8.10, 487.00	4.90, 487.00	4.90, 487.00
GM Fold-Rise	1.00	26.70	33.08	29.75
95% CI [2]	0.95, 1.04	24.15, 29.52	29.88, 36.62	27.69, 31.97

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Day 57				
n[3]	196	194	197	391
GM Level	6.208	121.718	144.407	132.665
95% CI [2]	5.670, 6.797	111.017, 133.450	131.159, 158.994	124.087, 141.837
Median	5.950	135.750	165.300	149.500
Min, Max	1.95, 298.30	7.20, 456.00	4.70, 487.00	4.70, 487.00
GM Fold-Rise	1.04	19.86	24.57	22.11
95% CI [2]	0.97, 1.12	17.88, 22.05	22.07, 27.36	20.50, 23.84

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	99	197	100	100	98	198
GM Level	6.496	7.193	6.195	6.673	5.492	5.259	5.572	5.411
95% CI [2]	5.976, 7.062	6.421, 8.057	5.750, 6.675	6.234, 7.143	5.053, 5.970	4.791, 5.772	4.994, 6.217	5.039, 5.811
Median	6.350	6.850	6.400	6.600	5.600	5.500	5.850	5.650
Min, Max	1.95, 16.80	1.95, 108.70	1.95, 16.30	1.95, 108.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	94	97	98	195	100	99	97	196
GM Level	6.521	25.332	32.417	28.675	5.413	16.470	19.640	17.969
95% CI [2]	5.890, 7.219	22.361, 28.698	28.417, 36.979	26.165, 31.425	4.941, 5.930	14.647, 18.520	17.077, 22.586	16.404, 19.683
Median	6.100	24.300	30.950	28.300	5.600	16.300	18.600	17.400
Min, Max	1.95, 40.40	7.30, 414.30	4.80, 285.00	4.80, 414.30	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise	1.00	3.54	5.24	4.31	0.99	3.13	3.52	3.32
95% CI [2]	0.95, 1.06	3.13, 4.02	4.54, 6.04	3.91, 4.76	0.95, 1.02	2.74, 3.58	3.06, 4.05	3.02, 3.65
Day 43								
n[3]	94	95	99	194	100	96	96	192
GM Level	6.526	188.777	228.416	208.061	5.379	144.616	165.365	154.643
95% CI [2]	5.792, 7.353	172.952, 206.050	203.047, 256.955	193.144, 224.130	4.906, 5.898	125.311, 166.896	145.621, 187.785	140.572, 170.122
Median	6.300	197.600	238.800	217.450	5.600	151.400	186.100	171.000
Min, Max	1.95, 313.10	44.80, 487.00	4.90, 487.00	4.90, 487.00	1.95, 17.80	8.10, 487.00	20.10, 487.00	8.10, 487.00
GM Fold-Rise	1.01	26.29	36.87	31.24	0.98	27.11	29.58	28.32
95% CI [2]	0.93, 1.11	23.02, 30.03	32.21, 42.20	28.35, 34.42	0.94, 1.02	23.27, 31.58	25.42, 34.42	25.45, 31.51

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 57								
n[3]	96	95	99	194	100	99	98	197
GM Level	7.093	145.446	171.160	158.045	5.462	102.597	121.625	111.658
95% CI [2]	6.227, 8.080	131.887, 160.398	150.454, 194.715	145.675, 171.465	4.828, 6.179	88.490, 118.953	106.065, 139.469	100.968, 123.481
Median	6.400	148.300	182.800	168.350	5.550	123.500	146.550	130.700
Min, Max	1.95, 199.40	33.50, 408.10	4.70, 487.00	4.70, 487.00	1.95, 298.30	7.20, 456.00	23.10, 487.00	7.20, 487.00
GM Fold-Rise	1.09	20.26	27.63	23.73	0.99	19.48	21.83	20.62
95% CI [2]	0.98, 1.22	17.62, 23.29	23.92, 31.90	21.43, 26.28	0.90, 1.09	16.64, 22.82	18.62, 25.59	18.44, 23.04

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Table 14.2.1.1.2
Summary of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GM Level	10.74	10.51	10.50	10.51
95% CI [2]	9.54, 12.10	9.36, 11.81	9.37, 11.78	9.69, 11.40
Median	11.20	10.90	11.40	11.10
Min, Max	4.5, 57.7	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29				
n[3]	183	183	189	372
GM Level	10.41	10.12	9.91	10.01
95% CI [2]	9.22, 11.74	9.02, 11.34	8.84, 11.10	9.24, 10.85
Median	10.60	10.20	10.40	10.35
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.97	0.97	0.94	0.96
95% CI [2]	0.93, 1.01	0.94, 1.00	0.91, 0.98	0.93, 0.98
Day 43				
n[3]	179	174	181	355
GM Level	10.68	10.09	10.21	10.15
95% CI [2]	9.49, 12.02	8.96, 11.36	9.12, 11.44	9.36, 11.01
Median	11.10	10.65	10.50	10.50
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise	0.98	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.97	0.94, 1.01	0.93, 0.98

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	175	177	352
GM Level	10.52	9.85	10.22	10.03
95% CI [2]	9.29, 11.91	8.74, 11.10	9.11, 11.46	9.24, 10.89
Median	10.65	10.20	11.00	10.60
Min, Max	4.5, 59.5	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise	0.98	0.94	0.97	0.96
95% CI [2]	0.93, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.98

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint	Placebo	50 µg	100 µg	Total	Placebo	50 µg	100 µg	Total
Statistic	(N=91)	(N=90)	(N=95)	(N=185)	(N=94)	(N=94)	(N=94)	(N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GM Level	9.12	9.90	10.15	10.03	12.59	11.13	10.88	11.00
95% CI [2]	7.65, 10.87	8.46, 11.60	8.69, 11.85	8.99, 11.19	10.76, 14.73	9.38, 13.21	9.16, 12.92	9.76, 12.41
Median	4.50	10.40	11.50	10.90	14.00	12.10	11.00	11.40
Min, Max	4.5, 57.7	4.5, 55.6	4.5, 54.8	4.5, 55.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	89	89	95	184	94	94	94	188
GM Level	8.91	9.20	9.49	9.34	12.05	11.07	10.35	10.71
95% CI [2]	7.46, 10.65	7.86, 10.76	8.13, 11.07	8.38, 10.42	10.26, 14.16	9.38, 13.08	8.73, 12.28	9.52, 12.05
Median	4.50	9.30	10.10	9.65	13.85	11.50	10.50	11.15
Min, Max	4.5, 60.9	4.5, 53.7	4.5, 55.6	4.5, 55.6	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise	0.99	0.94	0.93	0.94	0.96	0.99	0.95	0.97
95% CI [2]	0.93, 1.05	0.90, 0.99	0.88, 0.99	0.90, 0.97	0.91, 1.01	0.96, 1.03	0.91, 0.99	0.95, 1.00
Day 43								
n[3]	86	84	94	178	93	90	87	177
GM Level	9.19	9.22	10.00	9.63	12.27	10.97	10.44	10.71
95% CI [2]	7.70, 10.97	7.83, 10.85	8.61, 11.63	8.63, 10.74	10.51, 14.33	9.24, 13.04	8.77, 12.44	9.49, 12.09
Median	4.50	10.05	10.40	10.20	12.70	11.40	10.70	11.10
Min, Max	4.5, 55.7	4.5, 53.6	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise	0.99	0.94	0.98	0.96	0.97	0.95	0.96	0.95
95% CI [2]	0.91, 1.08	0.89, 0.98	0.92, 1.03	0.92, 0.99	0.94, 1.00	0.90, 1.00	0.92, 1.01	0.92, 0.99

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 57								
n[3]	83	84	87	171	91	91	90	181
GM Level	9.10	9.20	9.68	9.44	12.00	10.49	10.76	10.63
95% CI [2]	7.53, 11.00	7.80, 10.84	8.24, 11.36	8.42, 10.57	10.20, 14.11	8.81, 12.49	9.12, 12.71	9.43, 11.97
Median	4.50	9.70	11.00	10.40	12.70	10.20	11.25	10.80
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 59.0	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise	1.02	0.95	0.98	0.97	0.94	0.94	0.97	0.95
95% CI [2]	0.94, 1.11	0.90, 1.00	0.92, 1.04	0.93, 1.00	0.90, 0.98	0.89, 0.98	0.91, 1.02	0.92, 0.99

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GM Level	5.951	6.074	5.875	5.973
95% CI [2]	5.589, 6.336	5.640, 6.542	5.485, 6.293	5.680, 6.281
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 106.00	1.95, 106.00
Day 29				
n[3]	183	183	189	372
GM Level	5.802	20.415	25.229	22.733
95% CI [2]	5.417, 6.215	18.683, 22.307	22.777, 27.944	21.231, 24.342
Median	5.900	20.400	25.600	22.050
Min, Max	1.95, 40.40	4.10, 106.50	4.30, 431.60	4.10, 431.60
GM Fold-Rise	0.98	3.38	4.29	3.81
95% CI [2]	0.95, 1.01	3.07, 3.71	3.87, 4.76	3.55, 4.10
Day 43				
n[3]	179	174	181	355
GM Level	5.732	170.139	198.134	183.880
95% CI [2]	5.356, 6.134	156.864, 184.538	182.865, 214.678	173.631, 194.734
Median	5.900	186.400	204.300	197.600
Min, Max	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise	0.97	27.58	33.51	30.46
95% CI [2]	0.95, 1.00	24.97, 30.47	30.37, 36.96	28.39, 32.68

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	175	177	352
GM Level	5.862	124.611	147.415	135.599
95% CI [2]	5.459, 6.294	113.750, 136.509	134.466, 161.612	127.061, 144.711
Median	5.900	136.200	166.100	149.650
Min, Max	1.95, 62.50	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise	0.98	20.52	25.04	22.68
95% CI [2]	0.94, 1.03	18.43, 22.84	22.51, 27.86	21.02, 24.47

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GM Level	6.487	6.978	6.207	6.571	5.474	5.318	5.558	5.437
95% CI [2]	5.942, 7.081	6.266, 7.771	5.743, 6.709	6.153, 7.017	5.014, 5.976	4.829, 5.858	4.959, 6.230	5.049, 5.856
Median	6.500	6.650	6.500	6.500	5.600	5.500	5.850	5.800
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 16.30	1.95, 37.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	89	89	95	184	94	94	94	188
GM Level	6.322	25.291	32.678	28.868	5.349	16.668	19.424	17.994
95% CI [2]	5.734, 6.970	22.538, 28.379	28.761, 37.127	26.449, 31.509	4.862, 5.885	14.755, 18.829	16.826, 22.423	16.380, 19.766
Median	6.100	25.500	30.900	28.350	5.600	16.150	18.150	17.250
Min, Max	1.95, 40.40	7.30, 106.50	9.50, 285.00	7.30, 285.00	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise	0.98	3.65	5.26	4.41	0.98	3.13	3.49	3.31
95% CI [2]	0.94, 1.02	3.20, 4.16	4.57, 6.06	3.99, 4.87	0.94, 1.02	2.73, 3.60	3.03, 4.03	3.00, 3.65
Day 43								
n[3]	86	84	94	178	93	90	87	177
GM Level	6.187	188.765	239.140	213.881	5.341	154.417	161.693	157.952
95% CI [2]	5.637, 6.790	172.505, 206.557	221.120, 258.629	201.166, 227.400	4.844, 5.890	135.426, 176.072	141.614, 184.620	144.007, 173.246
Median	6.250	196.550	238.750	217.800	5.600	156.750	183.200	168.900
Min, Max	1.95, 14.80	46.70, 487.00	71.10, 487.00	46.70, 487.00	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise	0.97	26.82	38.47	32.45	0.98	28.31	28.86	28.58
95% CI [2]	0.93, 1.00	23.46, 30.67	34.54, 42.85	29.71, 35.45	0.94, 1.02	24.40, 32.84	24.49, 34.01	25.61, 31.88

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 57								
n[3]	83	84	87	171	91	91	90	181
GM Level	6.546	145.710	181.147	162.776	5.300	107.857	120.792	114.106
95% CI [2]	5.915, 7.244	131.724, 161.182	164.168, 199.883	151.519, 174.869	4.811, 5.840	93.380, 124.578	104.603, 139.486	103.123, 126.258
Median	6.300	147.300	191.400	169.000	5.500	127.300	146.550	135.700
Min, Max	1.95, 62.50	36.70, 408.10	33.60, 487.00	33.60, 487.00	1.95, 14.00	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise	1.02	20.70	29.13	24.63	0.96	20.35	21.63	20.98
95% CI [2]	0.95, 1.08	17.92, 23.90	25.68, 33.03	22.33, 27.16	0.90, 1.01	17.33, 23.91	18.29, 25.59	18.70, 23.54

Notes are listed on last page.

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Table 14.2.1.1.3
Sensitivity Analysis of Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GM value and GM fold-rise, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GM Value [2]	10.81	10.50	10.51	10.50
95% CI [2]	9.63, 12.14	9.35, 11.79	9.37, 11.79	9.68, 11.39
Median	11.25	10.90	11.40	11.10
Min, Max	4.5, 57.7	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29				
n[3]	184	184	189	373
GM Value [2]	10.30	10.23	9.98	10.11
95% CI [2]	9.95, 10.65	9.89, 10.59	9.65, 10.32	9.87, 10.35
Median	10.70	10.40	10.40	10.40
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.97	0.97	0.94	0.95
95% CI [2]	0.94, 1.01	0.93, 1.00	0.91, 0.98	0.93, 0.98
Day 43				
n[3]	180	175	181	356
GM Value [2]	10.56	10.11	10.40	10.26
95% CI [2]	10.17, 10.95	9.74, 10.50	10.03, 10.79	9.99, 10.53
Median	11.15	10.80	10.50	10.55
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise [2]	0.98	0.94	0.97	0.96
95% CI [2]	0.95, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.98

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GM Value [2]	10.38	9.99	10.30	10.15
95% CI [2]	9.98, 10.81	9.60, 10.40	9.90, 10.72	9.87, 10.43
Median	10.70	10.20	11.00	10.70
Min, Max	4.5, 59.5	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise [2]	0.98	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.99

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Value [2]	9.27	9.90	10.15	10.03	12.59	11.14	10.88	11.01
95% CI [2]	7.88, 10.91	8.40, 11.67	8.65, 11.91	8.95, 11.24	10.68, 14.85	9.45, 13.13	9.22, 12.83	9.80, 12.36
Median	4.50	10.40	11.50	10.90	14.00	12.10	11.00	11.70
Min, Max	4.5, 57.7	4.5, 55.6	4.5, 54.8	4.5, 55.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	90	89	95	184	94	95	94	189
GM Value [2]	9.57	9.13	9.10	9.11	11.05	11.43	10.94	11.18
95% CI [2]	9.06, 10.10	8.64, 9.64	8.63, 9.60	8.77, 9.47	10.61, 11.52	10.97, 11.91	10.49, 11.40	10.86, 11.51
Median	4.50	9.30	10.10	9.65	13.85	11.40	10.50	11.10
Min, Max	4.5, 60.9	4.5, 53.7	4.5, 55.6	4.5, 55.6	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.98	0.94	0.94	0.94	0.96	0.99	0.95	0.97
95% CI [2]	0.93, 1.04	0.89, 0.99	0.89, 0.99	0.90, 0.97	0.92, 1.00	0.95, 1.03	0.91, 0.99	0.94, 1.00
Day 43								
n[3]	87	84	94	178	93	91	87	178
GM Value [2]	9.73	9.21	9.65	9.44	11.40	11.07	11.21	11.14
95% CI [2]	9.15, 10.36	8.65, 9.81	9.09, 10.25	9.04, 9.86	10.94, 11.88	10.62, 11.54	10.74, 11.70	10.81, 11.47
Median	4.50	10.05	10.40	10.20	12.70	11.50	10.70	11.20
Min, Max	4.5, 55.7	4.5, 53.6	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise [2]	0.99	0.94	0.98	0.96	0.98	0.95	0.96	0.95
95% CI [2]	0.93, 1.05	0.88, 1.00	0.92, 1.04	0.92, 1.00	0.94, 1.02	0.91, 0.99	0.92, 1.00	0.92, 0.98

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GM Value [2]	9.71	9.08	9.37	9.23	11.04	10.92	11.25	11.08
95% CI [2]	9.10, 10.35	8.52, 9.68	8.80, 9.98	8.82, 9.65	10.51, 11.60	10.40, 11.47	10.71, 11.82	10.71, 11.47
Median	4.50	9.70	11.00	10.40	12.70	10.20	11.25	10.85
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 59.0	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise [2]	1.02	0.95	0.98	0.97	0.95	0.94	0.96	0.95
95% CI [2]	0.95, 1.08	0.89, 1.01	0.92, 1.05	0.92, 1.01	0.90, 0.99	0.89, 0.98	0.92, 1.01	0.92, 0.98

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GM Value [2]	5.958	6.093	5.873	5.981
95% CI [2]	5.572, 6.371	5.697, 6.516	5.495, 6.276	5.704, 6.270
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 106.00	1.95, 106.00
Day 29				
n[3]	184	184	189	373
GM Value [2]	5.831	20.238	25.382	22.700
95% CI [2]	5.405, 6.291	18.759, 21.834	23.551, 27.356	21.505, 23.961
Median	5.900	20.200	25.600	22.000
Min, Max	1.95, 40.40	4.10, 106.50	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	0.98	3.40	4.26	3.81
95% CI [2]	0.91, 1.06	3.15, 3.67	3.96, 4.60	3.61, 4.03
Day 43				
n[3]	180	175	181	356
GM Value [2]	5.786	168.205	198.414	182.950
95% CI [2]	5.399, 6.201	156.797, 180.442	185.183, 212.591	174.089, 192.261
Median	5.900	186.300	204.300	197.550
Min, Max	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise [2]	0.97	28.07	33.11	30.53
95% CI [2]	0.90, 1.03	26.17, 30.11	30.90, 35.48	29.05, 32.09

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GM Value [2]	5.895	123.839	148.493	135.648
95% CI [2]	5.450, 6.376	114.518, 133.918	137.352, 160.537	128.296, 143.422
Median	5.900	136.000	166.100	149.600
Min, Max	1.95, 62.50	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise [2]	0.99	20.73	24.85	22.70
95% CI [2]	0.91, 1.07	19.17, 22.41	22.99, 26.87	21.47, 24.00

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Value [2]	6.483	6.978	6.207	6.571	5.474	5.332	5.558	5.444
95% CI [2]	5.923, 7.097	6.369, 7.646	5.679, 6.784	6.164, 7.005	4.958, 6.045	4.832, 5.885	5.034, 6.137	5.076, 5.837
Median	6.450	6.650	6.500	6.500	5.600	5.500	5.850	5.800
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 16.30	1.95, 37.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	90	89	95	184	94	95	94	189
GM Value [2]	6.350	24.526	33.474	28.803	5.338	16.768	19.221	17.946
95% CI [2]	5.717, 7.054	22.059, 27.269	30.213, 37.087	26.704, 31.066	4.792, 5.946	15.061, 18.669	17.255, 21.412	16.627, 19.371
Median	6.050	25.500	30.900	28.350	5.600	16.000	18.150	17.100
Min, Max	1.95, 40.40	7.30, 106.50	9.50, 285.00	7.30, 285.00	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	0.97	3.76	5.14	4.42	0.98	3.07	3.52	3.29
95% CI [2]	0.88, 1.08	3.39, 4.19	4.64, 5.69	4.10, 4.77	0.88, 1.09	2.76, 3.42	3.16, 3.93	3.05, 3.55

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 43								
n[3]	87	84	94	178	93	91	87	178
GM Value [2]	6.230	183.934	243.224	213.239	5.359	153.890	160.587	157.127
95% CI [2]	5.748, 6.752	169.409, 199.704	225.070, 262.843	201.098, 226.114	4.797, 5.986	137.591, 172.119	143.211, 180.070	145.056, 170.203
Median	6.300	196.550	238.750	217.800	5.600	154.300	183.200	168.550
Min, Max	1.95, 14.80	46.70, 487.00	71.10, 487.00	46.70, 487.00	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise [2]	0.95	28.17	37.26	32.66	0.97	27.93	29.14	28.51
95% CI [2]	0.88, 1.03	25.95, 30.59	34.48, 40.26	30.80, 34.64	0.87, 1.09	24.97, 31.23	25.99, 32.68	26.32, 30.89
Day 57								
n[3]	84	84	87	171	91	92	90	182
GM Value [2]	6.569	142.654	183.994	162.409	5.274	108.163	119.884	113.811
95% CI [2]	5.971, 7.228	129.602, 157.021	167.468, 202.150	151.634, 173.951	4.665, 5.961	95.743, 122.194	105.981, 135.611	104.357, 124.122
Median	6.300	147.300	191.400	169.000	5.500	127.000	146.550	134.900
Min, Max	1.95, 62.50	36.70, 408.10	33.60, 487.00	33.60, 487.00	1.95, 14.00	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise [2]	1.00	21.76	28.07	24.78	0.96	19.74	21.88	20.77
95% CI [2]	0.91, 1.10	19.77, 23.95	25.55, 30.84	23.13, 26.54	0.85, 1.09	17.47, 22.30	19.34, 24.75	19.05, 22.65

Notes are listed on last page.

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Table 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

[1] Number of subjects with non-missing baseline.

[2] The GM values, GM fold-rise, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed level with baseline level as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Baseline				
n[1]	196	198	197	395
GM Value [2]	11.07	10.74	10.41	10.57
95% CI [2]	9.88, 12.41	9.59, 12.03	9.29, 11.65	9.76, 11.45
Median	11.95	11.05	11.10	11.10
Min, Max	4.5, 57.7	4.5, 130.6	4.5, 90.1	4.5, 130.6
Day 29				
n[3]	194	196	195	391
GM Value [2]	10.46	10.46	10.17	10.31
95% CI [2]	10.11, 10.82	10.11, 10.82	9.83, 10.52	10.07, 10.57
Median	11.25	10.65	10.40	10.60
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.97	0.97	0.95	0.96
95% CI [2]	0.94, 1.01	0.94, 1.01	0.91, 0.98	0.94, 0.98
Day 43				
n[3]	194	191	195	386
GM Value [2]	10.56	10.23	10.52	10.38
95% CI [2]	10.20, 10.95	9.87, 10.60	10.16, 10.90	10.12, 10.64
Median	11.25	11.30	10.50	10.75
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise [2]	0.98	0.95	0.97	0.96
95% CI [2]	0.94, 1.01	0.91, 0.98	0.94, 1.01	0.94, 0.98

Notes are listed on last page.

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Day 57				
n[3]	196	194	197	391
GM Value [2]	10.76	10.17	10.39	10.28
95% CI [2]	10.29, 11.25	9.73, 10.64	9.94, 10.86	9.97, 10.61
Median	11.05	10.35	11.00	11.00
Min, Max	4.5, 241.6	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise [2]	1.00	0.94	0.96	0.95
95% CI [2]	0.95, 1.04	0.90, 0.99	0.92, 1.01	0.92, 0.98

Notes are listed on last page.

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	99	197	100	100	98	198
GM Value [2]	9.50	10.09	9.91	10.00	12.88	11.44	10.93	11.18
95% CI [2]	8.08, 11.17	8.59, 11.84	8.45, 11.62	8.93, 11.19	10.97, 15.12	9.75, 13.43	9.29, 12.85	9.98, 12.53
Median	4.50	10.40	11.10	10.60	14.30	12.10	11.40	11.90
Min, Max	4.5, 57.7	4.5, 130.6	4.5, 54.8	4.5, 130.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	94	97	98	195	100	99	97	196
GM Value [2]	9.63	9.36	9.25	9.31	11.32	11.67	11.16	11.42
95% CI [2]	9.10, 10.19	8.86, 9.89	8.76, 9.78	8.95, 9.68	10.88, 11.79	11.21, 12.15	10.71, 11.63	11.09, 11.75
Median	4.50	9.80	9.80	9.80	14.00	11.60	10.60	11.35
Min, Max	4.5, 60.9	4.5, 72.0	4.5, 55.6	4.5, 72.0	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.98	0.95	0.94	0.95	0.96	0.99	0.95	0.97
95% CI [2]	0.93, 1.04	0.90, 1.01	0.89, 1.00	0.91, 0.98	0.93, 1.00	0.95, 1.04	0.91, 0.99	0.94, 1.00
Day 43								
n[3]	94	95	99	194	100	96	96	192
GM Value [2]	9.72	9.27	9.70	9.49	11.44	11.30	11.42	11.36
95% CI [2]	9.17, 10.30	8.75, 9.82	9.17, 10.27	9.11, 9.88	10.97, 11.92	10.83, 11.78	10.94, 11.91	11.02, 11.70
Median	4.50	10.20	10.20	10.20	12.60	11.50	10.95	11.35
Min, Max	4.5, 55.7	4.5, 56.2	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise [2]	0.98	0.94	0.98	0.96	0.97	0.96	0.97	0.96
95% CI [2]	0.93, 1.04	0.88, 0.99	0.93, 1.04	0.92, 1.00	0.93, 1.01	0.92, 1.00	0.93, 1.01	0.93, 0.99

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 57								
n[3]	96	95	99	194	100	99	98	197
GM Value [2]	9.91	9.35	9.55	9.45	11.64	11.06	11.29	11.17
95% CI [2]	9.34, 10.53	8.80, 9.93	9.00, 10.14	9.06, 9.86	10.89, 12.43	10.35, 11.81	10.56, 12.07	10.66, 11.71
Median	4.50	10.40	11.00	10.75	13.10	10.30	11.25	11.00
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 241.6	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise [2]	1.00	0.94	0.96	0.95	0.99	0.94	0.96	0.95
95% CI [2]	0.94, 1.06	0.89, 1.00	0.91, 1.02	0.91, 1.00	0.93, 1.06	0.88, 1.01	0.90, 1.03	0.91, 1.00

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Baseline				
n[1]	196	198	197	395
GM Value [2]	5.975	6.146	5.874	6.009
95% CI [2]	5.593, 6.383	5.755, 6.564	5.499, 6.275	5.736, 6.296
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 108.70	1.95, 106.00	1.95, 108.70
Day 29				
n[3]	194	196	195	391
GM Value [2]	5.960	20.160	25.509	22.671
95% CI [2]	5.528, 6.426	18.707, 21.727	23.666, 27.497	21.484, 23.924
Median	5.900	19.900	25.800	21.900
Min, Max	1.95, 40.40	4.10, 414.30	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	1.00	3.37	4.26	3.79
95% CI [2]	0.92, 1.07	3.12, 3.63	3.95, 4.59	3.59, 4.00
Day 43				
n[3]	194	191	195	386
GM Value [2]	5.951	163.206	196.003	179.030
95% CI [2]	5.512, 6.424	151.091, 176.292	181.603, 211.544	169.502, 189.093
Median	5.900	185.700	205.700	197.600
Min, Max	1.95, 313.10	8.10, 487.00	4.90, 487.00	4.90, 487.00
GM Fold-Rise [2]	0.99	27.20	32.67	29.84
95% CI [2]	0.92, 1.07	25.18, 29.38	30.27, 35.26	28.25, 31.52

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=197)	Total (N=395)
Day 57				
n[3]	196	194	197	391
GM Value [2]	6.233	120.929	145.368	132.683
95% CI [2]	5.718, 6.795	110.879, 131.889	133.379, 158.435	124.771, 141.097
Median	5.950	135.750	165.300	149.500
Min, Max	1.95, 298.30	7.20, 456.00	4.70, 487.00	4.70, 487.00
GM Fold-Rise [2]	1.04	20.19	24.28	22.16
95% CI [2]	0.95, 1.13	18.52, 22.02	22.27, 26.46	20.84, 23.56

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	99	197	100	100	98	198
GM Value [2]	6.496	7.193	6.195	6.673	5.492	5.259	5.572	5.411
95% CI [2]	5.925, 7.123	6.566, 7.879	5.658, 6.783	6.255, 7.119	4.996, 6.038	4.783, 5.781	5.064, 6.131	5.059, 5.788
Median	6.350	6.850	6.400	6.600	5.600	5.500	5.850	5.650
Min, Max	1.95, 16.80	1.95, 108.70	1.95, 16.30	1.95, 108.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	94	97	98	195	100	99	97	196
GM Value [2]	6.572	24.222	33.630	28.572	5.384	16.788	19.369	18.020
95% CI [2]	5.894, 7.329	21.747, 26.980	30.214, 37.432	26.432, 30.887	4.857, 5.967	15.138, 18.618	17.447, 21.502	16.738, 19.400
Median	6.100	24.300	30.950	28.300	5.600	16.300	18.600	17.400
Min, Max	1.95, 40.40	7.30, 414.30	4.80, 285.00	4.80, 414.30	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	1.00	3.67	5.09	4.33	0.99	3.09	3.56	3.31
95% CI [2]	0.89, 1.11	3.29, 4.08	4.57, 5.67	4.00, 4.68	0.89, 1.10	2.78, 3.42	3.21, 3.95	3.08, 3.57

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=99)	Total (N=197)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 43								
n[3]	94	95	99	194	100	96	96	192
GM Value [2]	6.575	183.395	233.173	207.367	5.369	146.339	163.718	154.786
95% CI [2]	5.918, 7.305	165.074, 203.749	210.390, 258.424	192.497, 223.387	4.805, 6.000	130.653, 163.908	146.172, 183.370	142.849, 167.721
Median	6.300	197.600	238.800	217.450	5.600	151.400	186.100	171.000
Min, Max	1.95, 313.10	44.80, 487.00	4.90, 487.00	4.90, 487.00	1.95, 17.80	8.10, 487.00	20.10, 487.00	8.10, 487.00
GM Fold-Rise [2]	1.00	27.84	35.40	31.48	0.98	26.75	29.92	28.29
95% CI [2]	0.90, 1.11	25.06, 30.93	31.94, 39.23	29.22, 33.91	0.88, 1.10	23.88, 29.96	26.71, 33.51	26.11, 30.65
Day 57								
n[3]	96	95	99	194	100	99	98	197
GM Value [2]	7.132	141.541	174.769	157.654	5.439	104.105	120.352	111.896
95% CI [2]	6.350, 8.010	125.876, 159.154	155.837, 196.001	145.184, 171.194	4.786, 6.182	91.530, 118.407	105.751, 136.969	102.121, 122.606
Median	6.400	148.300	182.800	168.350	5.550	123.500	146.550	130.700
Min, Max	1.95, 199.40	33.50, 408.10	4.70, 487.00	4.70, 487.00	1.95, 298.30	7.20, 456.00	23.10, 487.00	7.20, 487.00
GM Fold-Rise [2]	1.08	21.43	26.46	23.87	1.00	19.13	22.12	20.56
95% CI [2]	0.96, 1.21	19.06, 24.10	23.59, 29.67	21.98, 25.92	0.88, 1.14	16.82, 21.76	19.43, 25.17	18.77, 22.53

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Table 14.2.1.2.2
Analysis of Binding Antibody Levels
Full Analysis Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

[1] Number of subjects with non-missing baseline.

[2] The GM values, GM fold-rise, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed level with baseline level as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GM Value [2]	10.73	10.49	10.51	10.50
95% CI [2]	9.56, 12.04	9.34, 11.79	9.37, 11.78	9.68, 11.39
Median	11.20	10.90	11.40	11.10
Min, Max	4.5, 57.7	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29				
n[3]	183	183	189	372
GM Value [2]	10.26	10.21	9.96	10.08
95% CI [2]	9.91, 10.61	9.87, 10.56	9.63, 10.30	9.84, 10.32
Median	10.60	10.20	10.40	10.35
Min, Max	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.97	0.97	0.94	0.95
95% CI [2]	0.94, 1.01	0.93, 1.00	0.91, 0.98	0.93, 0.98
Day 43				
n[3]	179	174	181	355
GM Value [2]	10.52	10.08	10.38	10.23
95% CI [2]	10.14, 10.92	9.71, 10.47	10.00, 10.77	9.96, 10.50
Median	11.10	10.65	10.50	10.50
Min, Max	4.5, 55.7	4.5, 88.0	4.5, 57.1	4.5, 88.0
GM Fold-Rise [2]	0.98	0.94	0.97	0.96
95% CI [2]	0.95, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.98

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	175	177	352
GM Value [2]	10.35	9.96	10.27	10.12
95% CI [2]	9.94, 10.77	9.57, 10.37	9.87, 10.69	9.84, 10.41
Median	10.65	10.20	11.00	10.60
Min, Max	4.5, 59.5	4.5, 84.8	4.5, 59.8	4.5, 84.8
GM Fold-Rise [2]	0.98	0.94	0.97	0.96
95% CI [2]	0.94, 1.02	0.91, 0.98	0.93, 1.01	0.93, 0.99

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GM Value [2]	9.12	9.90	10.15	10.03	12.59	11.13	10.88	11.00
95% CI [2]	7.75, 10.73	8.41, 11.66	8.66, 11.90	8.95, 11.24	10.67, 14.86	9.43, 13.13	9.22, 12.83	9.79, 12.36
Median	4.50	10.40	11.50	10.90	14.00	12.10	11.00	11.40
Min, Max	4.5, 57.7	4.5, 55.6	4.5, 54.8	4.5, 55.6	4.5, 55.3	4.5, 87.7	4.5, 90.1	4.5, 90.1
Day 29								
n[3]	89	89	95	184	94	94	94	188
GM Value [2]	9.49	9.08	9.05	9.07	11.05	11.44	10.93	11.18
95% CI [2]	8.98, 10.02	8.59, 9.59	8.58, 9.55	8.73, 9.42	10.60, 11.52	10.97, 11.92	10.49, 11.40	10.86, 11.51
Median	4.50	9.30	10.10	9.65	13.85	11.50	10.50	11.15
Min, Max	4.5, 60.9	4.5, 53.7	4.5, 55.6	4.5, 55.6	4.5, 64.8	4.5, 84.9	4.5, 60.3	4.5, 84.9
GM Fold-Rise [2]	0.98	0.94	0.94	0.94	0.96	0.99	0.95	0.97
95% CI [2]	0.93, 1.04	0.89, 0.99	0.89, 0.99	0.90, 0.98	0.92, 1.00	0.95, 1.04	0.91, 0.99	0.94, 1.00
Day 43								
n[3]	86	84	94	178	93	90	87	177
GM Value [2]	9.66	9.17	9.61	9.40	11.40	11.06	11.21	11.14
95% CI [2]	9.08, 10.29	8.60, 9.77	9.05, 10.20	8.99, 9.81	10.94, 11.88	10.61, 11.54	10.74, 11.70	10.81, 11.47
Median	4.50	10.05	10.40	10.20	12.70	11.40	10.70	11.10
Min, Max	4.5, 55.7	4.5, 53.6	4.5, 57.1	4.5, 57.1	4.5, 55.1	4.5, 88.0	4.5, 56.4	4.5, 88.0
GM Fold-Rise [2]	0.99	0.94	0.98	0.96	0.98	0.95	0.96	0.95
95% CI [2]	0.93, 1.05	0.88, 1.00	0.92, 1.04	0.92, 1.00	0.94, 1.02	0.91, 0.99	0.92, 1.00	0.92, 0.98

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 57								
n[3]	83	84	87	171	91	91	90	181
GM Value [2]	9.64	9.03	9.32	9.18	11.04	10.91	11.25	11.08
95% CI [2]	9.04, 10.28	8.47, 9.63	8.75, 9.93	8.77, 9.60	10.51, 11.60	10.39, 11.46	10.71, 11.82	10.70, 11.47
Median	4.50	9.70	11.00	10.40	12.70	10.20	11.25	10.80
Min, Max	4.5, 59.5	4.5, 53.2	4.5, 59.8	4.5, 59.8	4.5, 59.0	4.5, 84.8	4.5, 56.9	4.5, 84.8
GM Fold-Rise [2]	1.02	0.95	0.98	0.97	0.95	0.93	0.96	0.95
95% CI [2]	0.95, 1.08	0.89, 1.01	0.92, 1.05	0.92, 1.01	0.90, 0.99	0.89, 0.98	0.92, 1.01	0.92, 0.98

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GM Value [2]	5.960	6.086	5.873	5.977
95% CI [2]	5.572, 6.375	5.689, 6.511	5.494, 6.277	5.700, 6.267
Median	6.000	6.300	5.900	6.000
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 106.00	1.95, 106.00
Day 29				
n[3]	183	183	189	372
GM Value [2]	5.834	20.316	25.379	22.748
95% CI [2]	5.407, 6.296	18.827, 21.922	23.548, 27.352	21.550, 24.013
Median	5.900	20.400	25.600	22.050
Min, Max	1.95, 40.40	4.10, 106.50	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	0.98	3.41	4.27	3.82
95% CI [2]	0.91, 1.06	3.16, 3.68	3.96, 4.60	3.62, 4.04
Day 43				
n[3]	179	174	181	355
GM Value [2]	5.786	168.797	198.403	183.302
95% CI [2]	5.398, 6.202	157.317, 181.114	185.171, 212.581	174.414, 192.642
Median	5.900	186.400	204.300	197.600
Min, Max	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise [2]	0.97	28.18	33.12	30.60
95% CI [2]	0.90, 1.04	26.26, 30.23	30.91, 35.49	29.12, 32.16

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	175	177	352
GM Value [2]	5.899	124.478	148.476	136.021
95% CI [2]	5.453, 6.381	115.095, 134.626	137.349, 160.504	128.651, 143.814
Median	5.900	136.200	166.100	149.650
Min, Max	1.95, 62.50	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise [2]	0.99	20.84	24.86	22.77
95% CI [2]	0.91, 1.07	19.27, 22.54	23.00, 26.87	21.54, 24.08

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GM Value [2]	6.487	6.978	6.207	6.571	5.474	5.318	5.558	5.437
95% CI [2]	5.922, 7.105	6.368, 7.647	5.678, 6.785	6.163, 7.006	4.957, 6.045	4.816, 5.873	5.033, 6.138	5.069, 5.832
Median	6.500	6.650	6.500	6.500	5.600	5.500	5.850	5.800
Min, Max	1.95, 16.80	1.95, 37.70	1.95, 16.30	1.95, 37.70	1.95, 16.20	1.95, 12.30	1.95, 106.00	1.95, 106.00
Day 29								
n[3]	89	89	95	184	94	94	94	188
GM Value [2]	6.353	24.528	33.477	28.805	5.336	16.895	19.212	18.016
95% CI [2]	5.715, 7.062	22.057, 27.276	30.210, 37.097	26.703, 31.073	4.791, 5.943	15.169, 18.818	17.249, 21.397	16.691, 19.447
Median	6.100	25.500	30.900	28.350	5.600	16.150	18.150	17.250
Min, Max	1.95, 40.40	7.30, 106.50	9.50, 285.00	7.30, 285.00	1.95, 22.10	4.10, 104.70	4.30, 431.60	4.10, 431.60
GM Fold-Rise [2]	0.97	3.76	5.14	4.42	0.98	3.10	3.53	3.31
95% CI [2]	0.88, 1.08	3.39, 4.19	4.64, 5.69	4.10, 4.77	0.88, 1.09	2.78, 3.45	3.17, 3.93	3.06, 3.57

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 43								
n[3]	86	84	94	178	93	90	87	177
GM Value [2]	6.228	183.946	243.241	213.253	5.357	155.021	160.528	157.704
95% CI [2]	5.743, 6.754	169.394, 199.749	225.051, 262.900	201.088, 226.153	4.796, 5.984	138.534, 173.471	143.178, 179.982	145.571, 170.848
Median	6.250	196.550	238.750	217.800	5.600	156.750	183.200	168.900
Min, Max	1.95, 14.80	46.70, 487.00	71.10, 487.00	46.70, 487.00	1.95, 17.80	33.80, 487.00	20.10, 487.00	20.10, 487.00
GM Fold-Rise [2]	0.95	28.17	37.25	32.66	0.97	28.15	29.15	28.64
95% CI [2]	0.88, 1.03	25.94, 30.59	34.47, 40.26	30.80, 34.63	0.87, 1.09	25.16, 31.50	26.00, 32.69	26.44, 31.03
Day 57								
n[3]	83	84	87	171	91	91	90	181
GM Value [2]	6.578	142.664	184.005	162.419	5.272	109.293	119.837	114.417
95% CI [2]	5.974, 7.244	129.587, 157.061	167.448, 202.199	151.623, 173.984	4.665, 5.957	96.715, 123.507	105.980, 135.507	104.921, 124.774
Median	6.300	147.300	191.400	169.000	5.500	127.300	146.550	135.700
Min, Max	1.95, 62.50	36.70, 408.10	33.60, 487.00	33.60, 487.00	1.95, 14.00	21.40, 456.00	23.10, 487.00	21.40, 487.00
GM Fold-Rise [2]	1.00	21.76	28.07	24.77	0.96	19.96	21.89	20.90
95% CI [2]	0.91, 1.10	19.77, 23.96	25.54, 30.84	23.13, 26.54	0.85, 1.09	17.66, 22.56	19.36, 24.75	19.16, 22.79

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Table 14.2.1.2.3
Sensitivity Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

[1] Number of subjects with non-missing baseline.

[2] The GM values, GM fold-rise, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed level with baseline level as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb at the corresponding visit.

Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Baseline				
n[1]	181	179	186	365
GMT	20.0	20.3	20.0	20.1
95% CI [2]	NE, NE	19.9, 20.7	NE, NE	19.9, 20.3
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 29				
n[3]	178	168	180	348
GMT	21.0	113.4	149.3	130.8
95% CI [2]	19.7, 22.3	94.6, 136.0	126.5, 176.2	115.6, 147.9
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.05	5.59	7.46	6.49
95% CI [2]	0.99, 1.11	4.65, 6.71	6.32, 8.81	5.74, 7.34
Seroconversion [4]				
n[5] (%)	3 (1.7)	131 (78.0)	160 (88.9)	291 (83.6)
95% CI [6]	0.3, 4.8	70.9, 84.0	83.4, 93.1	79.3, 87.4
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	132 (78.6)	160 (88.9)	292 (83.9)
95% CI [6]	0.3, 4.8	71.6, 84.5	83.4, 93.1	79.6, 87.6
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	119 (70.8)	146 (81.1)	265 (76.1)
95% CI [6]	0.1, 4.0	63.3, 77.6	74.6, 86.5	71.3, 80.5
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	110 (65.5)	130 (72.2)	240 (69.0)
95% CI [6]	0.1, 4.0	57.8, 72.6	65.1, 78.6	63.8, 73.8

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 43				
n[3]	175	141	150	291
GMT	20.4	1144.7	1179.4	1162.4
95% CI [2]	19.6, 21.4	1094.4, 1197.2	1130.5, 1230.5	1127.3, 1198.7
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR	1.02	56.23	58.97	57.63
95% CI [2]	0.98, 1.07	53.29, 59.34	56.52, 61.52	55.71, 59.62
Seroconversion [4]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 57				
n[3]	171	150	152	302
GMT	21.2	1091.0	1095.8	1093.4
95% CI [2]	19.8, 22.6	1035.5, 1149.5	1038.8, 1155.9	1053.5, 1134.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR	1.06	53.65	54.79	54.22
95% CI [2]	0.99, 1.13	50.54, 56.95	51.94, 57.80	52.11, 56.42
Seroconversion [4]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Baseline								
n[1]	92	90	95	185	89	89	91	180
GMT	20.0	20.4	20.0	20.2	20.0	20.2	20.0	20.1
95% CI [2]	NE, NE	19.6, 21.2	NE, NE	19.8, 20.6	NE, NE	19.8, 20.5	NE, NE	19.9, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 20	20, 40	20, 20	20, 40

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Day 29								
n[3]	90	89	94	183	88	79	86	165
GMT	20.9	126.4	183.4	153.0	21.1	100.4	119.2	109.8
95% CI [2]	19.2, 22.7	100.8, 158.5	147.1, 228.7	130.6, 179.4	19.3, 23.0	74.9, 134.7	93.3, 152.4	91.0, 132.6
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.04	6.19	9.17	7.58	1.05	4.98	5.96	5.47
95% CI [2]	0.96, 1.14	4.94, 7.77	7.36, 11.43	6.46, 8.89	0.96, 1.15	3.70, 6.70	4.66, 7.62	4.52, 6.61
Seroconversion [4]								
n[5] (%)	1 (1.1)	75 (84.3)	86 (91.5)	161 (88.0)	2 (2.3)	56 (70.9)	74 (86.0)	130 (78.8)
95% CI [6]	0.0, 6.0	75.0, 91.1	83.9, 96.3	82.4, 92.3	0.3, 8.0	59.6, 80.6	76.9, 92.6	71.8, 84.8
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	76 (85.4)	86 (91.5)	162 (88.5)	2 (2.3)	56 (70.9)	74 (86.0)	130 (78.8)
95% CI [6]	0.0, 6.0	76.3, 92.0	83.9, 96.3	83.0, 92.8	0.3, 8.0	59.6, 80.6	76.9, 92.6	71.8, 84.8
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	70 (78.7)	80 (85.1)	150 (82.0)	1 (1.1)	49 (62.0)	66 (76.7)	115 (69.7)
95% CI [6]	0.0, 6.0	68.7, 86.6	76.3, 91.6	75.6, 87.2	0.0, 6.2	50.4, 72.7	66.4, 85.2	62.1, 76.6

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	76 (80.9)	138 (75.4)	1 (1.1)	48 (60.8)	54 (62.8)	102 (61.8)
95% CI [6]	0.0, 6.0	59.0, 79.0	71.4, 88.2	68.5, 81.5	0.0, 6.2	49.1, 71.6	51.7, 73.0	53.9, 69.3
Day 43								
n[3]	87	78	88	166	88	63	62	125
GMT	20.0	1132.8	1233.5	1185.1	20.9	1159.6	1106.7	1133.0
95% CI [2]	NE, NE	1060.0, 1210.5	1201.4, 1266.6	1145.0, 1226.6	19.1, 22.8	1092.3, 1231.0	1006.5, 1216.7	1072.1, 1197.4
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR	1.00	55.35	61.68	58.62	1.04	57.34	55.33	56.34
95% CI [2]	NE, NE	51.16, 59.89	60.07, 63.33	56.32, 61.01	0.96, 1.14	53.31, 61.68	50.33, 60.84	53.11, 59.76
Seroconversion [4]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0
Day 57								
n[3]	84	80	82	162	87	70	70	140
GMT	21.5	1083.4	1126.9	1105.2	20.8	1099.7	1060.5	1079.9
95% CI [2]	19.4, 23.9	1006.1, 1166.7	1061.2, 1196.6	1054.3, 1158.5	19.2, 22.5	1020.0, 1185.5	965.9, 1164.4	1017.7, 1145.9
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR	1.08	52.97	56.34	54.65	1.04	54.44	53.03	53.73
95% CI [2]	0.97, 1.20	48.69, 57.63	53.06, 59.83	51.93, 57.52	0.96, 1.13	49.94, 59.35	48.30, 58.22	50.46, 57.21
Seroconversion [4]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Baseline				
n[1]	181	179	186	365
GMT	45.550	45.886	45.550	45.714
95% CI [2]	NE, NE	45.225, 46.556	NE, NE	45.392, 46.040
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 29				
n[3]	178	168	180	348
GMT	47.321	172.202	226.487	198.423
95% CI [2]	44.875, 49.900	145.249, 204.156	192.585, 266.358	176.386, 223.214
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.75	4.97	4.34
95% CI [2]	0.99, 1.10	3.16, 4.45	4.23, 5.85	3.86, 4.88
Seroconversion [4]				
n[5] (%)	2 (1.1)	110 (65.5)	138 (76.7)	248 (71.3)
95% CI [6]	0.1, 4.0	57.8, 72.6	69.8, 82.6	66.2, 76.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	110 (65.5)	138 (76.7)	248 (71.3)
95% CI [6]	0.1, 4.0	57.8, 72.6	69.8, 82.6	66.2, 76.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	98 (58.3)	127 (70.6)	225 (64.7)
95% CI [6]	0.1, 4.0	50.5, 65.9	63.3, 77.1	59.4, 69.7
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	84 (50.0)	106 (58.9)	190 (54.6)
95% CI [6]	0.1, 4.0	42.2, 57.8	51.3, 66.2	49.2, 59.9

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 43				
n[3]	175	141	150	291
GMT	46.442	1774.345	1813.420	1794.381
95% CI [2]	44.698, 48.255	1691.196, 1861.582	1730.358, 1900.471	1735.500, 1855.259
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.02	38.59	39.81	39.22
95% CI [2]	0.98, 1.06	36.68, 40.60	37.99, 41.72	37.89, 40.58
Seroconversion [4]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	141 (100)	150 (100)	291 (100)
95% CI [6]	0.0, 3.1	97.4, 100.0	97.6, 100.0	98.7, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=181)	50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 57				
n[3]	171	150	152	302
GMT	47.808	1639.612	1655.087	1647.382
95% CI [2]	45.240, 50.522	1550.751, 1733.564	1563.172, 1752.405	1583.283, 1714.076
Median	45.550	1810.193	2031.870	1810.193
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.05	35.68	36.34	36.01
95% CI [2]	0.99, 1.11	33.67, 37.81	34.32, 38.47	34.58, 37.50
Seroconversion [4]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	150 (100)	152 (100)	302 (100)
95% CI [6]	0.4, 5.0	97.6, 100.0	97.6, 100.0	98.8, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Baseline								
n[1]	92	90	95	185	89	89	91	180
GMT	45.550	46.221	45.550	45.875	45.550	45.550	45.550	45.550
95% CI [2]	NE, NE	44.898, 47.582	NE, NE	45.236, 46.523	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Day 29								
n[3]	90	89	94	183	88	79	86	165
GMT	47.301	184.278	272.772	225.405	47.341	159.542	184.831	172.258
95% CI [2]	43.885, 50.982	147.555, 230.140	220.239, 337.837	192.975, 263.285	43.847, 51.114	122.318, 208.093	144.939, 235.703	144.169, 205.821
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.99	5.99	4.91	1.04	3.50	4.06	3.78
95% CI [2]	0.96, 1.12	3.19, 4.98	4.84, 7.42	4.21, 5.74	0.96, 1.12	2.69, 4.57	3.18, 5.17	3.17, 4.52
Seroconversion [4]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	48 (60.8)	60 (69.8)	108 (65.5)
95% CI [6]	0.0, 6.0	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 6.2	49.1, 71.6	58.9, 79.2	57.7, 72.7
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	48 (60.8)	60 (69.8)	108 (65.5)
95% CI [6]	0.0, 6.0	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 6.2	49.1, 71.6	58.9, 79.2	57.7, 72.7
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	56 (62.9)	73 (77.7)	129 (70.5)	1 (1.1)	42 (53.2)	54 (62.8)	96 (58.2)
95% CI [6]	0.0, 6.0	52.0, 72.9	67.9, 85.6	63.3, 77.0	0.0, 6.2	41.6, 64.5	51.7, 73.0	50.3, 65.8

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	49 (55.1)	65 (69.1)	114 (62.3)	1 (1.1)	35 (44.3)	41 (47.7)	76 (46.1)
95% CI [6]	0.0, 6.0	44.1, 65.6	58.8, 78.3	54.8, 69.3	0.0, 6.2	33.1, 55.9	36.8, 58.7	38.3, 54.0
Day 43								
n[3]	87	78	88	166	88	63	62	125
GMT	45.550	1732.954	1908.818	1824.065	47.341	1826.963	1686.145	1755.706
95% CI [2]	NE, NE	1610.602, 1864.601	1848.732, 1970.858	1754.929, 1895.924	43.847, 51.114	1722.098, 1938.213	1521.066, 1869.141	1655.524, 1861.950
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.00	37.41	41.91	39.73	1.04	40.11	37.02	38.54
95% CI [2]	NE, NE	34.57, 40.48	40.59, 43.27	38.13, 41.40	0.96, 1.12	37.81, 42.55	33.39, 41.03	36.35, 40.88
Seroconversion [4]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	63 (100)	62 (100)	125 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.3, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Day 57								
n[3]	84	80	82	162	87	70	70	140
GMT	48.508	1612.789	1691.943	1652.381	47.142	1670.813	1612.932	1641.617
95% CI [2]	44.389, 53.009	1488.489, 1747.468	1585.691, 1805.314	1570.184, 1738.879	44.030, 50.475	1544.792, 1807.114	1459.962, 1781.929	1541.880, 1747.806
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.06	34.83	37.14	35.98	1.03	36.68	35.41	36.04
95% CI [2]	0.97, 1.16	31.97, 37.94	34.81, 39.63	34.12, 37.95	0.97, 1.11	33.91, 39.67	32.05, 39.12	33.85, 38.37
Seroconversion [4]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	70 (100)	70 (100)	140 (100)
95% CI [6]	0.3, 8.3	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.9, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit (n[3]).

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] $\geq$ z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GMT	20.8	20.6	20.6	20.6
95% CI [2]	20.1, 21.4	20.0, 21.2	19.7, 21.5	20.0, 21.1
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 120	20, 960	20, 960

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	mRNA-1273 Total (N=374)
Day 29				
n[3]	184	179	185	364
GMT	21.9	112.2	148.4	129.3
95% CI [2]	20.5, 23.5	94.5, 133.1	126.2, 174.5	114.9, 145.5
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.05	5.45	7.36	6.35
95% CI [2]	0.99, 1.12	4.58, 6.47	6.26, 8.66	5.64, 7.15
Seroconversion [4]				
n[5] (%)	3 (1.6)	132 (73.7)	162 (87.6)	294 (80.8)
95% CI [6]	0.3, 4.7	66.7, 80.0	81.9, 92.0	76.3, 84.7
>=2-fold Increase from Baseline [7]				
n[5] (%)	4 (2.2)	142 (79.3)	165 (89.2)	307 (84.3)
95% CI [6]	0.6, 5.5	72.7, 85.0	83.8, 93.3	80.2, 87.9
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	129 (72.1)	151 (81.6)	280 (76.9)
95% CI [6]	0.3, 4.7	64.9, 78.5	75.3, 86.9	72.2, 81.2
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	120 (67.0)	134 (72.4)	254 (69.8)
95% CI [6]	0.3, 4.7	59.6, 73.9	65.4, 78.7	64.8, 74.5

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 43				
n[3]	180	169	176	345
GMT	21.2	1150.2	1189.9	1170.3
95% CI [2]	20.1, 22.4	1106.3, 1195.9	1147.2, 1234.1	1139.6, 1201.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR	1.02	55.75	57.74	56.76
95% CI [2]	0.98, 1.07	53.00, 58.64	54.49, 61.18	54.62, 58.98
Seroconversion [4]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	168	171	339
GMT	21.8	1088.7	1105.9	1097.3
95% CI [2]	20.4, 23.4	1035.3, 1144.8	1053.2, 1161.2	1059.8, 1136.2
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR	1.06	53.19	54.85	54.02
95% CI [2]	0.99, 1.13	50.03, 56.56	52.13, 57.71	51.92, 56.20
Seroconversion [4]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GMT	20.0	20.4	20.0	20.2	21.5	20.7	21.2	20.9
95% CI [2]	NE, NE	19.6, 21.2	NE, NE	19.8, 20.6	20.2, 23.0	19.9, 21.7	19.4, 23.1	20.0, 22.0
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 80	20, 80	20, 960	20, 960

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 29								
n[3]	90	89	94	183	94	90	91	181
GMT	20.9	126.4	183.4	153.0	22.9	99.6	119.2	109.1
95% CI [2]	19.2, 22.7	100.8, 158.5	147.1, 228.7	130.6, 179.4	20.6, 25.5	76.8, 129.2	94.5, 150.5	91.7, 129.7
Median	20.0	160.0	240.0	200.0	20.0	80.0	120.0	100.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.04	6.19	9.17	7.58	1.07	4.79	5.87	5.31
95% CI [2]	0.96, 1.14	4.94, 7.77	7.36, 11.43	6.46, 8.89	0.98, 1.16	3.69, 6.23	4.65, 7.41	4.46, 6.32
Seroconversion [4]								
n[5] (%)	1 (1.1)	75 (84.3)	86 (91.5)	161 (88.0)	2 (2.1)	57 (63.3)	76 (83.5)	133 (73.5)
95% CI [6]	0.0, 6.0	75.0, 91.1	83.9, 96.3	82.4, 92.3	0.3, 7.5	52.5, 73.2	74.3, 90.5	66.4, 79.8
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	76 (85.4)	86 (91.5)	162 (88.5)	3 (3.2)	66 (73.3)	79 (86.8)	145 (80.1)
95% CI [6]	0.0, 6.0	76.3, 92.0	83.9, 96.3	83.0, 92.8	0.7, 9.0	63.0, 82.1	78.1, 93.0	73.5, 85.7
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	70 (78.7)	80 (85.1)	150 (82.0)	2 (2.1)	59 (65.6)	71 (78.0)	130 (71.8)
95% CI [6]	0.0, 6.0	68.7, 86.6	76.3, 91.6	75.6, 87.2	0.3, 7.5	54.8, 75.3	68.1, 86.0	64.7, 78.2

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	76 (80.9)	138 (75.4)	2 (2.1)	58 (64.4)	58 (63.7)	116 (64.1)
95% CI [6]	0.0, 6.0	59.0, 79.0	71.4, 88.2	68.5, 81.5	0.3, 7.5	53.7, 74.3	53.0, 73.6	56.6, 71.1
Day 43								
n[3]	87	82	93	175	93	87	83	170
GMT	20.0	1139.5	1232.2	1187.9	22.5	1160.3	1144.2	1152.4
95% CI [2]	NE, NE	1069.6, 1214.0	1201.0, 1264.1	1149.5, 1227.5	20.3, 24.9	1106.3, 1217.0	1064.9, 1229.3	1104.7, 1202.2
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR	1.00	55.75	61.61	58.79	1.04	55.75	53.70	54.74
95% CI [2]	NE, NE	51.71, 60.10	60.05, 63.21	56.59, 61.07	0.96, 1.13	52.00, 59.77	47.69, 60.47	51.17, 58.56
Seroconversion [4]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0
Day 57								
n[3]	84	84	86	170	91	84	85	169
GMT	21.5	1066.9	1133.6	1100.1	22.1	1110.9	1078.6	1094.5
95% CI [2]	19.4, 23.9	988.5, 1151.5	1070.2, 1200.6	1049.2, 1153.5	20.1, 24.3	1039.3, 1187.5	995.7, 1168.3	1039.5, 1152.5
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR	1.08	52.22	56.68	54.43	1.04	54.19	53.06	53.62
95% CI [2]	0.97, 1.20	47.95, 56.86	53.51, 60.03	51.72, 57.28	0.96, 1.12	49.53, 59.29	48.75, 57.75	50.44, 57.00
Seroconversion [4]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GMT	47.109	46.500	46.684	46.593
95% CI [2]	45.745, 48.512	45.425, 47.600	44.957, 48.477	45.570, 47.638
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 169.71	45.55, 1357.65	45.55, 1357.65

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	mRNA-1273 Total (N=374)
Day 29				
n[3]	184	179	185	364
GMT	49.231	172.769	225.260	197.708
95% CI [2]	46.355, 52.285	147.165, 202.827	192.345, 263.808	176.610, 221.327
Median	45.550	169.706	254.559	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.71	4.91	4.28
95% CI [2]	0.99, 1.10	3.16, 4.36	4.19, 5.75	3.82, 4.79
Seroconversion [4]				
n[5] (%)	2 (1.1)	111 (62.0)	139 (75.1)	250 (68.7)
95% CI [6]	0.1, 3.9	54.5, 69.1	68.3, 81.2	63.6, 73.4
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	120 (67.0)	143 (77.3)	263 (72.3)
95% CI [6]	0.3, 4.7	59.6, 73.9	70.6, 83.1	67.3, 76.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	108 (60.3)	131 (70.8)	239 (65.7)
95% CI [6]	0.3, 4.7	52.8, 67.6	63.7, 77.2	60.5, 70.5
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	85 (47.5)	106 (57.3)	191 (52.5)
95% CI [6]	0.1, 3.9	40.0, 55.1	49.8, 64.5	47.2, 57.7

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	mRNA-1273 Total (N=374)
Day 43				
n[3]	180	169	176	345
GMT	48.059	1768.676	1821.316	1795.337
95% CI [2]	45.820, 50.408	1696.326, 1844.111	1749.410, 1896.176	1744.204, 1847.968
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.02	37.96	38.94	38.46
95% CI [2]	0.98, 1.06	36.19, 39.82	36.81, 41.20	37.07, 39.91
Seroconversion [4]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	169 (100)	175 (99.4)	344 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	168	171	339
GMT	49.141	1630.572	1671.653	1651.167
95% CI [2]	46.267, 52.194	1545.698, 1720.107	1587.406, 1760.372	1591.170, 1713.426
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.05	35.25	36.43	35.84
95% CI [2]	0.99, 1.11	33.21, 37.43	34.54, 38.42	34.44, 37.30
Seroconversion [4]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	168 (100)	171 (100)	339 (100)
95% CI [6]	0.4, 4.9	97.8, 100.0	97.9, 100.0	98.9, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GMT	45.550	46.221	45.550	45.875	48.686	46.766	47.858	47.306
95% CI [2]	NE, NE	44.898, 47.582	NE, NE	45.236, 46.523	45.950, 51.584	45.077, 48.519	44.348, 51.646	45.369, 49.325
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 29								
n[3]	90	89	94	183	94	90	91	181
GMT	47.301	184.278	272.772	225.405	51.152	162.094	184.854	173.163
95% CI [2]	43.885, 50.982	147.555, 230.140	220.239, 337.837	192.975, 263.285	46.555, 56.203	128.178, 204.985	146.874, 232.656	147.116, 203.823
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.99	5.99	4.91	1.05	3.46	4.00	3.72
95% CI [2]	0.96, 1.12	3.19, 4.98	4.84, 7.42	4.21, 5.74	0.97, 1.13	2.74, 4.37	3.18, 5.04	3.16, 4.38
Seroconversion [4]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	49 (54.4)	61 (67.0)	110 (60.8)
95% CI [6]	0.0, 6.0	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 5.8	43.6, 65.0	56.4, 76.5	53.3, 67.9
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	2 (2.1)	58 (64.4)	65 (71.4)	123 (68.0)
95% CI [6]	0.0, 6.0	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.3, 7.5	53.7, 74.3	61.0, 80.4	60.6, 74.7
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	56 (62.9)	73 (77.7)	129 (70.5)	2 (2.1)	52 (57.8)	58 (63.7)	110 (60.8)
95% CI [6]	0.0, 6.0	52.0, 72.9	67.9, 85.6	63.3, 77.0	0.3, 7.5	46.9, 68.1	53.0, 73.6	53.3, 67.9

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	49 (55.1)	65 (69.1)	114 (62.3)	1 (1.1)	36 (40.0)	41 (45.1)	77 (42.5)
95% CI [6]	0.0, 6.0	44.1, 65.6	58.8, 78.3	54.8, 69.3	0.0, 5.8	29.8, 50.9	34.6, 55.8	35.2, 50.1
Day 43								
n[3]	87	82	93	175	93	87	83	170
GMT	45.550	1741.544	1902.223	1825.167	50.532	1794.634	1734.741	1765.138
95% CI [2]	NE, NE	1624.230, 1867.332	1843.979, 1962.307	1759.188, 1893.620	46.091, 55.400	1709.145, 1884.400	1605.198, 1874.739	1687.494, 1846.356
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.00	37.63	41.76	39.77	1.04	38.28	36.01	37.16
95% CI [2]	NE, NE	34.90, 40.56	40.48, 43.08	38.24, 41.36	0.96, 1.12	36.01, 40.70	32.15, 40.33	34.88, 39.58
Seroconversion [4]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	87 (100)	82 (98.8)	169 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	84	84	86	170	91	84	85	169
GMT	48.508	1584.249	1701.834	1642.681	49.733	1678.250	1641.663	1659.747
95% CI [2]	44.389, 53.009	1459.163, 1720.058	1599.460, 1810.760	1560.834, 1728.819	45.745, 54.069	1565.612, 1798.991	1509.213, 1785.736	1572.376, 1751.973
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.06	34.24	37.36	35.79	1.03	36.30	35.51	35.90
95% CI [2]	0.97, 1.16	31.39, 37.35	35.11, 39.75	33.94, 37.73	0.97, 1.10	33.39, 39.46	32.53, 38.78	33.81, 38.12
Seroconversion [4]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	84 (100)	85 (100)	169 (100)
95% CI [6]	0.3, 8.3	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.1.2
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit (n[3]).

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] $\geq$ z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Baseline				
n[1]	191	192	195	387
GMT	20.0	20.7	20.0	20.3
95% CI [2]	NE, NE	19.8, 21.7	NE, NE	19.9, 20.8
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 29				
n[3]	188	180	187	367
GMT	21.5	119.0	149.0	133.4
95% CI [2]	20.1, 23.1	99.8, 141.8	126.5, 175.5	118.4, 150.4
Median	20.0	160.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.08	5.73	7.45	6.55
95% CI [2]	1.00, 1.15	4.81, 6.83	6.32, 8.78	5.81, 7.39
Seroconversion [4]				
n[5] (%)	5 (2.7)	141 (78.3)	165 (88.2)	306 (83.4)
95% CI [6]	0.9, 6.1	71.6, 84.1	82.7, 92.5	79.2, 87.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	5 (2.7)	142 (78.9)	165 (88.2)	307 (83.7)
95% CI [6]	0.9, 6.1	72.2, 84.6	82.7, 92.5	79.5, 87.3
>=3-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	129 (71.7)	151 (80.7)	280 (76.3)
95% CI [6]	0.6, 5.4	64.5, 78.1	74.4, 86.1	71.6, 80.6
>=4-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	120 (66.7)	135 (72.2)	255 (69.5)
95% CI [6]	0.6, 5.4	59.3, 73.5	65.2, 78.5	64.5, 74.2

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 43				
n[3]	189	157	162	319
GMT	20.8	1115.1	1154.5	1134.9
95% CI [2]	19.7, 22.1	1047.4, 1187.1	1083.5, 1230.1	1085.6, 1186.4
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	40, 1280	20, 1280	20, 1280
GMFR	1.04	53.44	57.72	55.58
95% CI [2]	0.98, 1.10	49.11, 58.16	54.17, 61.51	52.73, 58.57
Seroconversion [4]				
n[5] (%)	2 (1.1)	156 (99.4)	161 (99.4)	317 (99.4)
95% CI [6]	0.1, 3.8	96.5, 100.0	96.6, 100.0	97.8, 99.9
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	156 (99.4)	161 (99.4)	317 (99.4)
95% CI [6]	0.1, 3.8	96.5, 100.0	96.6, 100.0	97.8, 99.9
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 57				
n[3]	191	167	170	337
GMT	22.8	1073.4	1072.8	1073.1
95% CI [2]	20.7, 25.1	1003.5, 1148.1	1002.3, 1148.2	1023.2, 1125.4
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 1280	20, 1280	20, 1280	20, 1280
GMFR	1.14	51.58	53.64	52.61
95% CI [2]	1.03, 1.26	47.33, 56.21	50.11, 57.41	49.82, 55.55
Seroconversion [4]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=2-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Baseline								
n[1]	96	98	100	198	95	94	95	189
GMT	20.0	21.3	20.0	20.6	20.0	20.1	20.0	20.1
95% CI [2]	NE, NE	19.4, 23.3	NE, NE	19.7, 21.6	NE, NE	19.9, 20.4	NE, NE	19.9, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280	20, 20	20, 40	20, 20	20, 40

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Day 29								
n[3]	94	97	98	195	94	83	89	172
GMT	22.0	132.8	178.0	153.9	21.0	104.6	122.5	113.5
95% CI [2]	19.7, 24.7	106.5, 165.5	142.6, 222.4	131.6, 179.9	19.3, 22.8	78.9, 138.7	96.4, 155.6	94.5, 136.3
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.10	6.24	8.90	7.46	1.05	5.19	6.12	5.65
95% CI [2]	0.98, 1.23	5.01, 7.78	7.13, 11.12	6.38, 8.73	0.97, 1.14	3.90, 6.90	4.82, 7.78	4.70, 6.79
Seroconversion [4]								
n[5] (%)	3 (3.2)	81 (83.5)	88 (89.8)	169 (86.7)	2 (2.1)	60 (72.3)	77 (86.5)	137 (79.7)
95% CI [6]	0.7, 9.0	74.6, 90.3	82.0, 95.0	81.1, 91.1	0.3, 7.5	61.4, 81.6	77.6, 92.8	72.9, 85.4
>=2-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	82 (84.5)	88 (89.8)	170 (87.2)	2 (2.1)	60 (72.3)	77 (86.5)	137 (79.7)
95% CI [6]	0.7, 9.0	75.8, 91.1	82.0, 95.0	81.7, 91.5	0.3, 7.5	61.4, 81.6	77.6, 92.8	72.9, 85.4
>=3-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	76 (78.4)	82 (83.7)	158 (81.0)	1 (1.1)	53 (63.9)	69 (77.5)	122 (70.9)
95% CI [6]	0.7, 9.0	68.8, 86.1	74.8, 90.4	74.8, 86.3	0.0, 5.8	52.6, 74.1	67.4, 85.7	63.5, 77.6

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=4-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	68 (70.1)	78 (79.6)	146 (74.9)	1 (1.1)	52 (62.7)	57 (64.0)	109 (63.4)
95% CI [6]	0.7, 9.0	60.0, 79.0	70.3, 87.1	68.2, 80.8	0.0, 5.8	51.3, 73.0	53.2, 73.9	55.7, 70.6
Day 43								
n[3]	94	90	93	183	95	67	69	136
GMT	20.8	1120.7	1178.3	1149.6	20.8	1107.6	1123.1	1115.5
95% CI [2]	19.2, 22.6	1045.2, 1201.6	1075.1, 1291.4	1085.5, 1217.5	19.2, 22.6	987.1, 1242.9	1030.9, 1223.5	1039.5, 1197.0
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	200, 1280	20, 1280	20, 1280	20, 960	40, 1280	160, 1280	40, 1280
GMFR	1.04	52.45	58.91	55.64	1.04	54.81	56.16	55.49
95% CI [2]	0.96, 1.13	46.60, 59.03	53.76, 64.57	51.66, 59.93	0.96, 1.13	48.54, 61.89	51.55, 61.18	51.58, 59.69
Seroconversion [4]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	67 (100)	69 (100)	136 (100)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	94.6, 100.0	94.8, 100.0	97.3, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	67 (100)	69 (100)	136 (100)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	94.6, 100.0	94.8, 100.0	97.3, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0
Day 57								
n[3]	96	91	94	185	95	76	76	152
GMT	24.0	1090.2	1069.9	1079.8	21.7	1053.7	1076.4	1065.0
95% CI [2]	20.5, 28.1	1019.7, 1165.6	965.7, 1185.3	1015.9, 1147.7	19.4, 24.3	928.7, 1195.4	987.0, 1173.8	987.3, 1148.7
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	20, 1280	20, 1280	20, 1280	20, 1280	200, 1280	20, 1280
GMFR	1.20	51.06	53.49	52.28	1.08	52.20	53.82	53.01
95% CI [2]	1.02, 1.41	45.51, 57.29	48.29, 59.26	48.44, 56.42	0.97, 1.21	45.75, 59.57	49.35, 58.69	49.02, 57.31
Seroconversion [4]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=2-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Baseline				
n[1]	191	192	195	387
GMT	45.550	46.779	45.550	46.156
95% CI [2]	NE, NE	44.890, 48.748	NE, NE	45.224, 47.107
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	mRNA-1273 Total (N=387)
Day 29				
n[3]	188	180	187	367
GMT	48.393	181.497	226.588	203.223
95% CI [2]	45.519, 51.448	153.918, 214.018	193.237, 265.696	181.226, 227.890
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.06	3.87	4.97	4.40
95% CI [2]	1.00, 1.13	3.29, 4.56	4.24, 5.83	3.92, 4.93
Seroconversion [4]				
n[5] (%)	4 (2.1)	120 (66.7)	143 (76.5)	263 (71.7)
95% CI [6]	0.6, 5.4	59.3, 73.5	69.7, 82.4	66.8, 76.2
>=2-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	120 (66.7)	143 (76.5)	263 (71.7)
95% CI [6]	0.6, 5.4	59.3, 73.5	69.7, 82.4	66.8, 76.2
>=3-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	108 (60.0)	132 (70.6)	240 (65.4)
95% CI [6]	0.6, 5.4	52.4, 67.2	63.5, 77.0	60.3, 70.3
>=4-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	94 (52.2)	110 (58.8)	204 (55.6)
95% CI [6]	0.6, 5.4	44.7, 59.7	51.4, 66.0	50.3, 60.7

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 43				
n[3]	189	157	162	319
GMT	47.216	1724.688	1780.678	1752.898
95% CI [2]	44.914, 49.636	1613.294, 1843.773	1672.436, 1895.925	1674.849, 1834.585
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	36.65	39.09	37.87
95% CI [2]	0.99, 1.09	33.76, 39.79	36.72, 41.62	35.98, 39.86
Seroconversion [4]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	155 (98.7)	161 (99.4)	316 (99.1)
95% CI [6]	0.1, 3.8	95.5, 99.8	96.6, 100.0	97.3, 99.8

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=191)	50 µg (N=192)	100 µg (N=195)	mRNA-1273 Total (N=387)
Day 57				
n[3]	191	167	170	337
GMT	51.071	1623.482	1626.776	1625.143
95% CI [2]	46.919, 55.590	1519.605, 1734.460	1520.270, 1740.744	1550.387, 1703.503
Median	45.550	1810.193	2031.870	2031.870
Min, Max	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.12	34.57	35.71	35.14
95% CI [2]	1.03, 1.22	31.92, 37.43	33.38, 38.22	33.36, 37.01
Seroconversion [4]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=2-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	7 (3.7)	165 (98.8)	169 (99.4)	334 (99.1)
95% CI [6]	1.5, 7.4	95.7, 99.9	96.8, 100.0	97.4, 99.8

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Baseline								
n[1]	96	98	100	198	95	94	95	189
GMT	45.550	47.990	45.550	46.742	45.550	45.550	45.550	45.550
95% CI [2]	NE, NE	44.250, 52.046	NE, NE	44.910, 48.648	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Day 29								
n[3]	94	97	98	195	94	83	89	172
GMT	49.589	195.874	266.822	228.793	47.225	166.028	189.267	177.673
95% CI [2]	44.852, 54.827	157.686, 243.309	215.673, 330.101	196.503, 266.389	43.957, 50.736	128.574, 214.392	149.272, 239.979	149.505, 211.146
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.09	4.08	5.86	4.89	1.04	3.64	4.16	3.90
95% CI [2]	0.98, 1.20	3.29, 5.05	4.73, 7.25	4.20, 5.69	0.97, 1.11	2.82, 4.71	3.28, 5.27	3.28, 4.64
Seroconversion [4]								
n[5] (%)	3 (3.2)	68 (70.1)	80 (81.6)	148 (75.9)	1 (1.1)	52 (62.7)	63 (70.8)	115 (66.9)
95% CI [6]	0.7, 9.0	60.0, 79.0	72.5, 88.7	69.3, 81.7	0.0, 5.8	51.3, 73.0	60.2, 79.9	59.3, 73.8
>=2-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	68 (70.1)	80 (81.6)	148 (75.9)	1 (1.1)	52 (62.7)	63 (70.8)	115 (66.9)
95% CI [6]	0.7, 9.0	60.0, 79.0	72.5, 88.7	69.3, 81.7	0.0, 5.8	51.3, 73.0	60.2, 79.9	59.3, 73.8
>=3-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	62 (63.9)	75 (76.5)	137 (70.3)	1 (1.1)	46 (55.4)	57 (64.0)	103 (59.9)
95% CI [6]	0.7, 9.0	53.5, 73.4	66.9, 84.5	63.3, 76.6	0.0, 5.8	44.1, 66.3	53.2, 73.9	52.1, 67.3

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=4-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	55 (56.7)	67 (68.4)	122 (62.6)	1 (1.1)	39 (47.0)	43 (48.3)	82 (47.7)
95% CI [6]	0.7, 9.0	46.3, 66.7	58.2, 77.4	55.4, 69.4	0.0, 5.8	35.9, 58.3	37.6, 59.2	40.0, 55.4
Day 43								
n[3]	94	90	93	183	95	67	69	136
GMT	47.225	1715.379	1828.375	1771.902	47.207	1737.272	1718.353	1727.648
95% CI [2]	43.957, 50.736	1593.238, 1846.883	1678.393, 1991.760	1674.851, 1874.578	43.974, 50.678	1535.505, 1965.552	1565.263, 1886.416	1601.081, 1864.220
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87	226.27, 2031.87	45.55, 2031.87
GMFR	1.04	35.58	40.14	37.83	1.04	38.14	37.72	37.93
95% CI [2]	0.97, 1.11	31.83, 39.77	36.85, 43.73	35.28, 40.57	0.97, 1.11	33.71, 43.15	34.36, 41.41	35.15, 40.93
Seroconversion [4]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	89 (98.9)	92 (98.9)	181 (98.9)	1 (1.1)	66 (98.5)	69 (100)	135 (99.3)
95% CI [6]	0.0, 5.8	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.0, 5.7	92.0, 100.0	94.8, 100.0	96.0, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Day 57								
n[3]	96	91	94	185	95	76	76	152
GMT	53.289	1635.498	1614.091	1624.586	48.923	1609.210	1642.604	1625.821
95% CI [2]	46.437, 61.151	1522.568, 1756.805	1462.900, 1780.909	1529.118, 1726.014	44.246, 54.095	1428.166, 1813.204	1497.169, 1802.166	1508.775, 1751.947
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	282.84, 2031.87	45.55, 2031.87
GMFR	1.17	33.94	35.44	34.69	1.07	35.33	36.06	35.69
95% CI [2]	1.02, 1.34	30.44, 37.85	32.12, 39.10	32.26, 37.31	0.97, 1.19	31.35, 39.81	32.87, 39.56	33.12, 38.46
Seroconversion [4]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
>=3-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	90 (98.9)	93 (98.9)	183 (98.9)	2 (2.1)	75 (98.7)	76 (100)	151 (99.3)
95% CI [6]	1.7, 11.7	94.0, 100.0	94.2, 100.0	96.1, 99.9	0.3, 7.4	92.9, 100.0	95.3, 100.0	96.4, 100.0

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Table 14.2.2.1.2.1
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit (n[3]).

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] >=z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Baseline				
n[1]	196	198	198	396
GMT	20.7	21.0	20.5	20.8
95% CI [2]	20.1, 21.4	20.0, 22.0	19.7, 21.4	20.1, 21.4
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 1280	20, 960	20, 1280

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 29				
n[3]	194	191	192	383
GMT	22.4	117.4	148.1	131.9
95% CI [2]	20.8, 24.1	99.4, 138.6	126.2, 173.8	117.5, 148.0
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.08	5.59	7.35	6.41
95% CI [2]	1.01, 1.16	4.73, 6.60	6.27, 8.63	5.71, 7.20
Seroconversion [4]				
n[5] (%)	5 (2.6)	142 (74.3)	167 (87.0)	309 (80.7)
95% CI [6]	0.8, 5.9	67.5, 80.4	81.4, 91.4	76.4, 84.5
>=2-fold Increase from Baseline [7]				
n[5] (%)	6 (3.1)	152 (79.6)	170 (88.5)	322 (84.1)
95% CI [6]	1.1, 6.6	73.2, 85.1	83.2, 92.7	80.0, 87.6
>=3-fold Increase from Baseline [7]				
n[5] (%)	5 (2.6)	139 (72.8)	156 (81.3)	295 (77.0)
95% CI [6]	0.8, 5.9	65.9, 79.0	75.0, 86.5	72.5, 81.1
>=4-fold Increase from Baseline [7]				
n[5] (%)	5 (2.6)	130 (68.1)	139 (72.4)	269 (70.2)
95% CI [6]	0.8, 5.9	60.9, 74.6	65.5, 78.6	65.4, 74.8

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 43				
n[3]	194	186	190	376
GMT	21.6	1122.4	1168.6	1145.5
95% CI [2]	20.2, 23.0	1063.6, 1184.5	1106.8, 1233.9	1102.7, 1190.0
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	40, 1280	20, 1280	20, 1280
GMFR	1.04	53.35	56.84	55.08
95% CI [2]	0.98, 1.10	49.53, 57.47	53.08, 60.85	52.38, 57.93
Seroconversion [4]				
n[5] (%)	2 (1.0)	185 (99.5)	188 (98.9)	373 (99.2)
95% CI [6]	0.1, 3.7	97.0, 100.0	96.2, 99.9	97.7, 99.8
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	185 (99.5)	188 (98.9)	373 (99.2)
95% CI [6]	0.1, 3.7	97.0, 100.0	96.2, 99.9	97.7, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 57				
n[3]	196	186	192	378
GMT	23.5	1074.1	1069.6	1071.8
95% CI [2]	21.3, 26.0	1008.8, 1143.6	1000.7, 1143.4	1024.0, 1121.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 1280	20, 1280	20, 1280	20, 1280
GMFR	1.14	51.05	53.10	52.08
95% CI [2]	1.03, 1.25	47.00, 55.45	49.62, 56.82	49.39, 54.92
Seroconversion [4]				
n[5] (%)	7 (3.6)	184 (98.9)	190 (99.0)	374 (98.9)
95% CI [6]	1.4, 7.2	96.2, 99.9	96.3, 99.9	97.3, 99.7
>=2-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	191 (99.5)	375 (99.2)
95% CI [6]	1.4, 7.2	96.2, 99.9	97.1, 100.0	97.7, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	191 (99.5)	375 (99.2)
95% CI [6]	1.4, 7.2	96.2, 99.9	97.1, 100.0	97.7, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	191 (99.5)	375 (99.2)
95% CI [6]	1.4, 7.2	96.2, 99.9	97.1, 100.0	97.7, 99.8

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	100	198	100	100	98	198
GMT	20.0	21.3	20.0	20.6	21.4	20.7	21.1	20.9
95% CI [2]	NE, NE	19.4, 23.3	NE, NE	19.7, 21.6	20.2, 22.8	19.9, 21.6	19.4, 22.9	20.0, 21.9
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280	20, 80	20, 80	20, 960	20, 960

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 29								
n[3]	94	97	98	195	100	94	94	188
GMT	22.0	132.8	178.0	153.9	22.7	103.3	122.3	112.4
95% CI [2]	19.7, 24.7	106.5, 165.5	142.6, 222.4	131.6, 179.9	20.6, 25.2	80.4, 132.9	97.4, 153.6	95.0, 133.1
Median	20.0	160.0	240.0	200.0	20.0	90.0	120.0	120.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.10	6.24	8.90	7.46	1.06	4.98	6.03	5.48
95% CI [2]	0.98, 1.23	5.01, 7.78	7.13, 11.12	6.38, 8.73	0.98, 1.15	3.86, 6.42	4.80, 7.57	4.62, 6.49
Seroconversion [4]								
n[5] (%)	3 (3.2)	81 (83.5)	88 (89.8)	169 (86.7)	2 (2.0)	61 (64.9)	79 (84.0)	140 (74.5)
95% CI [6]	0.7, 9.0	74.6, 90.3	82.0, 95.0	81.1, 91.1	0.2, 7.0	54.4, 74.5	75.0, 90.8	67.6, 80.5
>=2-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	82 (84.5)	88 (89.8)	170 (87.2)	3 (3.0)	70 (74.5)	82 (87.2)	152 (80.9)
95% CI [6]	0.7, 9.0	75.8, 91.1	82.0, 95.0	81.7, 91.5	0.6, 8.5	64.4, 82.9	78.8, 93.2	74.5, 86.2
>=3-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	76 (78.4)	82 (83.7)	158 (81.0)	2 (2.0)	63 (67.0)	74 (78.7)	137 (72.9)
95% CI [6]	0.7, 9.0	68.8, 86.1	74.8, 90.4	74.8, 86.3	0.2, 7.0	56.6, 76.4	69.1, 86.5	65.9, 79.1

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=4-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	68 (70.1)	78 (79.6)	146 (74.9)	2 (2.0)	62 (66.0)	61 (64.9)	123 (65.4)
95% CI [6]	0.7, 9.0	60.0, 79.0	70.3, 87.1	68.2, 80.8	0.2, 7.0	55.5, 75.4	54.4, 74.5	58.2, 72.2
Day 43								
n[3]	94	94	99	193	100	92	91	183
GMT	20.8	1127.0	1180.8	1154.3	22.3	1117.7	1155.5	1136.3
95% CI [2]	19.2, 22.6	1054.1, 1205.0	1083.3, 1287.0	1093.0, 1219.0	20.2, 24.5	1025.6, 1218.0	1082.1, 1234.0	1076.9, 1199.1
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	200, 1280	20, 1280	20, 1280	20, 960	40, 1280	160, 1280	40, 1280
GMFR	1.04	52.89	59.04	55.96	1.04	53.82	54.53	54.17
95% CI [2]	0.96, 1.13	47.22, 59.25	54.16, 64.35	52.15, 60.05	0.96, 1.12	48.80, 59.35	48.92, 60.79	50.39, 58.24
Seroconversion [4]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	92 (100)	90 (98.9)	182 (99.5)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	96.1, 100.0	94.0, 100.0	97.0, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	92 (100)	90 (98.9)	182 (99.5)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	96.1, 100.0	94.0, 100.0	97.0, 100.0

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9
Day 57								
n[3]	96	95	99	194	100	91	93	184
GMT	24.0	1075.2	1049.8	1062.1	23.1	1072.9	1091.2	1082.1
95% CI [2]	20.5, 28.1	1003.4, 1152.1	940.0, 1172.4	995.1, 1133.7	20.5, 26.1	963.6, 1194.7	1013.8, 1174.5	1014.8, 1154.0
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	20, 1280	20, 1280	20, 1280	20, 1280	200, 1280	20, 1280
GMFR	1.20	50.49	52.49	51.50	1.08	51.64	53.75	52.70
95% CI [2]	1.02, 1.41	45.10, 56.53	47.00, 58.62	47.62, 55.70	0.97, 1.20	45.65, 58.42	49.72, 58.11	49.04, 56.63
Seroconversion [4]								
n[5] (%)	5 (5.2)	94 (98.9)	97 (98.0)	191 (98.5)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	92.9, 99.8	95.5, 99.7	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=2-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	98 (99.0)	192 (99.0)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	94.5, 100.0	96.3, 99.9	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	98 (99.0)	192 (99.0)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	94.5, 100.0	96.3, 99.9	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	98 (99.0)	192 (99.0)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	94.5, 100.0	96.3, 99.9	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Baseline				
n[1]	196	198	198	396
GMT	47.028	47.336	46.632	46.983
95% CI [2]	45.735, 48.357	45.320, 49.442	44.984, 48.340	45.680, 48.322
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 29				
n[3]	194	191	192	383
GMT	50.209	181.507	225.403	202.325
95% CI [2]	46.995, 53.642	155.306, 212.129	192.988, 263.262	181.239, 225.863
Median	45.550	226.274	268.701	226.274
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.07	3.83	4.92	4.34
95% CI [2]	1.00, 1.13	3.28, 4.47	4.21, 5.74	3.89, 4.84
Seroconversion [4]				
n[5] (%)	4 (2.1)	121 (63.4)	144 (75.0)	265 (69.2)
95% CI [6]	0.6, 5.2	56.1, 70.2	68.3, 81.0	64.3, 73.8
>=2-fold Increase from Baseline [7]				
n[5] (%)	5 (2.6)	130 (68.1)	148 (77.1)	278 (72.6)
95% CI [6]	0.8, 5.9	60.9, 74.6	70.5, 82.8	67.8, 77.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	5 (2.6)	118 (61.8)	136 (70.8)	254 (66.3)
95% CI [6]	0.8, 5.9	54.5, 68.7	63.9, 77.2	61.3, 71.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	4 (2.1)	95 (49.7)	110 (57.3)	205 (53.5)
95% CI [6]	0.6, 5.2	42.4, 57.0	50.0, 64.4	48.4, 58.6

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	mRNA-1273 Total (N=396)
Day 43				
n[3]	194	186	190	376
GMT	48.719	1723.134	1793.177	1758.179
95% CI [2]	46.073, 51.516	1626.849, 1825.117	1699.470, 1892.051	1690.636, 1828.420
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	36.31	38.42	37.36
95% CI [2]	0.99, 1.09	33.79, 39.02	36.00, 40.99	35.60, 39.21
Seroconversion [4]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.0)	184 (98.9)	188 (98.9)	372 (98.9)
95% CI [6]	0.1, 3.7	96.2, 99.9	96.2, 99.9	97.3, 99.7

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=196)	50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 57				
n[3]	196	186	192	378
GMT	52.574	1618.893	1624.158	1621.565
95% CI [2]	48.222, 57.318	1521.647, 1722.354	1521.605, 1733.622	1550.499, 1695.889
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR	1.12	34.12	35.42	34.77
95% CI [2]	1.03, 1.21	31.59, 36.85	33.16, 37.85	33.06, 36.57
Seroconversion [4]				
n[5] (%)	7 (3.6)	184 (98.9)	190 (99.0)	374 (98.9)
95% CI [6]	1.4, 7.2	96.2, 99.9	96.3, 99.9	97.3, 99.7
>=2-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	191 (99.5)	375 (99.2)
95% CI [6]	1.4, 7.2	96.2, 99.9	97.1, 100.0	97.7, 99.8
>=3-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	191 (99.5)	375 (99.2)
95% CI [6]	1.4, 7.2	96.2, 99.9	97.1, 100.0	97.7, 99.8
>=4-fold Increase from Baseline [7]				
n[5] (%)	7 (3.6)	184 (98.9)	190 (99.0)	374 (98.9)
95% CI [6]	1.4, 7.2	96.2, 99.9	96.3, 99.9	97.3, 99.7

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	100	198	100	100	98	198
GMT	45.550	47.990	45.550	46.742	48.491	46.705	47.762	47.225
95% CI [2]	NE, NE	44.250, 52.046	NE, NE	44.910, 48.648	45.924, 51.202	45.101, 48.365	44.398, 51.380	45.378, 49.147
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 29								
n[3]	94	97	98	195	100	94	94	188
GMT	49.589	195.874	266.822	228.793	50.798	167.786	189.052	178.102
95% CI [2]	44.852, 54.827	157.686, 243.309	215.673, 330.101	196.503, 266.389	46.491, 55.503	133.691, 210.576	150.962, 236.751	151.978, 208.715
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.09	4.08	5.86	4.89	1.05	3.59	4.10	3.83
95% CI [2]	0.98, 1.20	3.29, 5.05	4.73, 7.25	4.20, 5.69	0.98, 1.13	2.86, 4.50	3.27, 5.13	3.27, 4.49
Seroconversion [4]								
n[5] (%)	3 (3.2)	68 (70.1)	80 (81.6)	148 (75.9)	1 (1.0)	53 (56.4)	64 (68.1)	117 (62.2)
95% CI [6]	0.7, 9.0	60.0, 79.0	72.5, 88.7	69.3, 81.7	0.0, 5.4	45.8, 66.6	57.7, 77.3	54.9, 69.2
>=2-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	68 (70.1)	80 (81.6)	148 (75.9)	2 (2.0)	62 (66.0)	68 (72.3)	130 (69.1)
95% CI [6]	0.7, 9.0	60.0, 79.0	72.5, 88.7	69.3, 81.7	0.2, 7.0	55.5, 75.4	62.2, 81.1	62.0, 75.7
>=3-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	62 (63.9)	75 (76.5)	137 (70.3)	2 (2.0)	56 (59.6)	61 (64.9)	117 (62.2)
95% CI [6]	0.7, 9.0	53.5, 73.4	66.9, 84.5	63.3, 76.6	0.2, 7.0	49.0, 69.6	54.4, 74.5	54.9, 69.2

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=4-fold Increase from Baseline [7]								
n[5] (%)	3 (3.2)	55 (56.7)	67 (68.4)	122 (62.6)	1 (1.0)	40 (42.6)	43 (45.7)	83 (44.1)
95% CI [6]	0.7, 9.0	46.3, 66.7	58.2, 77.4	55.4, 69.4	0.0, 5.4	32.4, 53.2	35.4, 56.3	36.9, 51.6
Day 43								
n[3]	94	94	99	193	100	92	91	183
GMT	47.225	1723.542	1827.289	1776.002	50.166	1722.717	1756.789	1739.577
95% CI [2]	43.957, 50.736	1605.710, 1850.021	1685.849, 1980.595	1683.468, 1873.622	46.050, 54.649	1570.686, 1889.465	1636.042, 1886.447	1641.765, 1843.216
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87	226.27, 2031.87	45.55, 2031.87
GMFR	1.04	35.84	40.12	37.97	1.03	36.81	36.65	36.73
95% CI [2]	0.97, 1.11	32.20, 39.88	37.01, 43.48	35.53, 40.57	0.97, 1.11	33.36, 40.61	33.03, 40.66	34.22, 39.42
Seroconversion [4]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	93 (98.9)	98 (99.0)	191 (99.0)	1 (1.0)	91 (98.9)	90 (98.9)	181 (98.9)
95% CI [6]	0.0, 5.8	94.2, 100.0	94.5, 100.0	96.3, 99.9	0.0, 5.4	94.1, 100.0	94.0, 100.0	96.1, 99.9

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 57								
n[3]	96	95	99	194	100	91	93	184
GMT	53.289	1608.933	1587.790	1598.109	51.897	1629.357	1663.788	1646.669
95% CI [2]	46.437, 61.151	1494.512, 1732.115	1430.248, 1762.684	1499.262, 1703.473	46.570, 57.833	1471.343, 1804.340	1539.417, 1798.206	1545.599, 1754.349
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	282.84, 2031.87	45.55, 2031.87
GMFR	1.17	33.47	34.86	34.17	1.07	34.80	36.04	35.42
95% CI [2]	1.02, 1.34	30.06, 37.27	31.40, 38.70	31.73, 36.81	0.97, 1.18	31.10, 38.95	33.23, 39.09	33.07, 37.93
Seroconversion [4]								
n[5] (%)	5 (5.2)	94 (98.9)	97 (98.0)	191 (98.5)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	92.9, 99.8	95.5, 99.7	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	98 (99.0)	192 (99.0)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	94.5, 100.0	96.3, 99.9	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
>=3-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	98 (99.0)	192 (99.0)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	94.5, 100.0	96.3, 99.9	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	5 (5.2)	94 (98.9)	97 (98.0)	191 (98.5)	2 (2.0)	90 (98.9)	93 (100)	183 (99.5)
95% CI [6]	1.7, 11.7	94.3, 100.0	92.9, 99.8	95.5, 99.7	0.2, 7.0	94.0, 100.0	96.1, 100.0	97.0, 100.0

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Table 14.2.2.1.2.2
Summary of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit (n[3]).

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] $\geq$ z-fold increase from baseline at participant level is defined a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Baseline				
n[1]	180	178	186	364
GMT	20.0	20.3	20.0	20.1
95% CI [2]	NE, NE	19.9, 20.7	NE, NE	19.9, 20.3
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120

Notes are listed on last page.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202010301.sas 19NOV2020 02:02 Database Lock Date: 05NOV2020

Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 29				
n[3]	177	167	180	347
GMT	21.0	113.7	149.3	130.9
95% CI [2]	19.7, 22.3	94.7, 136.5	126.5, 176.2	115.8, 148.1
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.05	5.60	7.46	6.50
95% CI [2]	0.99, 1.12	4.66, 6.73	6.32, 8.81	5.74, 7.36
Seroconversion [4]				
n[5] (%)	3 (1.7)	130 (77.8)	160 (88.9)	290 (83.6)
95% CI [6]	0.4, 4.9	70.8, 83.9	83.4, 93.1	79.2, 87.3
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	131 (78.4)	160 (88.9)	291 (83.9)
95% CI [6]	0.4, 4.9	71.4, 84.4	83.4, 93.1	79.6, 87.6
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	118 (70.7)	146 (81.1)	264 (76.1)
95% CI [6]	0.1, 4.0	63.1, 77.4	74.6, 86.5	71.2, 80.5
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	109 (65.3)	130 (72.2)	239 (68.9)
95% CI [6]	0.1, 4.0	57.5, 72.5	65.1, 78.6	63.7, 73.7

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202010301.sas 19NOV2020 02:02 Database Lock Date: 05NOV2020

Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 43				
n[3]	174	140	150	290
GMT	20.4	1143.8	1179.4	1162.1
95% CI [2]	19.6, 21.4	1093.2, 1196.6	1130.5, 1230.5	1126.8, 1198.4
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR	1.02	56.18	58.97	57.61
95% CI [2]	0.98, 1.07	53.22, 59.31	56.52, 61.52	55.68, 59.60
Seroconversion [4]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202010301.sas 19NOV2020 02:02 Database Lock Date: 05NOV2020

Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 57				
n[3]	170	149	152	301
GMT	21.2	1089.8	1095.8	1092.8
95% CI [2]	19.8, 22.6	1034.0, 1148.6	1038.8, 1155.9	1052.9, 1134.3
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR	1.06	53.59	54.79	54.19
95% CI [2]	0.99, 1.13	50.47, 56.91	51.94, 57.80	52.07, 56.40
Seroconversion [4]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Baseline								
n[1]	91	90	95	185	89	88	91	179
GMT	20.0	20.4	20.0	20.2	20.0	20.2	20.0	20.1
95% CI [2]	NE, NE	19.6, 21.2	NE, NE	19.8, 20.6	NE, NE	19.8, 20.5	NE, NE	19.9, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 20	20, 40	20, 20	20, 40

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202010301.sas 19NOV2020 02:02 Database Lock Date: 05NOV2020

Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Day 29								
n[3]	89	89	94	183	88	78	86	164
GMT	20.9	126.4	183.4	153.0	21.1	100.7	119.2	110.0
95% CI [2]	19.2, 22.8	100.8, 158.5	147.1, 228.7	130.6, 179.4	19.3, 23.0	74.8, 135.6	93.3, 152.4	91.0, 133.0
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.04	6.19	9.17	7.58	1.05	4.99	5.96	5.48
95% CI [2]	0.96, 1.14	4.94, 7.77	7.36, 11.43	6.46, 8.89	0.96, 1.15	3.70, 6.74	4.66, 7.62	4.53, 6.63
Seroconversion [4]								
n[5] (%)	1 (1.1)	75 (84.3)	86 (91.5)	161 (88.0)	2 (2.3)	55 (70.5)	74 (86.0)	129 (78.7)
95% CI [6]	0.0, 6.1	75.0, 91.1	83.9, 96.3	82.4, 92.3	0.3, 8.0	59.1, 80.3	76.9, 92.6	71.6, 84.7
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	76 (85.4)	86 (91.5)	162 (88.5)	2 (2.3)	55 (70.5)	74 (86.0)	129 (78.7)
95% CI [6]	0.0, 6.1	76.3, 92.0	83.9, 96.3	83.0, 92.8	0.3, 8.0	59.1, 80.3	76.9, 92.6	71.6, 84.7
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	70 (78.7)	80 (85.1)	150 (82.0)	1 (1.1)	48 (61.5)	66 (76.7)	114 (69.5)
95% CI [6]	0.0, 6.1	68.7, 86.6	76.3, 91.6	75.6, 87.2	0.0, 6.2	49.8, 72.3	66.4, 85.2	61.9, 76.5

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	76 (80.9)	138 (75.4)	1 (1.1)	47 (60.3)	54 (62.8)	101 (61.6)
95% CI [6]	0.0, 6.1	59.0, 79.0	71.4, 88.2	68.5, 81.5	0.0, 6.2	48.5, 71.2	51.7, 73.0	53.7, 69.1
Day 43								
n[3]	86	78	88	166	88	62	62	124
GMT	20.0	1132.8	1233.5	1185.1	20.9	1157.7	1106.7	1131.9
95% CI [2]	NE, NE	1060.0, 1210.5	1201.4, 1266.6	1145.0, 1226.6	19.1, 22.8	1089.5, 1230.2	1006.5, 1216.7	1070.6, 1196.7
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR	1.00	55.35	61.68	58.62	1.04	57.24	55.33	56.28
95% CI [2]	NE, NE	51.16, 59.89	60.07, 63.33	56.32, 61.01	0.96, 1.14	53.16, 61.64	50.33, 60.84	53.04, 59.72
Seroconversion [4]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0
Day 57								
n[3]	83	80	82	162	87	69	70	139
GMT	21.6	1083.4	1126.9	1105.2	20.8	1097.2	1060.5	1078.6
95% CI [2]	19.4, 24.0	1006.1, 1166.7	1061.2, 1196.6	1054.3, 1158.5	19.2, 22.5	1016.7, 1184.1	965.9, 1164.4	1016.1, 1144.9
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR	1.08	52.97	56.34	54.65	1.04	54.31	53.03	53.66
95% CI [2]	0.97, 1.20	48.69, 57.63	53.06, 59.83	51.93, 57.52	0.96, 1.13	49.76, 59.28	48.30, 58.22	50.37, 57.17
Seroconversion [4]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Baseline				
n[1]	180	178	186	364
GMT	45.550	45.888	45.550	45.715
95% CI [2]	NE, NE	45.224, 46.562	NE, NE	45.391, 46.041
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 29				
n[3]	177	167	180	347
GMT	47.331	172.635	226.487	198.745
95% CI [2]	44.871, 49.926	145.475, 204.866	192.585, 266.358	176.619, 223.642
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.76	4.97	4.35
95% CI [2]	0.99, 1.10	3.17, 4.46	4.23, 5.85	3.86, 4.89
Seroconversion [4]				
n[5] (%)	2 (1.1)	109 (65.3)	138 (76.7)	247 (71.2)
95% CI [6]	0.1, 4.0	57.5, 72.5	69.8, 82.6	66.1, 75.9
>=2-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	109 (65.3)	138 (76.7)	247 (71.2)
95% CI [6]	0.1, 4.0	57.5, 72.5	69.8, 82.6	66.1, 75.9
>=3-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	98 (58.7)	127 (70.6)	225 (64.8)
95% CI [6]	0.1, 4.0	50.8, 66.2	63.3, 77.1	59.6, 69.9
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	84 (50.3)	106 (58.9)	190 (54.8)
95% CI [6]	0.1, 4.0	42.5, 58.1	51.3, 66.2	49.4, 60.1

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 43				
n[3]	174	140	150	290
GMT	46.447	1772.628	1813.420	1793.612
95% CI [2]	44.693, 48.271	1689.038, 1860.354	1730.358, 1900.471	1734.574, 1854.659
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.02	38.55	39.81	39.20
95% CI [2]	0.98, 1.06	36.63, 40.57	37.99, 41.72	37.87, 40.57
Seroconversion [4]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	140 (100)	150 (100)	290 (100)
95% CI [6]	0.0, 3.2	97.4, 100.0	97.6, 100.0	98.7, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=180)	50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 57				
n[3]	170	149	152	301
GMT	47.822	1637.253	1655.087	1646.234
95% CI [2]	45.238, 50.553	1548.047, 1731.599	1563.172, 1752.405	1582.008, 1713.068
Median	45.550	1810.193	2031.870	1810.193
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.05	35.63	36.34	35.98
95% CI [2]	0.99, 1.11	33.61, 37.77	34.32, 38.47	34.55, 37.47
Seroconversion [4]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.8)	149 (100)	152 (100)	301 (100)
95% CI [6]	0.4, 5.1	97.6, 100.0	97.6, 100.0	98.8, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Baseline								
n[1]	91	90	95	185	89	88	91	179
GMT	45.550	46.221	45.550	45.875	45.550	45.550	45.550	45.550
95% CI [2]	NE, NE	44.898, 47.582	NE, NE	45.236, 46.523	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Day 29								
n[3]	89	89	94	183	88	78	86	164
GMT	47.321	184.278	272.772	225.405	47.341	160.247	184.831	172.700
95% CI [2]	43.867, 51.047	147.555, 230.140	220.239, 337.837	192.975, 263.285	43.847, 51.114	122.449, 209.711	144.939, 235.703	144.391, 206.561
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.99	5.99	4.91	1.04	3.52	4.06	3.79
95% CI [2]	0.96, 1.12	3.19, 4.98	4.84, 7.42	4.21, 5.74	0.96, 1.12	2.69, 4.60	3.18, 5.17	3.17, 4.53
Seroconversion [4]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	47 (60.3)	60 (69.8)	107 (65.2)
95% CI [6]	0.0, 6.1	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 6.2	48.5, 71.2	58.9, 79.2	57.4, 72.5
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	47 (60.3)	60 (69.8)	107 (65.2)
95% CI [6]	0.0, 6.1	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 6.2	48.5, 71.2	58.9, 79.2	57.4, 72.5
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	56 (62.9)	73 (77.7)	129 (70.5)	1 (1.1)	42 (53.8)	54 (62.8)	96 (58.5)
95% CI [6]	0.0, 6.1	52.0, 72.9	67.9, 85.6	63.3, 77.0	0.0, 6.2	42.2, 65.2	51.7, 73.0	50.6, 66.2

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	49 (55.1)	65 (69.1)	114 (62.3)	1 (1.1)	35 (44.9)	41 (47.7)	76 (46.3)
95% CI [6]	0.0, 6.1	44.1, 65.6	58.8, 78.3	54.8, 69.3	0.0, 6.2	33.6, 56.6	36.8, 58.7	38.5, 54.3
Day 43								
n[3]	86	78	88	166	88	62	62	124
GMT	45.550	1732.954	1908.818	1824.065	47.341	1823.833	1686.145	1753.638
95% CI [2]	NE, NE	1610.602, 1864.601	1848.732, 1970.858	1754.929, 1895.924	43.847, 51.114	1717.636, 1936.596	1521.066, 1869.141	1652.857, 1860.564
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.00	37.41	41.91	39.73	1.04	40.04	37.02	38.50
95% CI [2]	NE, NE	34.57, 40.48	40.59, 43.27	38.13, 41.40	0.96, 1.12	37.71, 42.52	33.39, 41.03	36.29, 40.85
Seroconversion [4]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	78 (100)	88 (100)	166 (100)	1 (1.1)	62 (100)	62 (100)	124 (100)
95% CI [6]	0.0, 4.2	95.4, 100.0	95.9, 100.0	97.8, 100.0	0.0, 6.2	94.2, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Day 57								
n[3]	83	80	82	162	87	69	70	139
GMT	48.545	1612.789	1691.943	1652.381	47.142	1666.082	1612.932	1639.100
95% CI [2]	44.375, 53.106	1488.489, 1747.468	1585.691, 1805.314	1570.184, 1738.879	44.030, 50.475	1538.942, 1803.725	1459.962, 1781.929	1538.927, 1745.794
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.07	34.83	37.14	35.98	1.03	36.58	35.41	35.98
95% CI [2]	0.97, 1.17	31.97, 37.94	34.81, 39.63	34.12, 37.95	0.97, 1.11	33.79, 39.60	32.05, 39.12	33.79, 38.33
Seroconversion [4]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	80 (100)	82 (100)	162 (100)	1 (1.1)	69 (100)	70 (100)	139 (100)
95% CI [6]	0.3, 8.4	95.5, 100.0	95.6, 100.0	97.7, 100.0	0.0, 6.2	94.8, 100.0	94.9, 100.0	97.4, 100.0

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Table 14.2.2.1.3.1
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit (n[3]).

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] >=z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GMT	20.8	20.6	20.6	20.6
95% CI [2]	20.1, 21.5	20.0, 21.2	19.7, 21.5	20.0, 21.1
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 120	20, 960	20, 960

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	mRNA-1273 Total (N=373)
Day 29				
n[3]	183	178	185	363
GMT	21.9	112.4	148.4	129.5
95% CI [2]	20.5, 23.5	94.6, 133.5	126.2, 174.5	115.0, 145.8
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.06	5.45	7.36	6.36
95% CI [2]	0.99, 1.12	4.58, 6.49	6.26, 8.66	5.64, 7.16
Seroconversion [4]				
n[5] (%)	3 (1.6)	131 (73.6)	162 (87.6)	293 (80.7)
95% CI [6]	0.3, 4.7	66.5, 79.9	81.9, 92.0	76.3, 84.6
>=2-fold Increase from Baseline [7]				
n[5] (%)	4 (2.2)	141 (79.2)	165 (89.2)	306 (84.3)
95% CI [6]	0.6, 5.5	72.5, 84.9	83.8, 93.3	80.1, 87.9
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	128 (71.9)	151 (81.6)	279 (76.9)
95% CI [6]	0.3, 4.7	64.7, 78.4	75.3, 86.9	72.2, 81.1
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	119 (66.9)	134 (72.4)	253 (69.7)
95% CI [6]	0.3, 4.7	59.4, 73.7	65.4, 78.7	64.7, 74.4

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	mRNA-1273 Total (N=373)
Day 43				
n[3]	179	168	176	344
GMT	21.2	1149.5	1189.9	1170.0
95% CI [2]	20.1, 22.4	1105.3, 1195.4	1147.2, 1234.1	1139.2, 1201.6
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR	1.02	55.70	57.74	56.74
95% CI [2]	0.98, 1.07	52.94, 58.61	54.49, 61.18	54.59, 58.97
Seroconversion [4]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	mRNA-1273 Total (N=373)
Day 57				
n[3]	174	167	171	338
GMT	21.8	1087.6	1105.9	1096.8
95% CI [2]	20.4, 23.4	1034.0, 1144.0	1053.2, 1161.2	1059.2, 1135.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR	1.06	53.14	54.85	53.99
95% CI [2]	0.99, 1.13	49.96, 56.52	52.13, 57.71	51.89, 56.18
Seroconversion [4]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GMT	20.0	20.4	20.0	20.2	21.5	20.8	21.2	20.9
95% CI [2]	NE, NE	19.6, 21.2	NE, NE	19.8, 20.6	20.2, 23.0	19.9, 21.7	19.4, 23.1	20.0, 22.0
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 80	20, 80	20, 960	20, 960

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 29								
n[3]	89	89	94	183	94	89	91	180
GMT	20.9	126.4	183.4	153.0	22.9	99.9	119.2	109.2
95% CI [2]	19.2, 22.8	100.8, 158.5	147.1, 228.7	130.6, 179.4	20.6, 25.5	76.8, 129.9	94.5, 150.5	91.8, 130.0
Median	20.0	160.0	240.0	200.0	20.0	80.0	120.0	100.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR	1.04	6.19	9.17	7.58	1.07	4.80	5.87	5.32
95% CI [2]	0.96, 1.14	4.94, 7.77	7.36, 11.43	6.46, 8.89	0.98, 1.16	3.68, 6.26	4.65, 7.41	4.46, 6.33
Seroconversion [4]								
n[5] (%)	1 (1.1)	75 (84.3)	86 (91.5)	161 (88.0)	2 (2.1)	56 (62.9)	76 (83.5)	132 (73.3)
95% CI [6]	0.0, 6.1	75.0, 91.1	83.9, 96.3	82.4, 92.3	0.3, 7.5	52.0, 72.9	74.3, 90.5	66.2, 79.6
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	76 (85.4)	86 (91.5)	162 (88.5)	3 (3.2)	65 (73.0)	79 (86.8)	144 (80.0)
95% CI [6]	0.0, 6.1	76.3, 92.0	83.9, 96.3	83.0, 92.8	0.7, 9.0	62.6, 81.9	78.1, 93.0	73.4, 85.6
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	70 (78.7)	80 (85.1)	150 (82.0)	2 (2.1)	58 (65.2)	71 (78.0)	129 (71.7)
95% CI [6]	0.0, 6.1	68.7, 86.6	76.3, 91.6	75.6, 87.2	0.3, 7.5	54.3, 75.0	68.1, 86.0	64.5, 78.1

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	76 (80.9)	138 (75.4)	2 (2.1)	57 (64.0)	58 (63.7)	115 (63.9)
95% CI [6]	0.0, 6.1	59.0, 79.0	71.4, 88.2	68.5, 81.5	0.3, 7.5	53.2, 73.9	53.0, 73.6	56.4, 70.9
Day 43								
n[3]	86	82	93	175	93	86	83	169
GMT	20.0	1139.5	1232.2	1187.9	22.5	1159.0	1144.2	1151.7
95% CI [2]	NE, NE	1069.6, 1214.0	1201.0, 1264.1	1149.5, 1227.5	20.3, 24.9	1104.5, 1216.3	1064.9, 1229.3	1103.8, 1201.7
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR	1.00	55.75	61.61	58.79	1.04	55.66	53.70	54.69
95% CI [2]	NE, NE	51.71, 60.10	60.05, 63.21	56.59, 61.07	0.96, 1.13	51.88, 59.72	47.69, 60.47	51.10, 58.52
Seroconversion [4]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0
Day 57								
n[3]	83	84	86	170	91	83	85	168
GMT	21.6	1066.9	1133.6	1100.1	22.1	1109.0	1078.6	1093.5
95% CI [2]	19.4, 24.0	988.5, 1151.5	1070.2, 1200.6	1049.2, 1153.5	20.1, 24.3	1036.7, 1186.4	995.7, 1168.3	1038.2, 1151.8
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR	1.08	52.22	56.68	54.43	1.04	54.08	53.06	53.56
95% CI [2]	0.97, 1.20	47.95, 56.86	53.51, 60.03	51.72, 57.28	0.96, 1.12	49.38, 59.23	48.75, 57.75	50.37, 56.95
Seroconversion [4]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GMT	47.117	46.505	46.684	46.595
95% CI [2]	45.747, 48.529	45.424, 47.612	44.957, 48.477	45.570, 47.644
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 169.71	45.55, 1357.65	45.55, 1357.65

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	mRNA-1273 Total (N=373)
Day 29				
n[3]	183	178	185	363
GMT	49.252	173.180	225.260	198.012
95% CI [2]	46.360, 52.324	147.392, 203.481	192.345, 263.808	176.833, 221.728
Median	45.550	169.706	254.559	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.72	4.91	4.29
95% CI [2]	0.99, 1.10	3.17, 4.37	4.19, 5.75	3.83, 4.80
Seroconversion [4]				
n[5] (%)	2 (1.1)	110 (61.8)	139 (75.1)	249 (68.6)
95% CI [6]	0.1, 3.9	54.2, 69.0	68.3, 81.2	63.5, 73.3
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	119 (66.9)	143 (77.3)	262 (72.2)
95% CI [6]	0.3, 4.7	59.4, 73.7	70.6, 83.1	67.3, 76.7
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.6)	108 (60.7)	131 (70.8)	239 (65.8)
95% CI [6]	0.3, 4.7	53.1, 67.9	63.7, 77.2	60.7, 70.7
>=4-fold Increase from Baseline [7]				
n[5] (%)	2 (1.1)	85 (47.8)	106 (57.3)	191 (52.6)
95% CI [6]	0.1, 3.9	40.2, 55.4	49.8, 64.5	47.3, 57.9

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	mRNA-1273 Total (N=373)
Day 43				
n[3]	179	168	176	344
GMT	48.074	1767.216	1821.316	1794.691
95% CI [2]	45.822, 50.436	1694.554, 1842.993	1749.410, 1896.176	1743.445, 1847.443
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.02	37.93	38.94	38.44
95% CI [2]	0.98, 1.06	36.15, 39.79	36.81, 41.20	37.05, 39.89
Seroconversion [4]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	1 (0.6)	168 (100)	175 (99.4)	343 (99.7)
95% CI [6]	0.0, 3.1	97.8, 100.0	96.9, 100.0	98.4, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Overall			
	Placebo (N=185)	50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	167	171	338
GMT	49.163	1628.425	1671.653	1650.153
95% CI [2]	46.271, 52.235	1543.262, 1718.288	1587.406, 1760.372	1590.050, 1712.529
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.05	35.20	36.43	35.82
95% CI [2]	0.99, 1.11	33.15, 37.39	34.54, 38.42	34.42, 37.28
Seroconversion [4]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=2-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=3-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0
>=4-fold Increase from Baseline [7]				
n[5] (%)	3 (1.7)	167 (100)	171 (100)	338 (100)
95% CI [6]	0.4, 5.0	97.8, 100.0	97.9, 100.0	98.9, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GMT	45.550	46.221	45.550	45.875	48.686	46.779	47.858	47.316
95% CI [2]	NE, NE	44.898, 47.582	NE, NE	45.236, 46.523	45.950, 51.584	45.071, 48.552	44.348, 51.646	45.369, 49.346
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 29								
n[3]	89	89	94	183	94	89	91	180
GMT	47.321	184.278	272.772	225.405	51.152	162.751	184.854	173.573
95% CI [2]	43.867, 51.047	147.555, 230.140	220.239, 337.837	192.975, 263.285	46.555, 56.203	128.369, 206.341	146.874, 232.656	147.339, 204.479
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR	1.04	3.99	5.99	4.91	1.05	3.47	4.00	3.73
95% CI [2]	0.96, 1.12	3.19, 4.98	4.84, 7.42	4.21, 5.74	0.97, 1.13	2.74, 4.40	3.18, 5.04	3.17, 4.40
Seroconversion [4]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	1 (1.1)	48 (53.9)	61 (67.0)	109 (60.6)
95% CI [6]	0.0, 6.1	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.0, 5.8	43.0, 64.6	56.4, 76.5	53.0, 67.7
>=2-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	62 (69.7)	78 (83.0)	140 (76.5)	2 (2.1)	57 (64.0)	65 (71.4)	122 (67.8)
95% CI [6]	0.0, 6.1	59.0, 79.0	73.8, 89.9	69.7, 82.4	0.3, 7.5	53.2, 73.9	61.0, 80.4	60.4, 74.5
>=3-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	56 (62.9)	73 (77.7)	129 (70.5)	2 (2.1)	52 (58.4)	58 (63.7)	110 (61.1)
95% CI [6]	0.0, 6.1	52.0, 72.9	67.9, 85.6	63.3, 77.0	0.3, 7.5	47.5, 68.8	53.0, 73.6	53.6, 68.3

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=4-fold Increase from Baseline [7]								
n[5] (%)	1 (1.1)	49 (55.1)	65 (69.1)	114 (62.3)	1 (1.1)	36 (40.4)	41 (45.1)	77 (42.8)
95% CI [6]	0.0, 6.1	44.1, 65.6	58.8, 78.3	54.8, 69.3	0.0, 5.8	30.2, 51.4	34.6, 55.8	35.4, 50.4
Day 43								
n[3]	86	82	93	175	93	86	83	169
GMT	45.550	1741.544	1902.223	1825.167	50.532	1792.045	1734.741	1763.669
95% CI [2]	NE, NE	1624.230, 1867.332	1843.979, 1962.307	1759.188, 1893.620	46.091, 55.400	1705.837, 1882.611	1605.198, 1874.739	1685.687, 1845.259
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR	1.00	37.63	41.76	39.77	1.04	38.21	36.01	37.12
95% CI [2]	NE, NE	34.90, 40.56	40.48, 43.08	38.24, 41.36	0.96, 1.12	35.92, 40.65	32.15, 40.33	34.83, 39.55
Seroconversion [4]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=2-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0
>=3-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	0	82 (100)	93 (100)	175 (100)	1 (1.1)	86 (100)	82 (98.8)	168 (99.4)
95% CI [6]	0.0, 4.2	95.6, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	95.8, 100.0	93.5, 100.0	96.7, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 57								
n[3]	83	84	86	170	91	83	85	168
GMT	48.545	1584.249	1701.834	1642.681	49.733	1674.388	1641.663	1657.750
95% CI [2]	44.375, 53.106	1459.163, 1720.058	1599.460, 1810.760	1560.834, 1728.819	45.745, 54.069	1560.913, 1796.112	1509.213, 1785.736	1570.055, 1750.342
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR	1.07	34.24	37.36	35.79	1.03	36.21	35.51	35.86
95% CI [2]	0.97, 1.17	31.39, 37.35	35.11, 39.75	33.94, 37.73	0.97, 1.10	33.28, 39.40	32.53, 38.78	33.76, 38.09
Seroconversion [4]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=2-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Data Category Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
>=3-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0
>=4-fold Increase from Baseline [7]								
n[5] (%)	2 (2.4)	84 (100)	86 (100)	170 (100)	1 (1.1)	83 (100)	85 (100)	168 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.9, 100.0	0.0, 6.0	95.7, 100.0	95.8, 100.0	97.8, 100.0

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Table 14.2.2.1.3.2
Sensitivity Analysis of Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline vs. baseline titers).
CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit (n[3]).

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

[1] Number of subjects with non-missing baseline.

[2] 95% CI is calculated based on the t-distribution of the log-transformed values or the difference in the log-transformed values for GMT and GMFR, respectively, then back transformed to the original scale for presentation.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

[4] Seroconversion at participant level is defined as a change of nAb titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ (respectively), or a 4-times or higher ratio in participants with pre-existing nAb titers.

[5] Number of subjects in the corresponding category at the corresponding time point.

[6] 95% CI is calculated using the Clopper-Pearson method.

[7] >=z-fold increase from baseline at participant level is defined as a z-times or higher ratio in participants with pre-existing nAb titers.

Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Baseline				
n[1]	181	179	186	365
GMT [2]	20.0	20.3	20.0	20.1
95% CI [2]	19.8, 20.2	20.0, 20.5	19.8, 20.2	20.0, 20.3
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120
Day 29				
n[3]	178	168	180	348
GMT [2]	20.9	112.7	148.6	130.1
95% CI [2]	18.2, 24.2	97.3, 130.6	128.9, 171.2	117.4, 144.1
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	5.61	7.39	6.47
95% CI [2]	0.90, 1.20	4.84, 6.50	6.42, 8.52	5.84, 7.17
Day 43				
n[3]	175	141	150	291
GMT [2]	20.4	1145.6	1177.6	1162.0
95% CI [2]	19.6, 21.3	1094.0, 1199.5	1126.2, 1231.4	1125.3, 1199.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR [2]	1.02	56.97	58.57	57.79
95% CI [2]	0.98, 1.06	54.41, 59.66	56.01, 61.24	55.96, 59.67

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 57				
n[3]	171	150	152	302
GMT [2]	21.2	1091.9	1093.7	1092.8
95% CI [2]	20.0, 22.4	1029.1, 1158.6	1031.3, 1159.9	1048.2, 1139.3
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR [2]	1.05	54.31	54.40	54.35
95% CI [2]	1.00, 1.11	51.19, 57.62	51.29, 57.69	52.14, 56.67

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Baseline								
n[1]	92	90	95	185	89	89	91	180
GMT [2]	20.0	20.4	20.0	20.2	20.0	20.2	20.0	20.1
95% CI [2]	19.6, 20.4	20.0, 20.9	19.6, 20.4	19.9, 20.5	19.8, 20.2	20.0, 20.3	19.8, 20.2	20.0, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 20	20, 40	20, 20	20, 40
Day 29								
n[3]	90	89	94	183	88	79	86	165
GMT [2]	20.9	125.8	183.8	152.9	20.9	101.9	118.5	110.2
95% CI [2]	17.3, 25.3	104.0, 152.2	152.8, 221.3	133.7, 174.9	16.9, 25.9	81.2, 127.7	95.4, 147.1	94.3, 128.8
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	6.25	9.13	7.60	1.04	5.08	5.91	5.50
95% CI [2]	0.86, 1.26	5.16, 7.56	7.59, 10.99	6.64, 8.69	0.84, 1.29	4.05, 6.37	4.76, 7.33	4.70, 6.42
Day 43								
n[3]	87	78	88	166	88	63	62	125
GMT [2]	20.0	1131.5	1234.1	1184.9	20.8	1171.3	1102.0	1136.3
95% CI [2]	19.3, 20.8	1087.0, 1177.8	1188.5, 1281.5	1152.3, 1218.4	19.3, 22.4	1072.6, 1279.0	1008.8, 1203.9	1067.7, 1209.3
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR [2]	0.99	56.18	61.27	58.83	1.04	58.37	54.92	56.63
95% CI [2]	0.96, 1.03	53.97, 58.48	59.01, 63.62	57.21, 60.49	0.96, 1.12	53.46, 63.74	50.27, 60.00	53.21, 60.27

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Day 57								
n[3]	84	80	82	162	87	70	70	140
GMT [2]	21.6	1081.9	1127.6	1104.9	20.7	1113.3	1054.7	1083.5
95% CI [2]	19.9, 23.4	995.9, 1175.3	1039.3, 1223.5	1042.6, 1170.8	19.2, 22.3	1024.2, 1210.2	970.5, 1146.2	1021.7, 1149.1
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR [2]	1.07	53.70	55.97	54.84	1.03	55.50	52.57	54.01
95% CI [2]	0.99, 1.16	49.44, 58.34	51.59, 60.73	51.75, 58.12	0.96, 1.11	51.06, 60.33	48.38, 57.13	50.93, 57.28

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Baseline				
n[1]	181	179	186	365
GMT [2]	45.548	45.885	45.548	45.713
95% CI [2]	45.175, 45.924	45.508, 46.266	45.180, 45.918	45.449, 45.978
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71
Day 29				
n[3]	178	168	180	348
GMT [2]	47.328	170.883	225.857	197.436
95% CI [2]	41.308, 54.225	148.523, 196.609	197.271, 258.585	179.005, 217.763
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	3.74	4.95	4.32
95% CI [2]	0.90, 1.19	3.25, 4.31	4.32, 5.66	3.92, 4.77
Day 43				
n[3]	175	141	150	291
GMT [2]	46.457	1772.421	1812.675	1793.020
95% CI [2]	44.576, 48.417	1692.443, 1856.180	1733.160, 1895.839	1736.167, 1851.734
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.02	38.80	39.68	39.25
95% CI [2]	0.98, 1.06	37.05, 40.64	37.94, 41.50	38.01, 40.54

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=181)	mRNA-1273		
		50 µg (N=179)	100 µg (N=186)	Total (N=365)
Day 57				
n[3]	171	150	152	302
GMT [2]	47.824	1638.146	1654.490	1646.358
95% CI [2]	45.324, 50.461	1546.737, 1734.957	1562.831, 1751.525	1581.152, 1714.254
Median	45.550	1810.193	2031.870	1810.193
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.05	35.86	36.22	36.04
95% CI [2]	0.99, 1.10	33.86, 37.98	34.21, 38.35	34.62, 37.53

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Baseline								
n[1]	92	90	95	185	89	89	91	180
GMT [2]	45.550	46.221	45.550	45.875	45.550	45.550	45.550	45.550
95% CI [2]	44.817, 46.295	45.469, 46.985	44.829, 46.283	45.353, 46.403	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55
Day 29								
n[3]	90	89	94	183	88	79	86	165
GMT [2]	47.408	183.418	273.390	225.238	47.341	159.542	184.831	172.258
95% CI [2]	39.454, 56.966	152.431, 220.704	228.419, 327.215	197.640, 256.690	38.699, 57.914	128.968, 197.363	150.738, 226.635	148.681, 199.574
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	4.01	5.97	4.92	1.04	3.50	4.06	3.78
95% CI [2]	0.86, 1.24	3.33, 4.82	4.99, 7.15	4.32, 5.61	0.85, 1.27	2.83, 4.33	3.31, 4.98	3.26, 4.38

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=89)	100 µg (N=91)	Total (N=180)
Day 43								
n[3]	87	78	88	166	88	63	62	125
GMT [2]	45.579	1730.479	1910.035	1823.655	47.341	1826.963	1686.145	1755.706
95% CI [2]	43.682, 47.558	1654.329, 1810.134	1830.986, 1992.497	1767.449, 1881.648	44.040, 50.890	1677.357, 1989.912	1547.009, 1837.796	1652.218, 1865.675
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.00	37.79	41.72	39.83	1.04	40.11	37.02	38.54
95% CI [2]	0.95, 1.04	36.13, 39.53	39.99, 43.52	38.60, 41.10	0.97, 1.12	36.82, 43.69	33.96, 40.35	36.27, 40.96
Day 57								
n[3]	84	80	82	162	87	70	70	140
GMT [2]	48.531	1611.199	1692.747	1652.061	47.142	1670.813	1612.932	1641.617
95% CI [2]	44.926, 52.426	1488.397, 1744.133	1565.519, 1830.315	1562.801, 1746.418	43.729, 50.822	1536.525, 1816.837	1483.296, 1753.897	1547.319, 1741.662
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.06	35.18	36.96	36.08	1.03	36.68	35.41	36.04
95% CI [2]	0.98, 1.14	32.50, 38.09	34.19, 39.97	34.13, 38.14	0.96, 1.12	33.73, 39.89	32.56, 38.50	33.97, 38.24

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Table 14.2.2.2.1.1
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GMT [2]	20.8	20.6	20.6	20.6
95% CI [2]	20.0, 21.5	19.9, 21.3	19.9, 21.3	20.1, 21.1
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 120	20, 960	20, 960
Day 29				
n[3]	184	179	185	364
GMT [2]	21.8	111.9	149.9	129.8
95% CI [2]	19.0, 25.0	97.2, 128.7	130.5, 172.1	117.5, 143.3
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.06	5.46	7.31	6.33
95% CI [2]	0.92, 1.22	4.74, 6.28	6.37, 8.39	5.73, 6.99
Day 43				
n[3]	180	169	176	345
GMT [2]	21.2	1150.8	1191.2	1171.2
95% CI [2]	20.3, 22.1	1101.9, 1201.8	1141.6, 1242.9	1136.2, 1207.3
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR [2]	1.03	55.66	57.61	56.65
95% CI [2]	0.98, 1.07	53.30, 58.13	55.21, 60.12	54.95, 58.39

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	168	171	339
GMT [2]	21.7	1087.8	1111.4	1099.6
95% CI [2]	20.6, 23.0	1027.6, 1151.6	1050.3, 1175.9	1056.4, 1144.6
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR [2]	1.06	53.26	54.41	53.84
95% CI [2]	1.01, 1.13	50.31, 56.38	51.42, 57.57	51.72, 56.04

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GMT [2]	20.0	20.4	20.0	20.2	21.5	20.7	21.2	20.9
95% CI [2]	19.6, 20.4	20.0, 20.9	19.6, 20.4	19.9, 20.5	20.1, 23.0	19.4, 22.2	19.8, 22.6	20.0, 21.9
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 80	20, 80	20, 960	20, 960
Day 29								
n[3]	90	89	94	183	94	90	91	181
GMT [2]	20.9	125.8	183.8	152.9	22.5	99.9	121.5	110.2
95% CI [2]	17.3, 25.3	104.0, 152.2	152.8, 221.3	133.7, 174.9	18.3, 27.5	81.3, 122.8	98.9, 149.3	95.3, 127.5
Median	20.0	160.0	240.0	200.0	20.0	80.0	120.0	100.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	6.25	9.13	7.60	1.08	4.79	5.82	5.28
95% CI [2]	0.86, 1.26	5.16, 7.56	7.59, 10.99	6.64, 8.69	0.88, 1.32	3.89, 5.88	4.74, 7.15	4.56, 6.11
Day 43								
n[3]	87	82	93	175	93	87	83	170
GMT [2]	20.0	1138.4	1232.7	1187.7	22.4	1167.3	1142.9	1155.3
95% CI [2]	19.3, 20.8	1095.2, 1183.4	1188.8, 1278.3	1156.2, 1220.0	20.8, 24.1	1081.6, 1259.8	1057.1, 1235.6	1094.1, 1219.9
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR [2]	0.99	56.53	61.22	58.98	1.05	54.99	53.84	54.43
95% CI [2]	0.96, 1.03	54.38, 58.76	59.03, 63.48	57.42, 60.58	0.98, 1.13	50.95, 59.35	49.80, 58.21	51.54, 57.47

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	84	84	86	170	91	84	85	169
GMT [2]	21.6	1065.3	1134.4	1099.8	21.8	1116.0	1087.7	1101.7
95% CI [2]	19.9, 23.4	982.1, 1155.5	1047.0, 1229.1	1038.8, 1164.3	20.2, 23.6	1029.9, 1209.3	1004.2, 1178.2	1041.1, 1165.8
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR [2]	1.07	52.89	56.32	54.60	1.05	53.90	52.53	53.21
95% CI [2]	0.99, 1.16	48.76, 57.37	51.98, 61.02	51.58, 57.81	0.98, 1.14	49.74, 58.41	48.50, 56.90	50.28, 56.31

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GMT [2]	47.098	46.473	46.689	46.582
95% CI [2]	45.678, 48.562	45.068, 47.922	45.292, 48.129	45.588, 47.598
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 169.71	45.55, 1357.65	45.55, 1357.65
Day 29				
n[3]	184	179	185	364
GMT [2]	48.803	172.761	227.446	198.642
95% CI [2]	42.779, 55.675	151.183, 197.418	199.440, 259.386	180.776, 218.272
Median	45.550	169.706	254.559	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.05	3.72	4.89	4.27
95% CI [2]	0.92, 1.20	3.25, 4.25	4.29, 5.58	3.89, 4.69
Day 43				
n[3]	180	169	176	345
GMT [2]	47.954	1771.835	1822.264	1797.377
95% CI [2]	46.006, 49.985	1697.608, 1849.308	1747.405, 1900.329	1744.354, 1852.012
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.02	37.82	38.90	38.37
95% CI [2]	0.98, 1.07	36.24, 39.48	37.30, 40.57	37.24, 39.53

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=186)	mRNA-1273		
		50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	168	171	339
GMT [2]	48.876	1632.005	1679.348	1655.699
95% CI [2]	46.318, 51.576	1544.970, 1723.943	1590.493, 1773.167	1593.035, 1720.829
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.05	35.22	36.24	35.73
95% CI [2]	1.00, 1.11	33.34, 37.20	34.32, 38.27	34.38, 37.14

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GMT [2]	45.550	46.221	45.550	45.875	48.686	46.766	47.858	47.306
95% CI [2]	44.817, 46.295	45.469, 46.985	44.829, 46.283	45.353, 46.403	45.914, 51.625	44.117, 49.574	45.133, 50.747	45.393, 49.300
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65
Day 29								
n[3]	90	89	94	183	94	90	91	181
GMT [2]	47.408	183.418	273.390	225.238	49.931	163.215	188.240	175.330
95% CI [2]	39.454, 56.966	152.431, 220.704	228.419, 327.215	197.640, 256.690	41.325, 60.329	134.609, 197.899	155.364, 228.073	153.019, 200.893
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	4.01	5.97	4.92	1.06	3.46	3.98	3.71
95% CI [2]	0.86, 1.24	3.33, 4.82	4.99, 7.15	4.32, 5.61	0.87, 1.28	2.85, 4.19	3.29, 4.83	3.24, 4.25

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=92)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 43								
n[3]	87	82	93	175	93	87	83	170
GMT [2]	45.577	1739.268	1903.357	1824.793	50.251	1808.299	1731.780	1770.492
95% CI [2]	43.699, 47.536	1665.340, 1816.478	1827.454, 1982.412	1770.681, 1880.558	46.848, 53.901	1681.803, 1944.308	1607.963, 1865.132	1681.094, 1864.645
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.00	37.99	41.58	39.86	1.05	37.73	36.13	36.94
95% CI [2]	0.95, 1.04	36.38, 39.68	39.92, 43.30	38.68, 41.08	0.98, 1.12	35.09, 40.56	33.55, 38.91	35.07, 38.90
Day 57								
n[3]	84	84	86	170	91	84	85	169
GMT [2]	48.534	1582.546	1702.738	1642.369	49.039	1690.920	1654.213	1672.357
95% CI [2]	44.892, 52.471	1463.564, 1711.202	1576.404, 1839.196	1554.649, 1735.037	45.516, 52.834	1564.992, 1826.981	1531.713, 1786.509	1583.617, 1766.071
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.06	34.56	37.19	35.87	1.05	36.07	35.28	35.67
95% CI [2]	0.98, 1.15	31.96, 37.37	34.43, 40.17	33.95, 37.89	0.97, 1.13	33.38, 38.97	32.67, 38.10	33.78, 37.67

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Table 14.2.2.2.1.2
Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87.

For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

For visit Day 29, visit window (-3/+7 days) is used to define per-protocol. If the visit (Day 29) is disrupted and cannot be completed at Day 29 (-3/+7 days) as a result of the COVID-19 pandemic, the window is extended to Day 29 + 21 days.

[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

Table 14.2.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Baseline				
n[1]	191	192	195	387
GMT [2]	20.0	20.7	20.0	20.3
95% CI [2]	19.5, 20.5	20.2, 21.3	19.5, 20.5	20.0, 20.7
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280
Day 29				
n[3]	188	180	187	367
GMT [2]	21.6	116.7	149.0	132.2
95% CI [2]	18.8, 24.9	101.0, 134.7	129.5, 171.6	119.5, 146.3
Median	20.0	160.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.07	5.76	7.36	6.53
95% CI [2]	0.93, 1.23	4.99, 6.66	6.40, 8.48	5.90, 7.23
Day 43				
n[3]	189	157	162	319
GMT [2]	20.8	1113.3	1153.0	1133.3
95% CI [2]	19.7, 22.1	1044.9, 1186.1	1083.4, 1227.1	1084.0, 1184.9
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	40, 1280	20, 1280	20, 1280
GMFR [2]	1.03	54.94	56.90	55.93
95% CI [2]	0.97, 1.09	51.57, 58.53	53.47, 60.56	53.50, 58.47

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 57				
n[3]	191	167	170	337
GMT [2]	22.8	1071.1	1070.3	1070.7
95% CI [2]	21.1, 24.6	986.0, 1163.5	986.1, 1161.6	1010.2, 1134.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 1280	20, 1280	20, 1280	20, 1280
GMFR [2]	1.13	52.88	52.84	52.86
95% CI [2]	1.04, 1.22	48.68, 57.45	48.69, 57.35	49.88, 56.03

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Table 14.2.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Baseline								
n[1]	96	98	100	198	95	94	95	189
GMT [2]	20.0	21.3	20.0	20.6	20.0	20.1	20.0	20.1
95% CI [2]	19.0, 21.1	20.2, 22.4	19.0, 21.1	19.9, 21.4	19.8, 20.2	20.0, 20.3	19.8, 20.2	20.0, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280	20, 20	20, 40	20, 20	20, 40
Day 29								
n[3]	94	97	98	195	94	83	89	172
GMT [2]	22.3	130.0	180.0	153.2	20.9	106.1	121.7	113.9
95% CI [2]	18.4, 27.0	107.5, 157.3	149.0, 217.4	133.8, 175.3	17.0, 25.6	85.4, 131.8	98.7, 150.0	98.0, 132.4
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.09	6.37	8.81	7.50	1.04	5.29	6.07	5.68
95% CI [2]	0.90, 1.32	5.26, 7.70	7.30, 10.65	6.55, 8.59	0.85, 1.28	4.26, 6.57	4.92, 7.48	4.89, 6.60
Day 43								
n[3]	94	90	93	183	95	67	69	136
GMT [2]	20.9	1118.7	1179.3	1149.2	20.8	1117.6	1119.0	1118.3
95% CI [2]	19.2, 22.6	1030.0, 1215.0	1087.5, 1278.8	1084.8, 1217.4	19.1, 22.5	1013.1, 1233.0	1016.1, 1232.3	1044.2, 1197.7
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	200, 1280	20, 1280	20, 1280	20, 960	40, 1280	160, 1280	40, 1280
GMFR [2]	1.02	54.75	57.71	56.24	1.03	55.71	55.78	55.75
95% CI [2]	0.94, 1.11	50.41, 59.46	53.22, 62.58	53.09, 59.58	0.95, 1.12	50.50, 61.46	50.65, 61.43	52.06, 59.70

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Day 57								
n[3]	96	91	94	185	95	76	76	152
GMT [2]	24.0	1087.9	1070.9	1079.2	21.6	1065.3	1071.1	1068.2
95% CI [2]	21.4, 26.9	966.0, 1225.1	953.2, 1203.3	993.4, 1172.5	19.5, 23.9	951.0, 1193.4	956.5, 1199.5	986.2, 1157.1
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	20, 1280	20, 1280	20, 1280	20, 1280	200, 1280	20, 1280
GMFR [2]	1.18	53.26	52.43	52.83	1.08	53.12	53.41	53.26
95% CI [2]	1.05, 1.32	47.29, 59.97	46.66, 58.90	48.63, 57.39	0.97, 1.19	47.42, 59.50	47.69, 59.81	49.17, 57.69

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Table 14.2.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Baseline				
n[1]	191	192	195	387
GMT [2]	45.548	46.771	45.540	46.147
95% CI [2]	44.481, 46.641	45.678, 47.890	44.484, 46.621	45.383, 46.923
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87
Day 29				
n[3]	188	180	187	367
GMT [2]	48.660	178.203	226.881	201.585
95% CI [2]	42.594, 55.591	155.479, 204.248	198.512, 259.303	183.161, 221.863
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.06	3.88	4.94	4.39
95% CI [2]	0.93, 1.21	3.38, 4.44	4.32, 5.64	3.98, 4.83
Day 43				
n[3]	189	157	162	319
GMT [2]	47.242	1720.842	1779.603	1750.479
95% CI [2]	44.671, 49.961	1617.879, 1830.357	1674.869, 1890.885	1676.248, 1827.997
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.03	37.40	38.68	38.04
95% CI [2]	0.97, 1.09	35.16, 39.78	36.40, 41.10	36.43, 39.73

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=191)	mRNA-1273		
		50 µg (N=192)	100 µg (N=195)	Total (N=387)
Day 57				
n[3]	191	167	170	337
GMT [2]	51.096	1619.361	1625.141	1622.277
95% CI [2]	47.575, 54.877	1500.004, 1748.217	1506.492, 1753.136	1537.242, 1712.016
Median	45.550	1810.193	2031.870	2031.870
Min, Max	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.11	35.21	35.33	35.27
95% CI [2]	1.03, 1.19	32.61, 38.01	32.75, 38.12	33.42, 37.22

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Baseline								
n[1]	96	98	100	198	95	94	95	189
GMT [2]	45.550	47.990	45.550	46.742	45.550	45.550	45.550	45.550
95% CI [2]	43.461, 47.739	45.811, 50.272	43.503, 47.694	45.235, 48.298	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55
Day 29								
n[3]	94	97	98	195	94	83	89	172
GMT [2]	50.123	191.769	269.692	227.722	47.225	166.028	189.267	177.673
95% CI [2]	41.645, 60.327	159.711, 230.261	224.931, 323.360	199.986, 259.305	38.967, 57.233	135.316, 203.710	155.342, 230.601	154.146, 204.789
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.08	4.14	5.82	4.91	1.04	3.64	4.16	3.90
95% CI [2]	0.90, 1.30	3.44, 4.97	4.85, 6.97	4.31, 5.59	0.86, 1.26	2.97, 4.47	3.41, 5.06	3.38, 4.50

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=95)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=94)	100 µg (N=95)	Total (N=189)
Day 43								
n[3]	94	90	93	183	95	67	69	136
GMT [2]	47.273	1711.792	1830.218	1771.168	47.207	1737.272	1718.353	1727.648
95% CI [2]	43.807, 51.013	1583.243, 1850.778	1695.337, 1975.831	1677.071, 1870.545	43.441, 51.300	1573.505, 1918.084	1558.621, 1894.456	1611.905, 1851.702
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87	226.27, 2031.87	45.55, 2031.87
GMFR [2]	1.02	36.89	39.45	38.17	1.04	38.14	37.72	37.93
95% CI [2]	0.94, 1.10	34.12, 39.89	36.54, 42.58	36.14, 40.31	0.95, 1.13	34.54, 42.11	34.22, 41.59	35.39, 40.65
Day 57								
n[3]	96	91	94	185	95	76	76	152
GMT [2]	53.347	1631.752	1615.865	1623.636	48.923	1609.210	1642.604	1625.821
95% CI [2]	48.019, 59.267	1464.088, 1818.617	1452.850, 1797.171	1505.365, 1751.199	44.421, 53.882	1444.569, 1792.616	1474.546, 1829.816	1506.576, 1754.504
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	282.84, 2031.87	45.55, 2031.87
GMFR [2]	1.15	35.18	34.83	35.00	1.07	35.33	36.06	35.69
95% CI [2]	1.04, 1.28	31.56, 39.21	31.32, 38.74	32.45, 37.75	0.98, 1.18	31.71, 39.35	32.37, 40.17	33.08, 38.52

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Table 14.2.2.2.1
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

Table 14.2.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Baseline				
n[1]	196	198	198	396
GMT [2]	20.7	21.0	20.5	20.8
95% CI [2]	19.9, 21.6	20.1, 21.8	19.7, 21.4	20.2, 21.4
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 1280	20, 960	20, 1280
Day 29				
n[3]	194	191	192	383
GMT [2]	22.4	115.9	149.9	131.8
95% CI [2]	19.6, 25.7	101.0, 133.0	130.7, 172.0	119.6, 145.3
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.09	5.62	7.27	6.39
95% CI [2]	0.95, 1.25	4.90, 6.45	6.34, 8.34	5.80, 7.05
Day 43				
n[3]	194	186	190	376
GMT [2]	21.6	1119.6	1171.2	1145.4
95% CI [2]	20.4, 22.8	1057.3, 1185.6	1106.6, 1239.5	1100.1, 1192.4
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	40, 1280	20, 1280	20, 1280
GMFR [2]	1.04	53.90	56.38	55.14
95% CI [2]	0.98, 1.10	50.90, 57.07	53.27, 59.67	52.96, 57.40

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Table 14.2.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 57				
n[3]	196	186	192	378
GMT [2]	23.5	1069.2	1075.3	1072.3
95% CI [2]	21.8, 25.4	988.1, 1157.0	995.0, 1162.2	1014.7, 1133.2
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 1280	20, 1280	20, 1280	20, 1280
GMFR [2]	1.14	51.83	52.13	51.98
95% CI [2]	1.06, 1.23	47.90, 56.09	48.23, 56.34	49.19, 54.94

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Table 14.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	100	198	100	100	98	198
GMT [2]	20.0	21.3	20.0	20.6	21.4	20.7	21.1	20.9
95% CI [2]	19.0, 21.1	20.2, 22.4	19.0, 21.1	19.9, 21.4	20.1, 22.8	19.4, 22.0	19.8, 22.5	20.0, 21.9
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 1280	20, 20	20, 1280	20, 80	20, 80	20, 960	20, 960
Day 29								
n[3]	94	97	98	195	100	94	94	188
GMT [2]	22.3	130.0	180.0	153.2	22.3	103.6	124.5	113.6
95% CI [2]	18.4, 27.0	107.5, 157.3	149.0, 217.4	133.8, 175.3	18.4, 27.1	84.9, 126.5	102.0, 152.0	98.6, 130.8
Median	20.0	160.0	240.0	200.0	20.0	90.0	120.0	120.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.09	6.37	8.81	7.50	1.07	4.97	5.98	5.45
95% CI [2]	0.90, 1.32	5.26, 7.70	7.30, 10.65	6.55, 8.59	0.88, 1.30	4.07, 6.07	4.89, 7.30	4.73, 6.28
Day 43								
n[3]	94	94	99	193	100	92	91	183
GMT [2]	20.9	1125.2	1181.7	1153.9	22.2	1123.8	1154.7	1139.0
95% CI [2]	19.3, 22.6	1039.3, 1218.3	1093.9, 1276.5	1091.9, 1219.5	20.5, 24.0	1034.6, 1220.6	1062.6, 1254.7	1074.3, 1207.7
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	200, 1280	20, 1280	20, 1280	20, 960	40, 1280	160, 1280	40, 1280
GMFR [2]	1.02	55.11	57.87	56.51	1.05	53.16	54.63	53.89
95% CI [2]	0.94, 1.11	50.90, 59.67	53.57, 62.52	53.48, 59.72	0.97, 1.14	48.95, 57.75	50.27, 59.36	50.82, 57.13

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Table 14.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 57								
n[3]	96	95	99	194	100	91	93	184
GMT [2]	24.0	1072.8	1050.9	1061.5	22.8	1074.6	1104.8	1089.8
95% CI [2]	21.3, 27.0	952.0, 1209.0	935.1, 1181.0	976.8, 1153.6	20.7, 25.2	969.9, 1190.7	998.0, 1223.1	1013.9, 1171.3
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	20, 1280	20, 1280	20, 1280	20, 1280	200, 1280	20, 1280
GMFR [2]	1.18	52.55	51.48	52.00	1.10	51.55	53.00	52.27
95% CI [2]	1.04, 1.32	46.63, 59.22	45.81, 57.85	47.85, 56.51	0.99, 1.21	46.52, 57.12	47.87, 58.67	48.64, 56.18

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Table 14.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Baseline				
n[1]	196	198	198	396
GMT [2]	47.015	47.330	46.638	46.983
95% CI [2]	45.336, 48.755	45.648, 49.073	44.981, 48.356	45.797, 48.199
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87
Day 29				
n[3]	194	191	192	383
GMT [2]	50.129	179.548	228.114	202.426
95% CI [2]	44.060, 57.034	157.643, 204.497	200.334, 259.747	184.583, 221.994
Median	45.550	226.274	268.701	226.274
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.07	3.84	4.88	4.33
95% CI [2]	0.94, 1.22	3.37, 4.37	4.28, 5.55	3.95, 4.75
Day 43				
n[3]	194	186	190	376
GMT [2]	48.721	1719.839	1796.472	1758.136
95% CI [2]	46.145, 51.440	1627.038, 1817.932	1700.512, 1897.847	1690.852, 1828.099
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	36.55	38.18	37.36
95% CI [2]	0.98, 1.09	34.58, 38.63	36.14, 40.33	35.93, 38.85

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Table 14.2.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=196)	mRNA-1273		
		50 µg (N=198)	100 µg (N=198)	Total (N=396)
Day 57				
n[3]	196	186	192	378
GMT [2]	52.494	1612.859	1632.724	1622.912
95% CI [2]	48.899, 56.354	1499.505, 1734.783	1519.643, 1754.219	1542.142, 1707.912
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.12	34.49	34.91	34.70
95% CI [2]	1.05, 1.21	32.06, 37.09	32.49, 37.51	32.98, 36.52

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Table 14.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Baseline								
n[1]	96	98	100	198	100	100	98	198
GMT [2]	45.550	47.990	45.550	46.742	48.491	46.705	47.762	47.225
95% CI [2]	43.461, 47.739	45.811, 50.272	43.503, 47.694	45.235, 48.298	45.878, 51.254	44.187, 49.365	45.162, 50.511	45.404, 49.119
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 2031.87	45.55, 45.55	45.55, 2031.87	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65
Day 29								
n[3]	94	97	98	195	100	94	94	188
GMT [2]	50.123	191.769	269.692	227.722	49.689	168.872	192.297	180.186
95% CI [2]	41.645, 60.327	159.711, 230.261	224.931, 323.360	199.986, 259.305	41.460, 59.551	140.183, 203.433	159.582, 231.718	157.931, 205.578
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.08	4.14	5.82	4.91	1.05	3.58	4.08	3.82
95% CI [2]	0.90, 1.30	3.44, 4.97	4.85, 6.97	4.31, 5.59	0.88, 1.26	2.97, 4.31	3.38, 4.91	3.35, 4.36

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Table 14.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=96)	mRNA-1273			Placebo (N=100)	mRNA-1273		
		50 µg (N=98)	100 µg (N=100)	Total (N=198)		50 µg (N=100)	100 µg (N=98)	Total (N=198)
Day 43								
n[3]	94	94	99	193	100	92	91	183
GMT [2]	47.270	1720.203	1829.015	1775.340	49.904	1734.730	1754.561	1744.571
95% CI [2]	43.858, 50.947	1595.678, 1854.447	1700.245, 1967.539	1684.896, 1870.639	46.138, 53.977	1598.430, 1882.653	1616.080, 1904.907	1646.447, 1848.543
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 2031.87	226.27, 2031.87	45.55, 2031.87
GMFR [2]	1.02	37.10	39.44	38.29	1.04	36.32	36.74	36.53
95% CI [2]	0.95, 1.10	34.41, 39.99	36.67, 42.43	36.34, 40.34	0.97, 1.13	33.47, 39.42	33.84, 39.89	34.47, 38.70
Day 57								
n[3]	96	95	99	194	100	91	93	184
GMT [2]	53.350	1605.119	1589.627	1597.172	51.152	1636.046	1683.075	1659.612
95% CI [2]	47.874, 59.454	1439.063, 1790.337	1428.801, 1768.555	1480.248, 1723.333	46.656, 56.083	1486.017, 1801.222	1530.091, 1851.357	1551.071, 1775.749
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 1357.65	339.41, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	45.55, 2031.87	282.84, 2031.87	45.55, 2031.87
GMFR [2]	1.15	34.62	34.29	34.45	1.08	34.67	35.67	35.17
95% CI [2]	1.03, 1.28	31.04, 38.62	30.82, 38.15	31.93, 37.17	0.99, 1.19	31.49, 38.17	32.43, 39.24	32.87, 37.63

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Table 14.2.2.2.2.2
Analysis of Neutralizing Antibody Titers
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87.

For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariate for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Baseline				
n[1]	180	178	186	364
GMT [2]	20.0	20.3	20.0	20.1
95% CI [2]	19.8, 20.2	20.0, 20.5	19.8, 20.2	20.0, 20.3
Median	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120
Day 29				
n[3]	177	167	180	347
GMT [2]	21.0	112.9	148.6	130.2
95% CI [2]	18.2, 24.2	97.3, 130.9	128.9, 171.3	117.5, 144.3
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	5.62	7.39	6.48
95% CI [2]	0.90, 1.20	4.84, 6.51	6.41, 8.52	5.84, 7.18
Day 43				
n[3]	174	140	150	290
GMT [2]	20.4	1144.6	1177.5	1161.5
95% CI [2]	19.6, 21.3	1092.8, 1198.8	1126.0, 1231.4	1124.7, 1199.5
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR [2]	1.02	56.92	58.56	57.76
95% CI [2]	0.98, 1.06	54.35, 59.62	56.00, 61.24	55.93, 59.66

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 57				
n[3]	170	149	152	301
GMT [2]	21.2	1090.6	1093.6	1092.1
95% CI [2]	20.0, 22.4	1027.5, 1157.5	1031.1, 1160.0	1047.4, 1138.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR [2]	1.05	54.24	54.39	54.32
95% CI [2]	1.00, 1.11	51.11, 57.57	51.29, 57.69	52.10, 56.64

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Baseline								
n[1]	91	90	95	185	89	88	91	179
GMT [2]	20.0	20.4	20.0	20.2	20.0	20.2	20.0	20.1
95% CI [2]	19.6, 20.5	20.0, 20.9	19.6, 20.4	19.9, 20.5	19.8, 20.2	20.0, 20.3	19.8, 20.2	20.0, 20.2
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 20	20, 40	20, 20	20, 40
Day 29								
n[3]	89	89	94	183	88	78	86	164
GMT [2]	20.9	125.8	183.8	152.9	20.9	102.2	118.5	110.4
95% CI [2]	17.3, 25.3	103.9, 152.3	152.7, 221.3	133.7, 175.0	16.9, 25.9	81.3, 128.3	95.4, 147.1	94.4, 129.2
Median	20.0	160.0	240.0	200.0	20.0	120.0	120.0	120.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	6.25	9.13	7.60	1.04	5.09	5.91	5.51
95% CI [2]	0.86, 1.26	5.16, 7.56	7.59, 10.99	6.64, 8.69	0.84, 1.29	4.06, 6.40	4.76, 7.34	4.71, 6.44
Day 43								
n[3]	86	78	88	166	88	62	62	124
GMT [2]	20.0	1131.5	1234.1	1184.9	20.8	1169.6	1102.0	1135.2
95% CI [2]	19.3, 20.8	1086.9, 1177.9	1188.4, 1281.6	1152.3, 1218.5	19.3, 22.4	1070.1, 1278.4	1008.5, 1204.1	1066.3, 1208.6
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR [2]	0.99	56.18	61.27	58.83	1.04	58.29	54.92	56.57
95% CI [2]	0.96, 1.03	53.96, 58.48	59.00, 63.63	57.20, 60.49	0.96, 1.12	53.33, 63.71	50.26, 60.01	53.14, 60.23

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Day 57								
n[3]	83	80	82	162	87	69	70	139
GMT [2]	21.6	1081.9	1127.6	1104.9	20.7	1111.1	1054.7	1082.2
95% CI [2]	19.9, 23.4	995.8, 1175.5	1039.1, 1223.7	1042.5, 1170.9	19.2, 22.3	1021.4, 1208.7	970.3, 1146.3	1020.1, 1148.1
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR [2]	1.07	53.70	55.97	54.84	1.03	55.39	52.57	53.95
95% CI [2]	0.99, 1.16	49.43, 58.35	51.58, 60.74	51.75, 58.12	0.96, 1.11	50.91, 60.25	48.37, 57.14	50.85, 57.23

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Baseline				
n[1]	180	178	186	364
GMT [2]	45.549	45.887	45.548	45.713
95% CI [2]	45.174, 45.926	45.507, 46.269	45.179, 45.919	45.448, 45.979
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71
Day 29				
n[3]	177	167	180	347
GMT [2]	47.362	171.221	225.861	197.711
95% CI [2]	41.312, 54.297	148.714, 197.133	197.227, 258.653	179.198, 218.135
Median	45.550	226.274	282.843	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	3.75	4.95	4.33
95% CI [2]	0.90, 1.19	3.26, 4.32	4.32, 5.66	3.92, 4.78
Day 43				
n[3]	174	140	150	290
GMT [2]	46.463	1770.555	1812.556	1792.123
95% CI [2]	44.573, 48.433	1690.213, 1854.717	1732.897, 1895.878	1735.074, 1851.047
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.02	38.76	39.68	39.23
95% CI [2]	0.98, 1.06	37.00, 40.60	37.94, 41.50	37.98, 40.52

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=180)	mRNA-1273		
		50 µg (N=178)	100 µg (N=186)	Total (N=364)
Day 57				
n[3]	170	149	152	301
GMT [2]	47.840	1635.619	1654.412	1645.091
95% CI [2]	45.328, 50.491	1543.887, 1732.801	1562.604, 1751.614	1579.708, 1713.180
Median	45.550	1810.193	2031.870	1810.193
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.05	35.81	36.22	36.02
95% CI [2]	0.99, 1.11	33.80, 37.94	34.21, 38.35	34.58, 37.51

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Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Baseline								
n[1]	91	90	95	185	89	88	91	179
GMT [2]	45.550	46.221	45.550	45.875	45.550	45.550	45.550	45.550
95% CI [2]	44.812, 46.300	45.467, 46.986	44.827, 46.284	45.352, 46.404	NE, NE	NE, NE	NE, NE	NE, NE
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 45.55	45.55, 45.55	45.55, 45.55
Day 29								
n[3]	89	89	94	183	88	78	86	164
GMT [2]	47.429	183.420	273.393	225.239	47.341	160.247	184.831	172.700
95% CI [2]	39.417, 57.069	152.380, 220.782	228.344, 327.328	197.593, 256.754	38.685, 57.934	129.313, 198.580	150.684, 226.716	148.960, 200.225
Median	45.550	226.274	339.411	282.843	45.550	169.706	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	4.01	5.97	4.92	1.04	3.52	4.06	3.79
95% CI [2]	0.86, 1.25	3.33, 4.82	4.99, 7.15	4.32, 5.61	0.85, 1.27	2.84, 4.36	3.31, 4.98	3.27, 4.40

Notes are listed on last page.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202020301.sas 19NOV2020 02:05 Database Lock Date: 05NOV2020

Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=89)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=88)	100 µg (N=91)	Total (N=179)
Day 43								
n[3]	86	78	88	166	88	62	62	124
GMT [2]	45.579	1730.483	1910.040	1823.658	47.341	1823.833	1686.145	1753.638
95% CI [2]	43.668, 47.574	1654.183, 1810.303	1830.833, 1992.673	1767.340, 1881.770	44.033, 50.898	1673.020, 1988.241	1546.717, 1838.142	1649.671, 1864.158
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.00	37.79	41.71	39.83	1.04	40.04	37.02	38.50
95% CI [2]	0.95, 1.04	36.13, 39.54	39.98, 43.52	38.60, 41.10	0.97, 1.12	36.73, 43.65	33.96, 40.35	36.22, 40.93
Day 57								
n[3]	83	80	82	162	87	69	70	139
GMT [2]	48.568	1611.202	1692.751	1652.063	47.142	1666.082	1612.932	1639.100
95% CI [2]	44.932, 52.499	1488.161, 1744.416	1565.274, 1830.610	1562.629, 1746.617	43.724, 50.828	1531.044, 1813.030	1483.100, 1754.129	1544.486, 1739.511
Median	45.550	1810.193	1810.193	1810.193	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.06	35.18	36.96	36.08	1.03	36.58	35.41	35.98
95% CI [2]	0.98, 1.15	32.50, 38.09	34.18, 39.97	34.12, 38.14	0.96, 1.12	33.61, 39.80	32.56, 38.51	33.91, 38.19

Notes are listed on last page.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202020301.sas 19NOV2020 02:05 Database Lock Date: 05NOV2020

Table 14.2.2.2.3.1
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariates for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot at the corresponding visit.

Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GMT [2]	20.8	20.6	20.6	20.6
95% CI [2]	20.0, 21.5	19.9, 21.3	19.9, 21.3	20.1, 21.1
Median	20.0	20.0	20.0	20.0
Min, Max	20, 80	20, 120	20, 960	20, 960
Day 29				
n[3]	183	178	185	363
GMT [2]	21.8	112.0	149.9	129.9
95% CI [2]	19.0, 25.0	97.3, 129.0	130.5, 172.2	117.6, 143.5
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.06	5.46	7.31	6.34
95% CI [2]	0.92, 1.22	4.74, 6.29	6.36, 8.40	5.74, 7.00
Day 43				
n[3]	179	168	176	344
GMT [2]	21.2	1150.1	1191.2	1170.9
95% CI [2]	20.3, 22.1	1101.0, 1201.3	1141.5, 1243.1	1135.8, 1207.2
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
GMFR [2]	1.03	55.62	57.61	56.63
95% CI [2]	0.98, 1.07	53.24, 58.09	55.20, 60.11	54.93, 58.38

Notes are listed on last page.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	167	171	338
GMT [2]	21.7	1086.7	1111.4	1099.1
95% CI [2]	20.6, 23.0	1026.3, 1150.7	1050.3, 1176.1	1055.8, 1144.2
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
GMFR [2]	1.06	53.20	54.41	53.81
95% CI [2]	1.01, 1.13	50.24, 56.33	51.42, 57.58	51.69, 56.02

Notes are listed on last page.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GMT [2]	20.0	20.4	20.0	20.2	21.5	20.8	21.2	20.9
95% CI [2]	19.6, 20.5	20.0, 20.9	19.6, 20.4	19.9, 20.5	20.1, 23.0	19.4, 22.2	19.8, 22.6	20.0, 22.0
Median	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Min, Max	20, 20	20, 120	20, 20	20, 120	20, 80	20, 80	20, 960	20, 960
Day 29								
n[3]	89	89	94	183	94	89	91	180
GMT [2]	20.9	125.8	183.8	152.9	22.5	100.1	121.5	110.4
95% CI [2]	17.3, 25.3	103.9, 152.3	152.7, 221.3	133.7, 175.0	18.3, 27.5	81.4, 123.3	98.9, 149.3	95.4, 127.8
Median	20.0	160.0	240.0	200.0	20.0	80.0	120.0	100.0
Min, Max	20, 960	20, 960	20, 1280	20, 1280	20, 960	20, 1280	20, 1280	20, 1280
GMFR [2]	1.04	6.25	9.13	7.60	1.08	4.80	5.82	5.29
95% CI [2]	0.86, 1.26	5.16, 7.56	7.59, 10.99	6.64, 8.69	0.88, 1.32	3.90, 5.90	4.74, 7.15	4.57, 6.12
Day 43								
n[3]	86	82	93	175	93	86	83	169
GMT [2]	20.0	1138.4	1232.7	1187.7	22.4	1165.9	1142.9	1154.5
95% CI [2]	19.3, 20.8	1095.1, 1183.5	1188.7, 1278.4	1156.2, 1220.1	20.8, 24.1	1079.6, 1259.0	1057.0, 1235.9	1093.1, 1219.5
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 20	240, 1280	640, 1280	240, 1280	20, 960	480, 1280	160, 1280	160, 1280
GMFR [2]	0.99	56.53	61.21	58.98	1.05	54.91	53.83	54.38
95% CI [2]	0.96, 1.03	54.38, 58.77	59.03, 63.48	57.41, 60.59	0.98, 1.13	50.85, 59.30	49.78, 58.21	51.48, 57.44

Notes are listed on last page.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN Endpoint Titer

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 57								
n[3]	83	84	86	170	91	83	85	168
GMT [2]	21.6	1065.3	1134.4	1099.8	21.8	1114.0	1087.8	1100.7
95% CI [2]	19.9, 23.4	982.0, 1155.7	1046.8, 1229.3	1038.7, 1164.4	20.2, 23.6	1027.5, 1207.9	1004.2, 1178.4	1039.9, 1165.1
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
GMFR [2]	1.07	52.89	56.32	54.60	1.05	53.80	52.53	53.15
95% CI [2]	0.99, 1.16	48.75, 57.38	51.97, 61.03	51.57, 57.81	0.98, 1.14	49.62, 58.33	48.49, 56.91	50.22, 56.26

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Baseline				
n[1]	185	184	189	373
GMT [2]	47.101	46.484	46.689	46.587
95% CI [2]	45.674, 48.572	45.072, 47.939	45.290, 48.131	45.590, 47.607
Median	45.550	45.550	45.550	45.550
Min, Max	45.55, 159.23	45.55, 169.71	45.55, 1357.65	45.55, 1357.65
Day 29				
n[3]	183	178	185	363
GMT [2]	48.843	173.083	227.458	198.905
95% CI [2]	42.788, 55.754	151.374, 197.906	199.404, 259.459	180.965, 218.623
Median	45.550	169.706	254.559	226.274
Min, Max	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.05	3.72	4.89	4.28
95% CI [2]	0.92, 1.20	3.26, 4.26	4.29, 5.58	3.89, 4.70
Day 43				
n[3]	179	168	176	344
GMT [2]	47.968	1770.372	1822.290	1796.738
95% CI [2]	46.011, 50.009	1695.874, 1848.143	1747.309, 1900.489	1743.568, 1851.531
Median	45.550	2031.870	2031.870	2031.870
Min, Max	45.55, 1357.65	339.41, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.02	37.79	38.90	38.35
95% CI [2]	0.98, 1.07	36.20, 39.45	37.30, 40.57	37.22, 39.52

Notes are listed on last page.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Overall			
	Placebo (N=185)	mRNA-1273		
		50 µg (N=184)	100 µg (N=189)	Total (N=373)
Day 57				
n[3]	174	167	171	338
GMT [2]	48.896	1629.856	1679.402	1654.719
95% CI [2]	46.325, 51.609	1542.549, 1722.103	1590.408, 1773.376	1591.900, 1720.015
Median	45.550	1810.193	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.06	35.17	36.24	35.71
95% CI [2]	1.00, 1.11	33.29, 37.16	34.32, 38.27	34.35, 37.12

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Baseline								
n[1]	91	90	95	185	94	94	94	188
GMT [2]	45.550	46.221	45.550	45.875	48.686	46.779	47.858	47.316
95% CI [2]	44.812, 46.300	45.467, 46.986	44.827, 46.284	45.352, 46.404	45.909, 51.630	44.111, 49.609	45.128, 50.753	45.393, 49.319
Median	45.550	45.550	45.550	45.550	45.550	45.550	45.550	45.550
Min, Max	45.55, 45.55	45.55, 169.71	45.55, 45.55	45.55, 169.71	45.55, 159.23	45.55, 159.23	45.55, 1357.65	45.55, 1357.65
Day 29								
n[3]	89	89	94	183	94	89	91	180
GMT [2]	47.429	183.420	273.393	225.239	49.938	163.851	188.257	175.745
95% CI [2]	39.417, 57.069	152.380, 220.782	228.344, 327.328	197.593, 256.754	41.318, 60.355	134.946, 198.947	155.329, 228.165	153.293, 201.486
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	169.706
Min, Max	45.55, 1357.65	45.55, 1357.65	45.55, 2031.87	45.55, 2031.87	45.55, 1357.65	45.55, 1810.19	45.55, 2031.87	45.55, 2031.87
GMFR [2]	1.04	4.01	5.97	4.92	1.06	3.47	3.98	3.72
95% CI [2]	0.86, 1.25	3.33, 4.82	4.99, 7.15	4.32, 5.61	0.87, 1.28	2.86, 4.21	3.29, 4.83	3.24, 4.26

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Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\t140202020302.sas 19NOV2020 02:06 Database Lock Date: 05NOV2020

Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Antibody: MN50

Timepoint Statistic	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
	Placebo (N=91)	mRNA-1273			Placebo (N=94)	mRNA-1273		
		50 µg (N=90)	100 µg (N=95)	Total (N=185)		50 µg (N=94)	100 µg (N=94)	Total (N=188)
Day 43								
n[3]	86	82	93	175	93	86	83	169
GMT [2]	45.577	1739.272	1903.361	1824.796	50.254	1805.610	1731.894	1768.991
95% CI [2]	43.685, 47.551	1665.203, 1816.636	1827.312, 1982.575	1770.580, 1880.672	46.846, 53.910	1678.397, 1942.465	1607.871, 1865.483	1679.276, 1863.498
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	2031.870
Min, Max	45.55, 45.55	339.41, 2031.87	905.10, 2031.87	339.41, 2031.87	45.55, 1357.65	678.82, 2031.87	226.27, 2031.87	226.27, 2031.87
GMFR [2]	1.00	37.99	41.58	39.86	1.05	37.66	36.13	36.90
95% CI [2]	0.95, 1.04	36.37, 39.68	39.91, 43.31	38.68, 41.08	0.98, 1.12	35.01, 40.52	33.54, 38.91	35.03, 38.87
Day 57								
n[3]	83	84	86	170	91	83	85	168
GMT [2]	48.571	1582.550	1702.741	1642.371	49.042	1686.975	1654.320	1670.374
95% CI [2]	44.898, 52.544	1463.344, 1711.467	1576.168, 1839.479	1554.485, 1735.226	45.514, 52.842	1560.451, 1823.758	1531.649, 1786.815	1581.371, 1764.387
Median	45.550	1810.193	1917.830	1810.193	45.550	1917.830	1917.830	1917.830
Min, Max	45.55, 905.10	339.41, 2031.87	452.55, 2031.87	339.41, 2031.87	45.55, 905.10	452.55, 2031.87	282.84, 2031.87	282.84, 2031.87
GMFR [2]	1.06	34.56	37.19	35.87	1.05	35.98	35.28	35.62
95% CI [2]	0.98, 1.15	31.96, 37.38	34.42, 40.17	33.95, 37.90	0.97, 1.13	33.28, 38.89	32.66, 38.11	33.73, 37.63

Notes are listed on last page.

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Table 14.2.2.2.3.2
Sensitivity Analysis of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

nAb = Neutralizing antibody. GMT = Geometric Mean Titer; GMFR = Geometric Mean Fold Rise (post-baseline / baseline titers).
CI = Confidence intervals.

This table only includes subjects whose Day 29 visit is within the -3/+7 window.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87.

For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

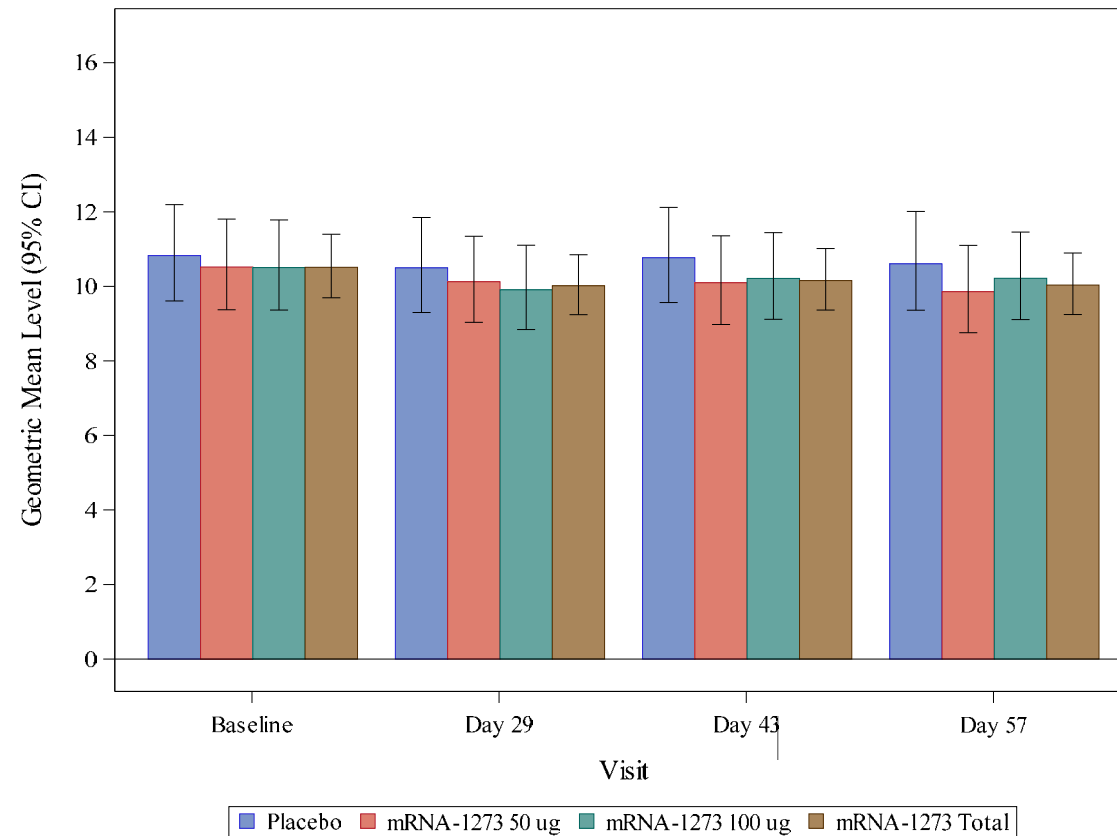
[1] Number of subjects with non-missing baseline.

[2] The GMT, GMFR, and corresponding 95% confidence intervals (CI) are estimated using ANCOVA model based on the log-transformed titer with baseline titer as a covariates for the post-baseline visits, then back transformed to the original scale for presentation. In addition for overall group, age cohort is considered as a factor in the ANCOVA model. For Placebo, mRNA 50 ug and mRNA 100 ug, the ANCOVA model is based on Placebo, mRNA 50 ug and mRNA 100 ug. For mRNA Total group, the ANCOVA model is based on Placebo and mRNA Total.

[3] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

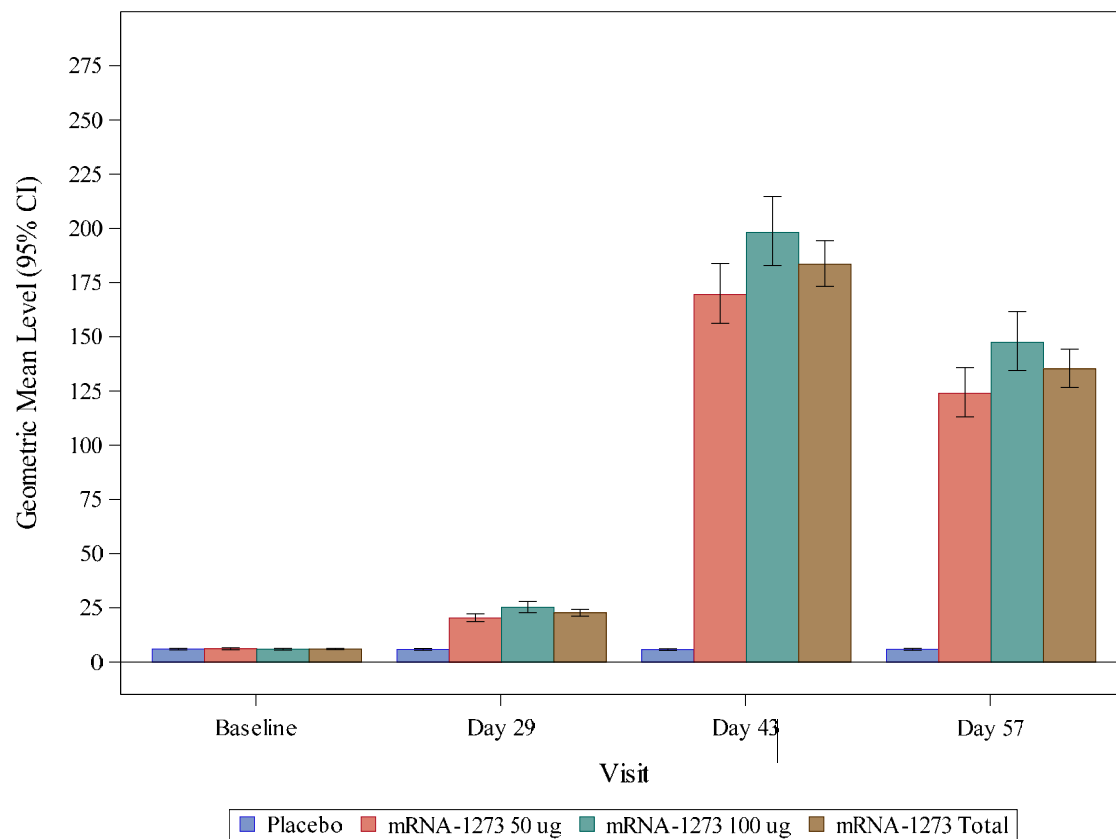
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

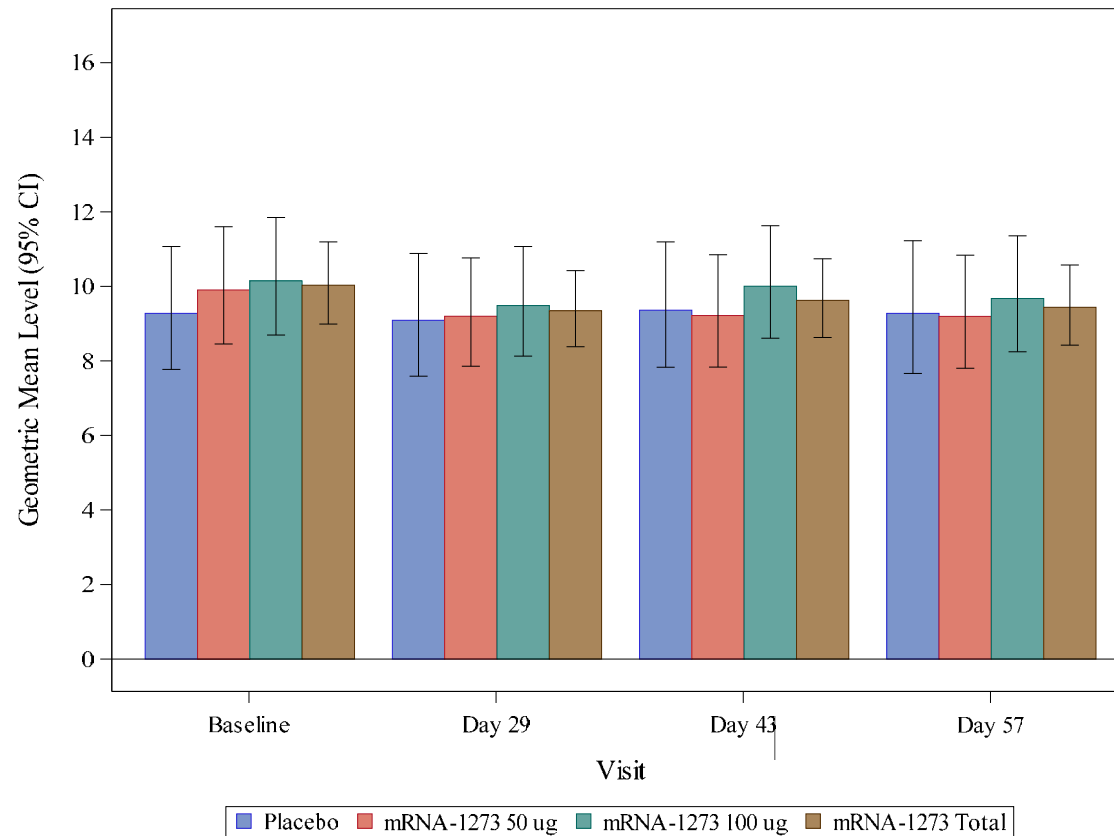
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

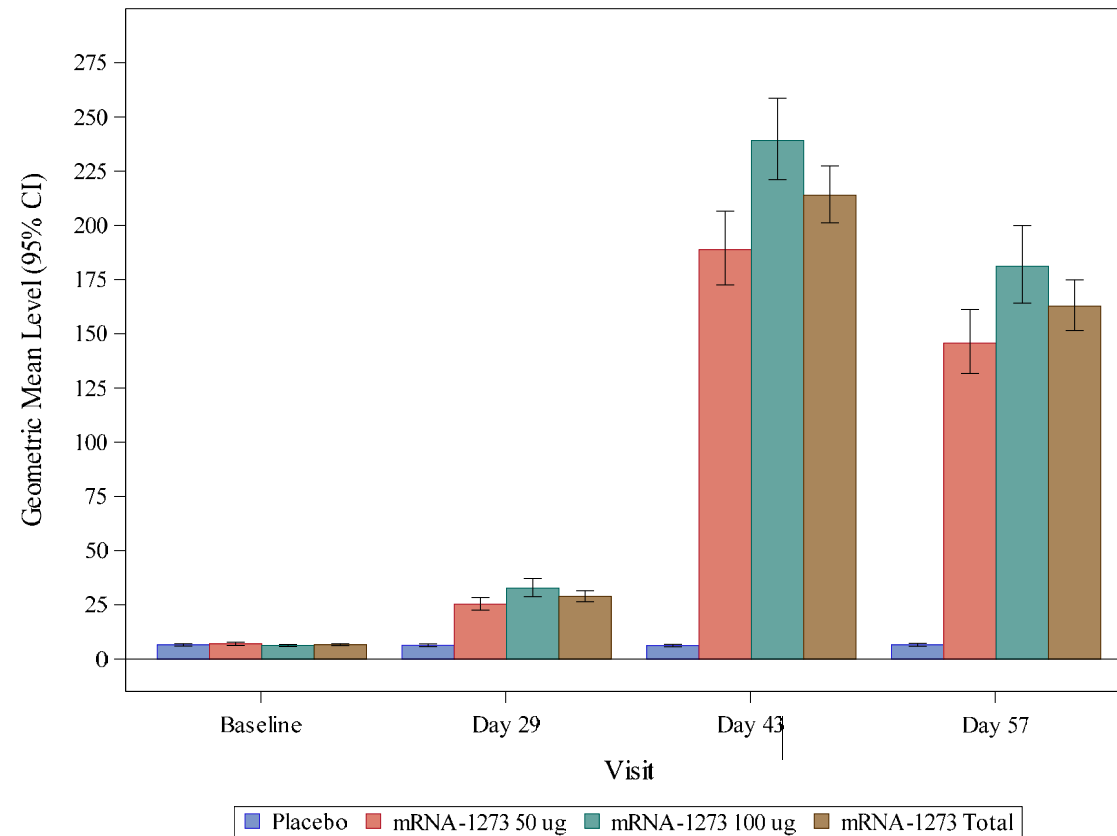
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

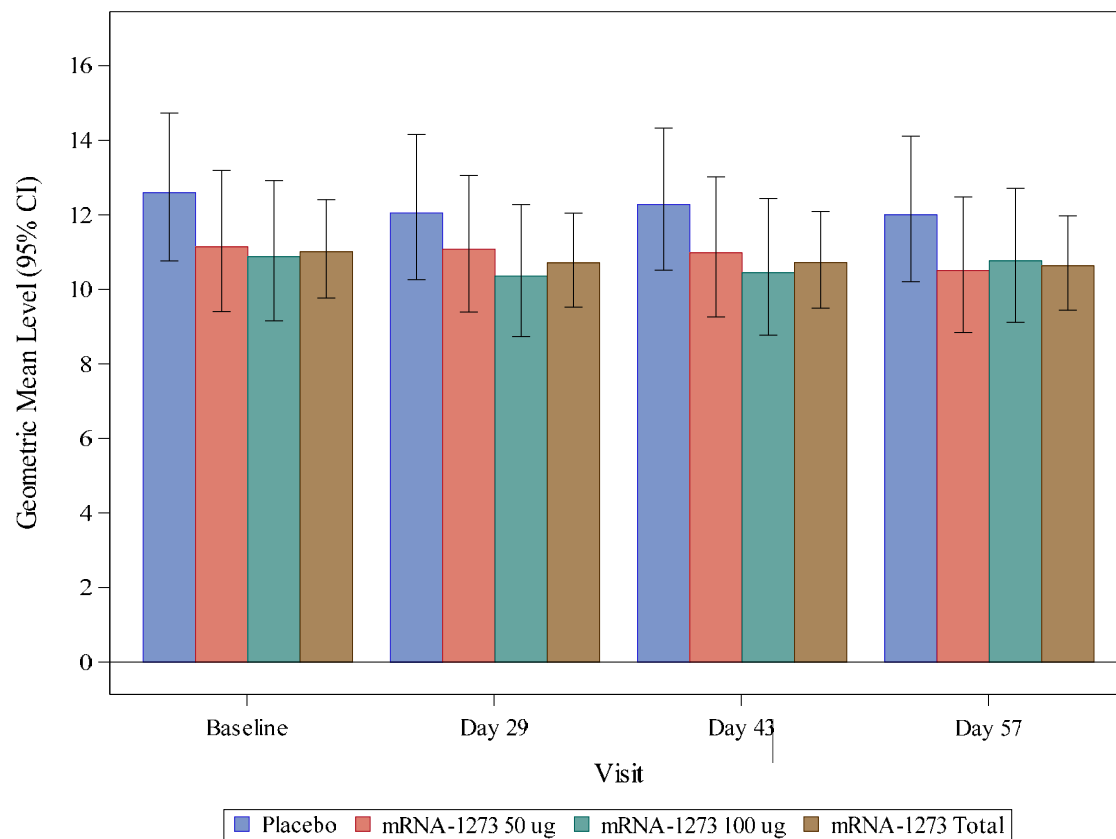
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

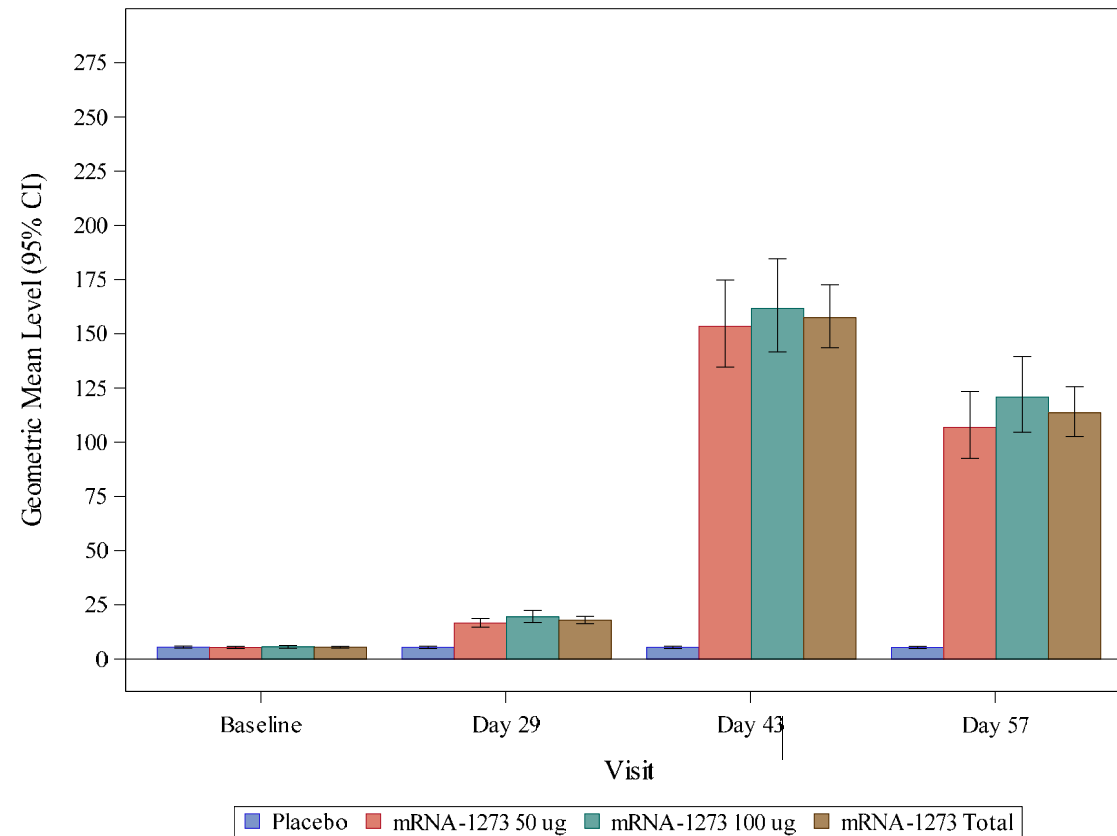
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

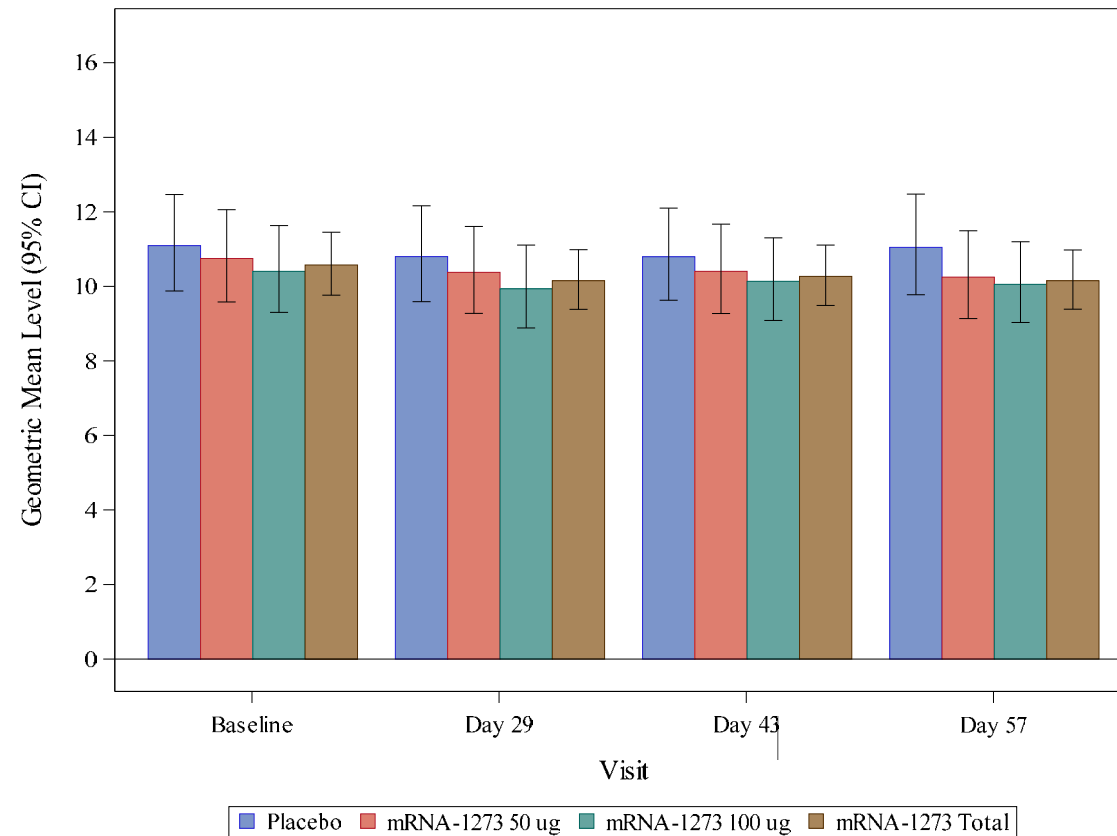
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020101.sas 19NOV2020 04:16 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

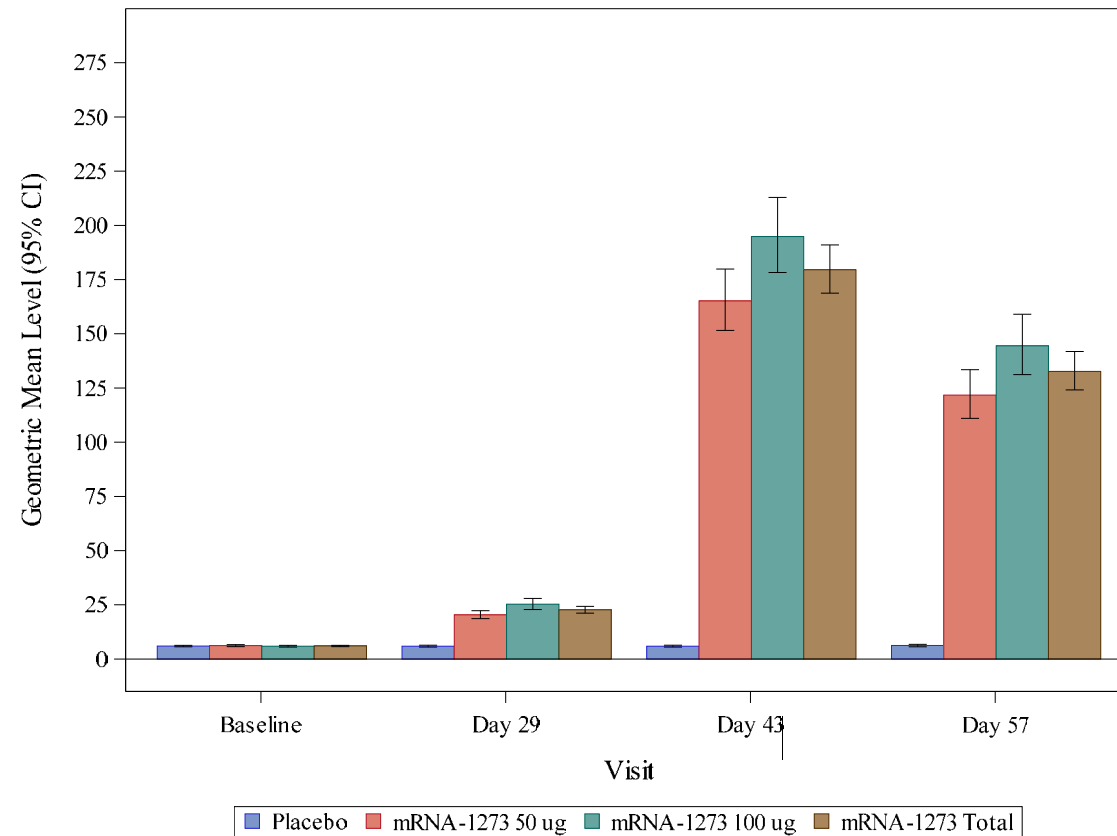
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

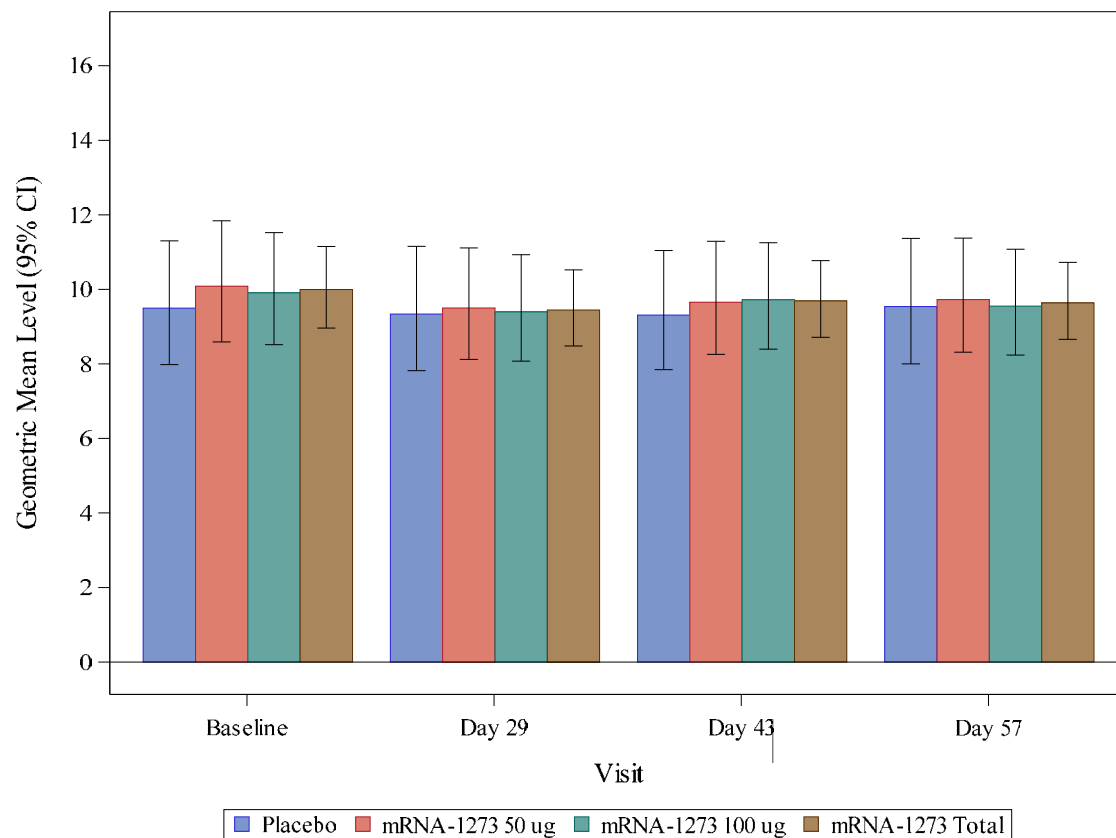
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

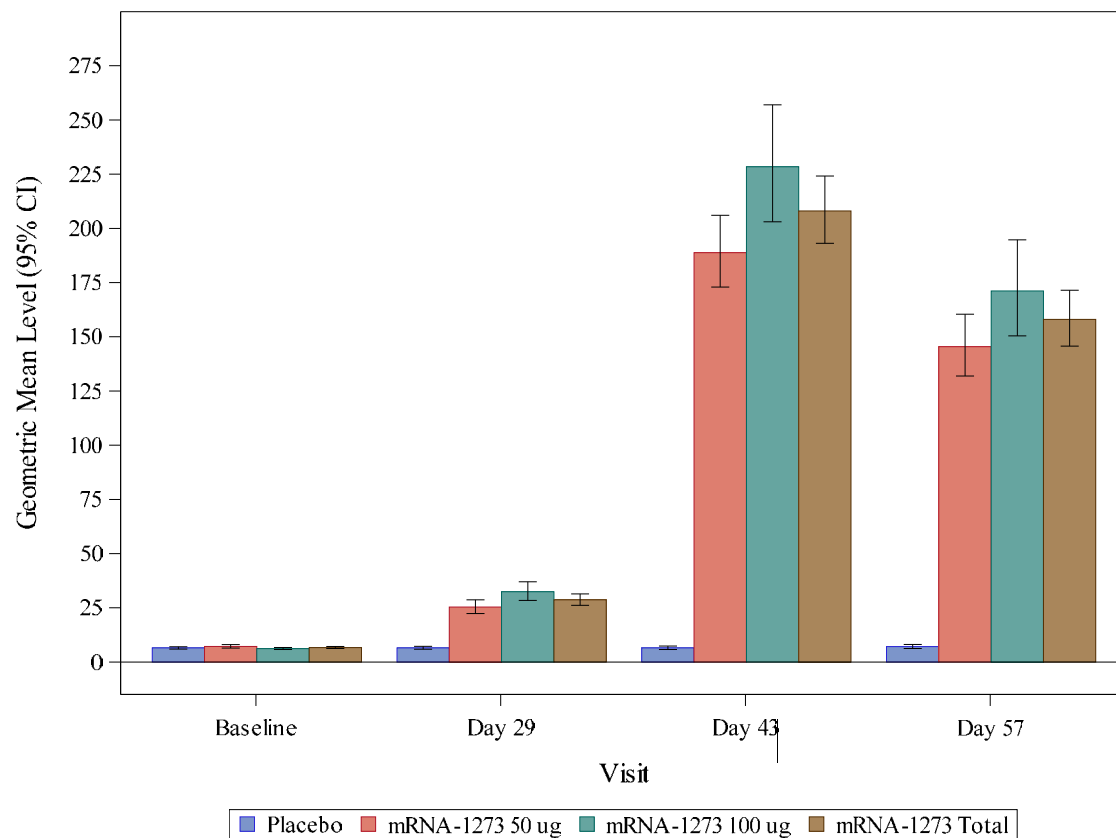
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

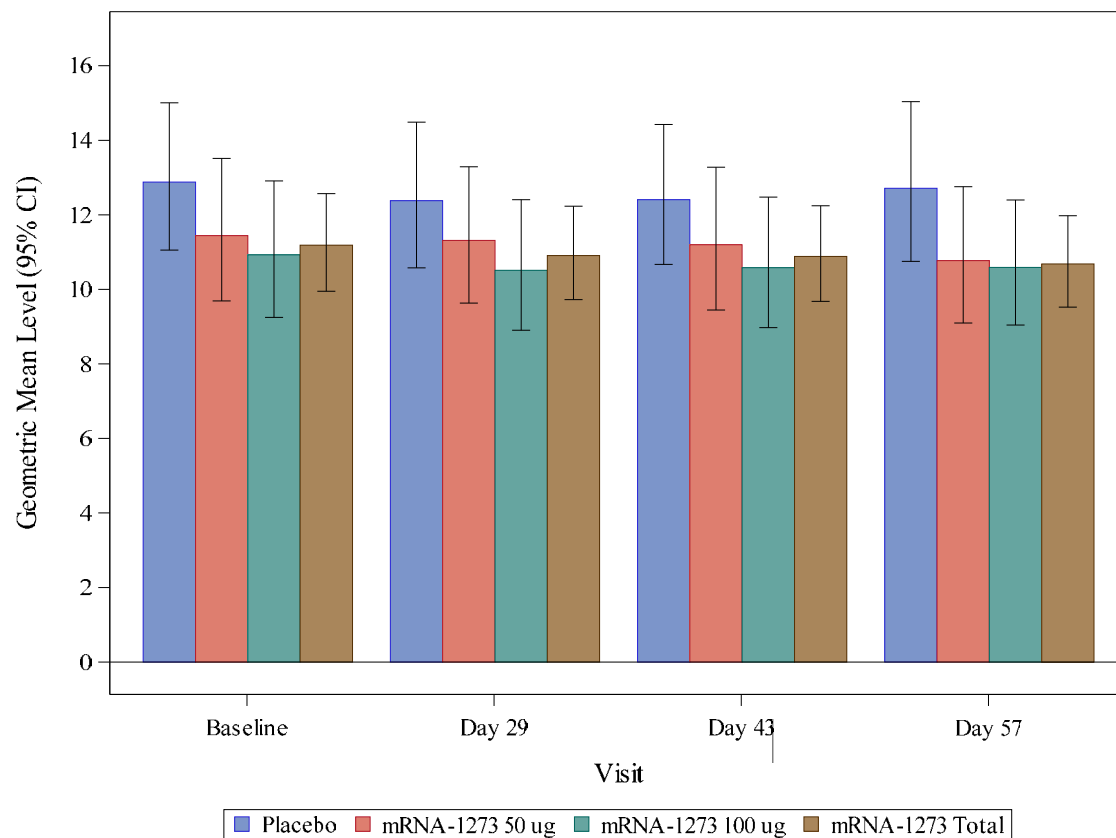
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

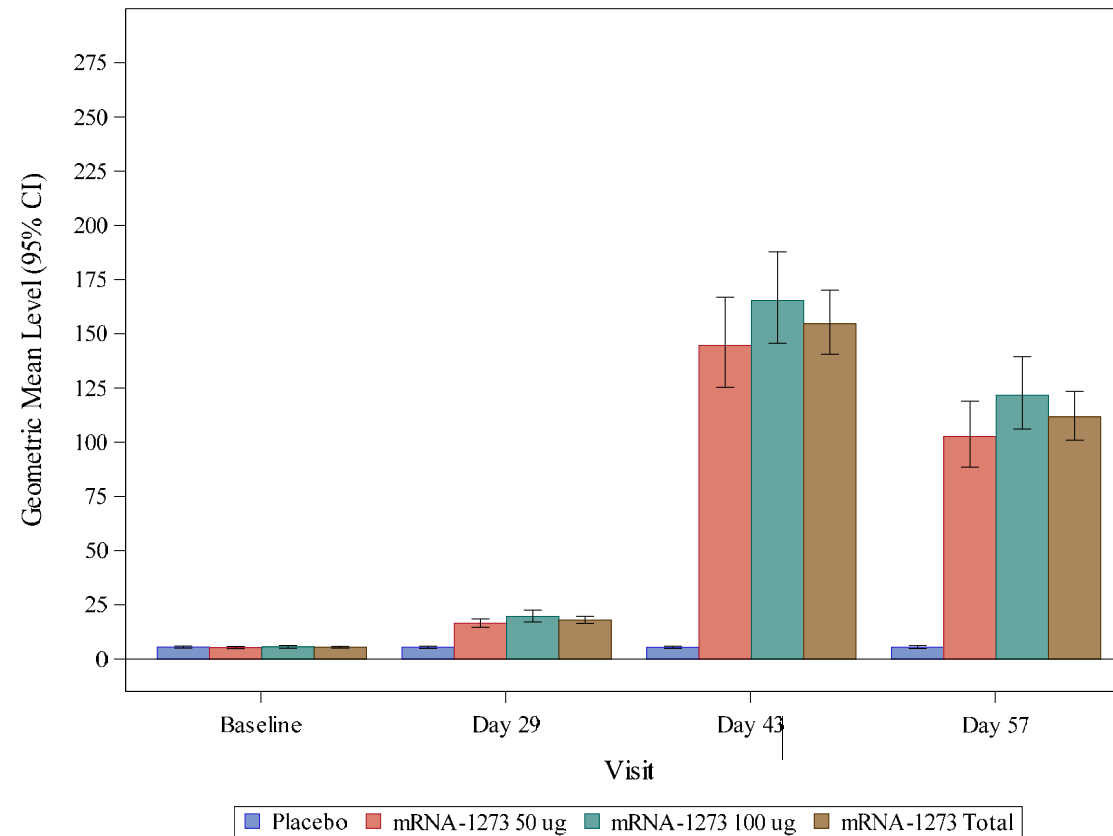
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.1.2
Geometric Mean Levels of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

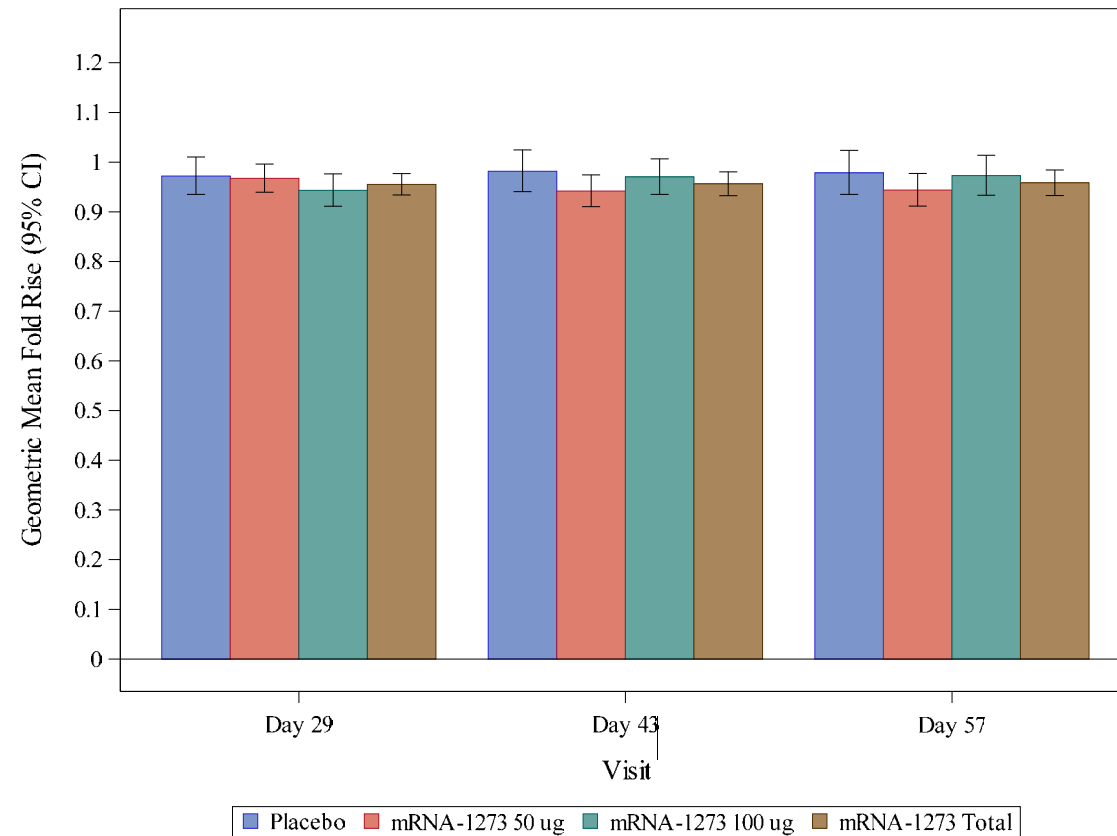
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020102.sas 19NOV2020 05:12 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

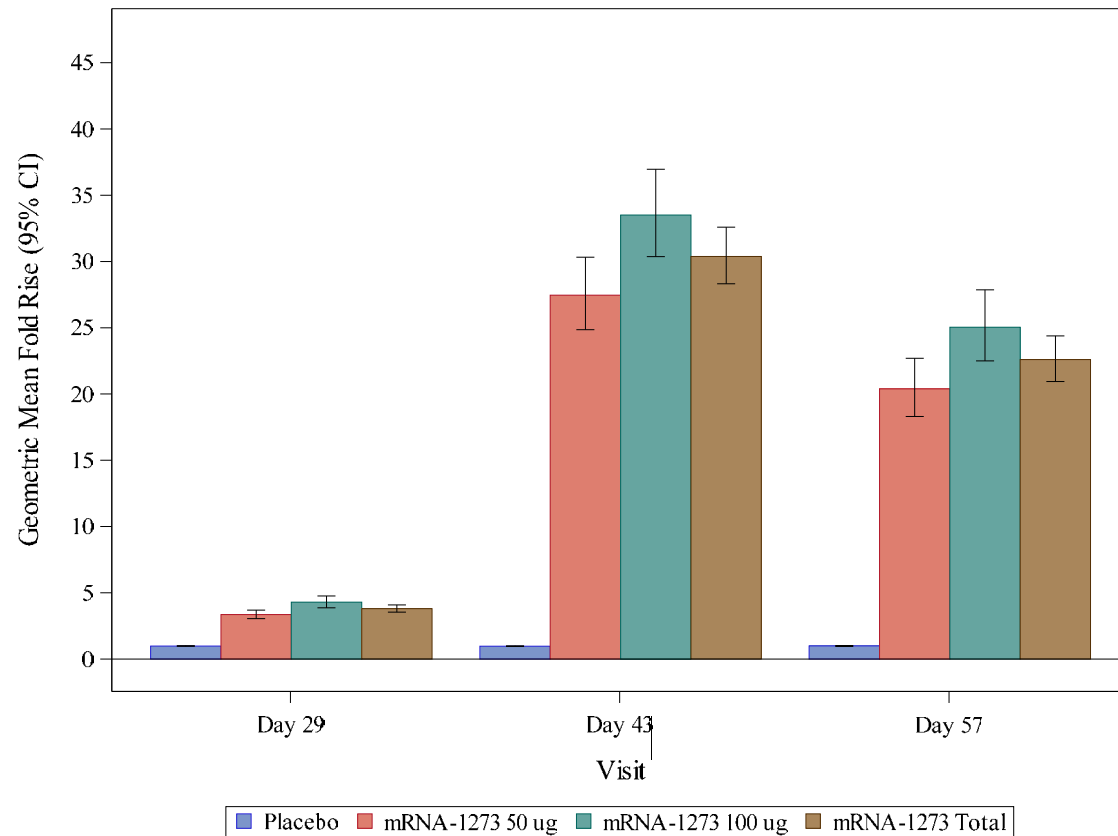
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

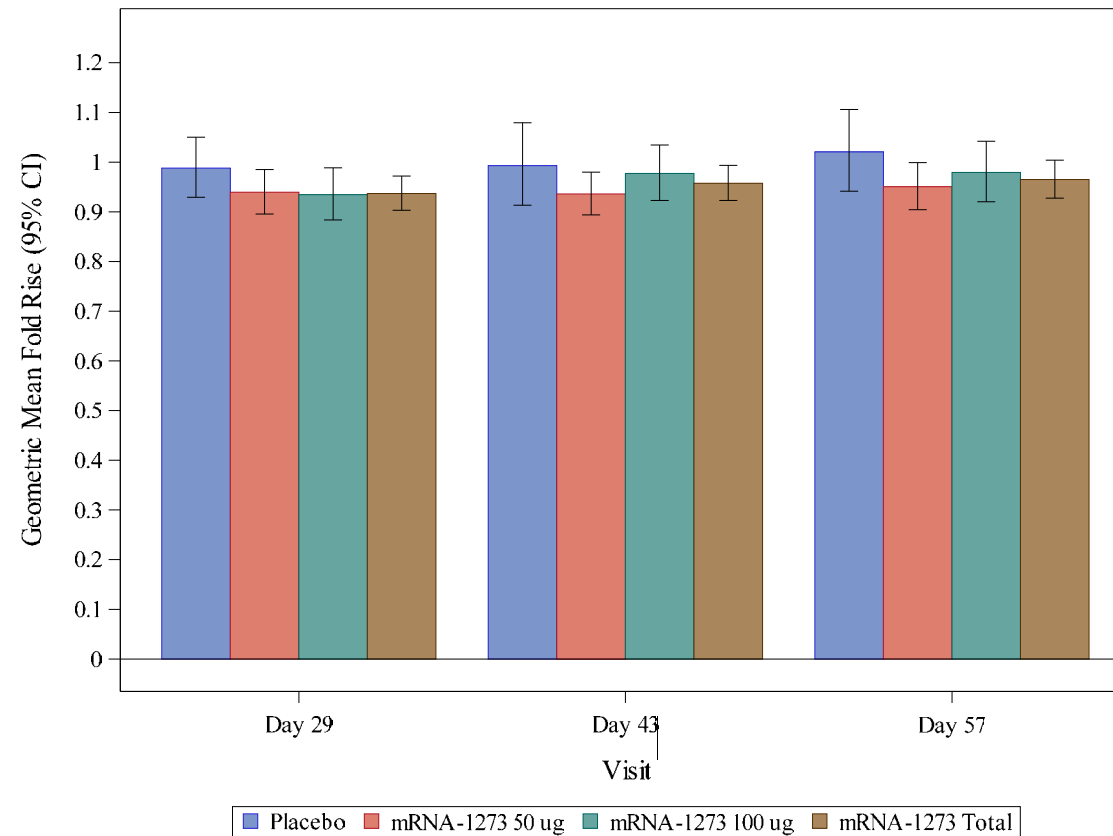
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

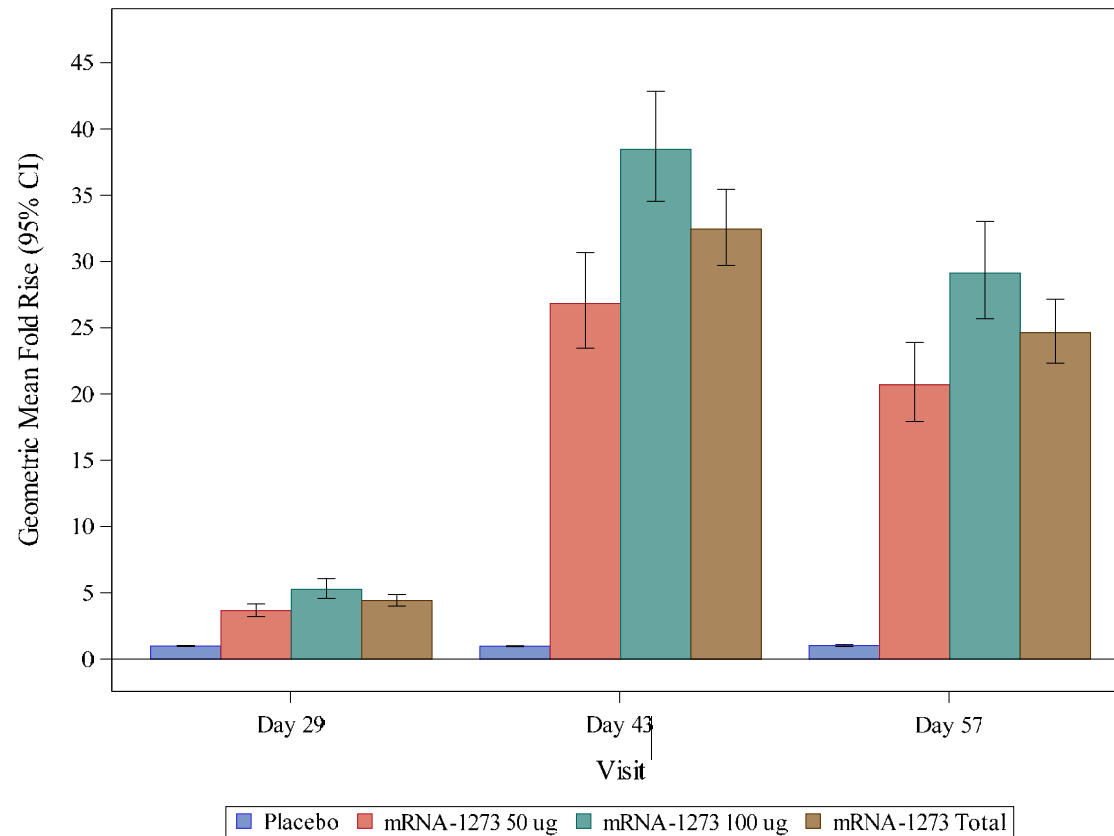
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

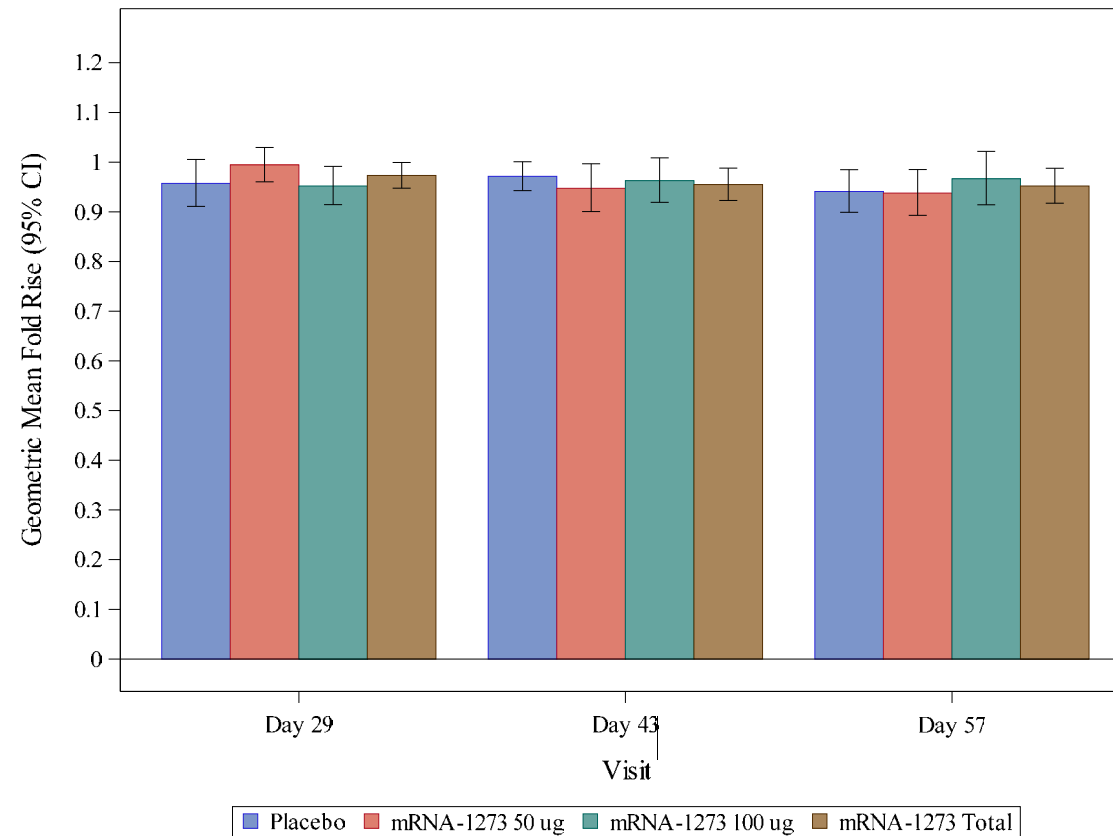
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.1

bAb = Binding antibody.

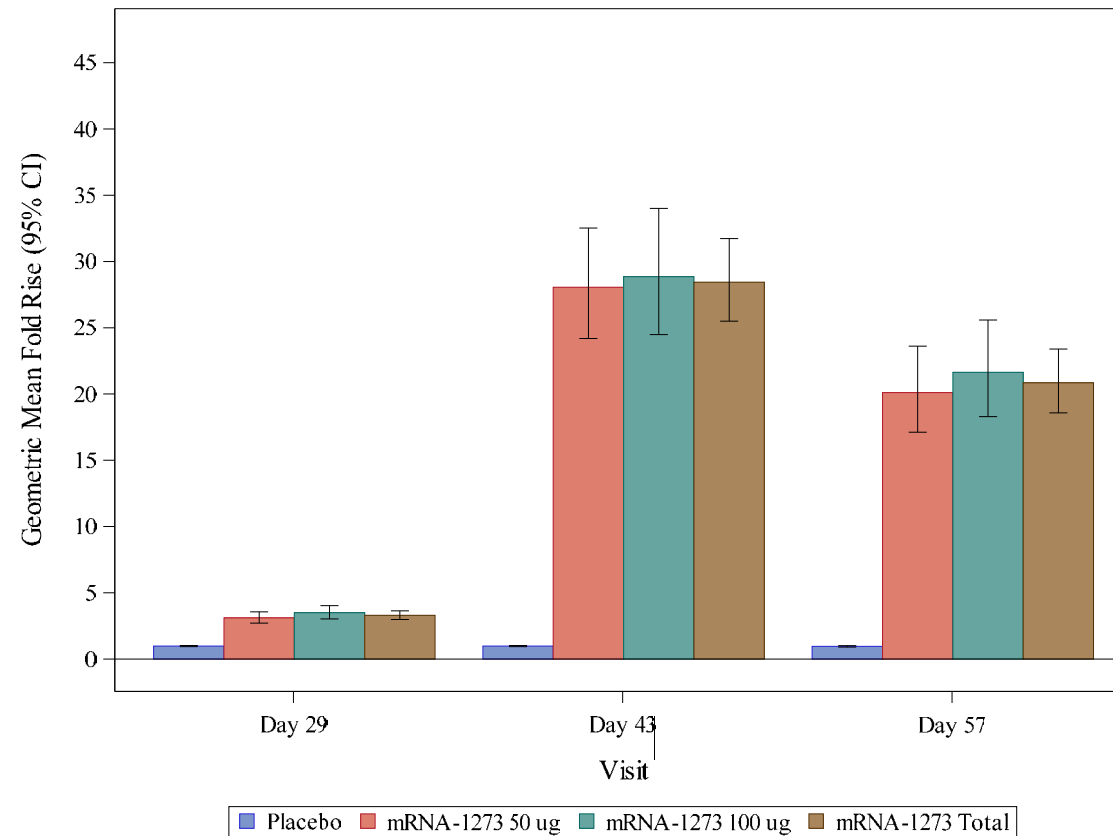
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.1

bAb = Binding antibody.

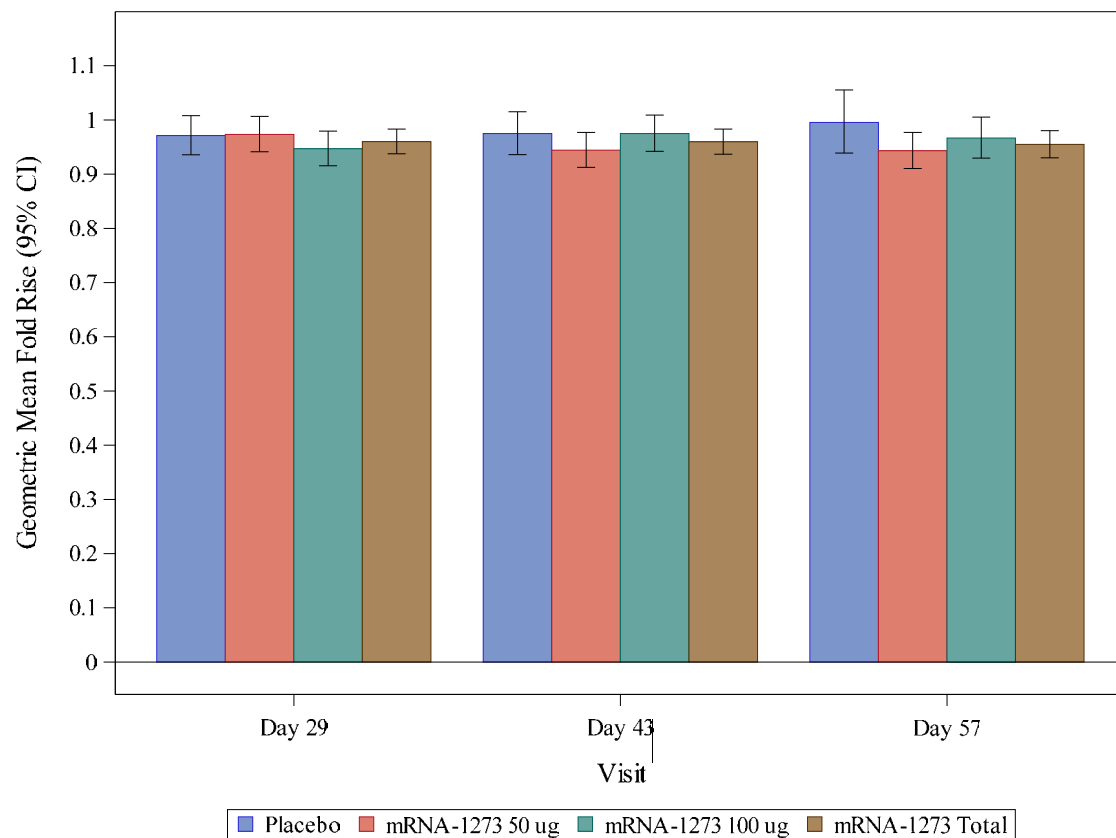
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020201.sas 19NOV2020 04:17 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

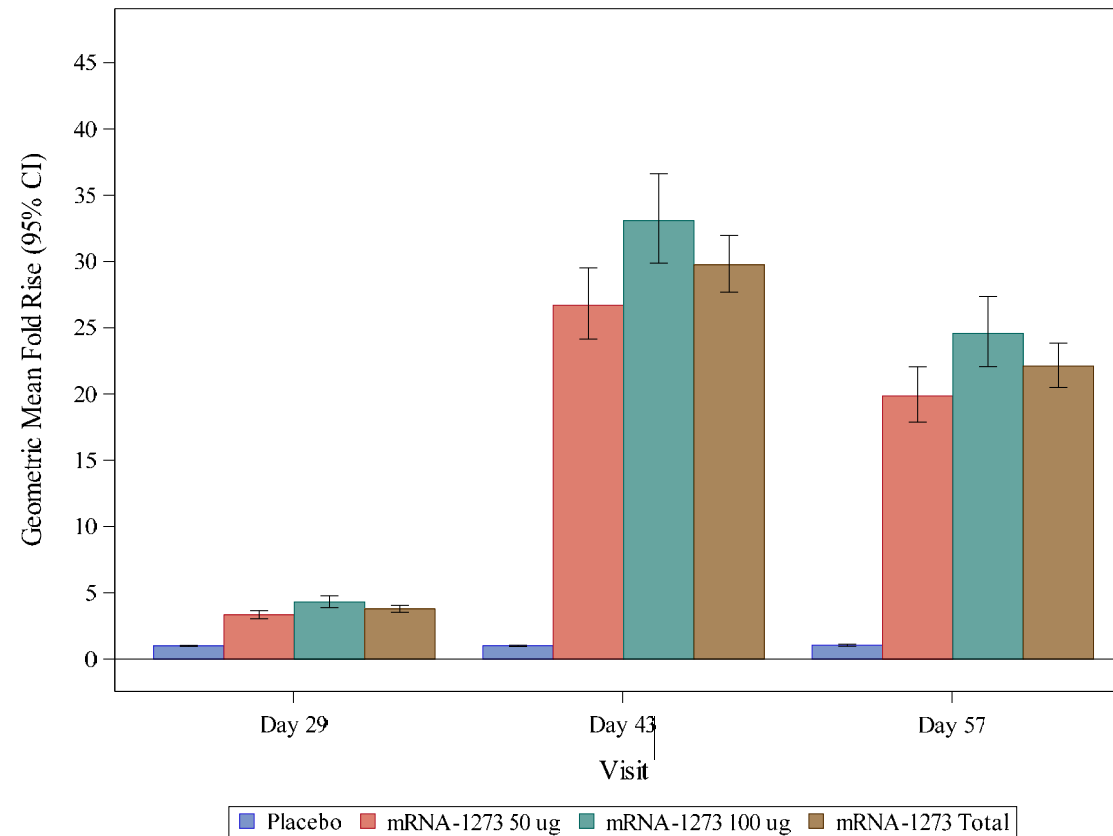
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

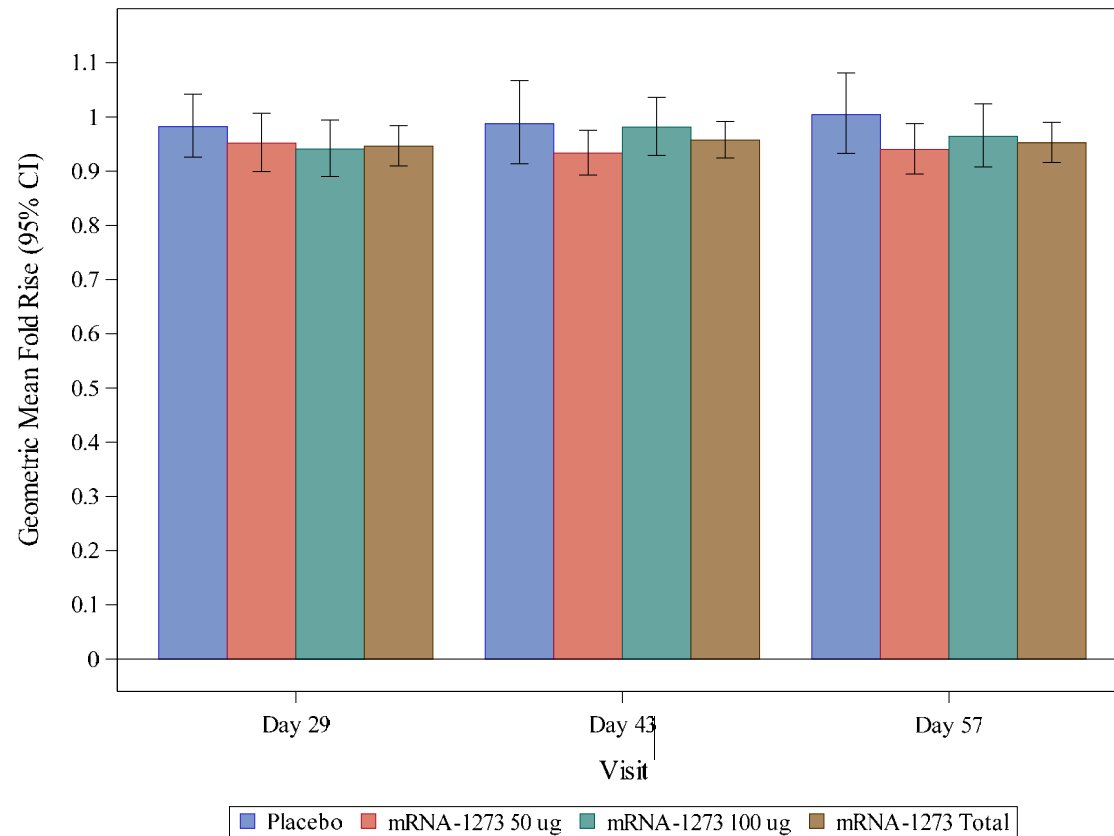
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

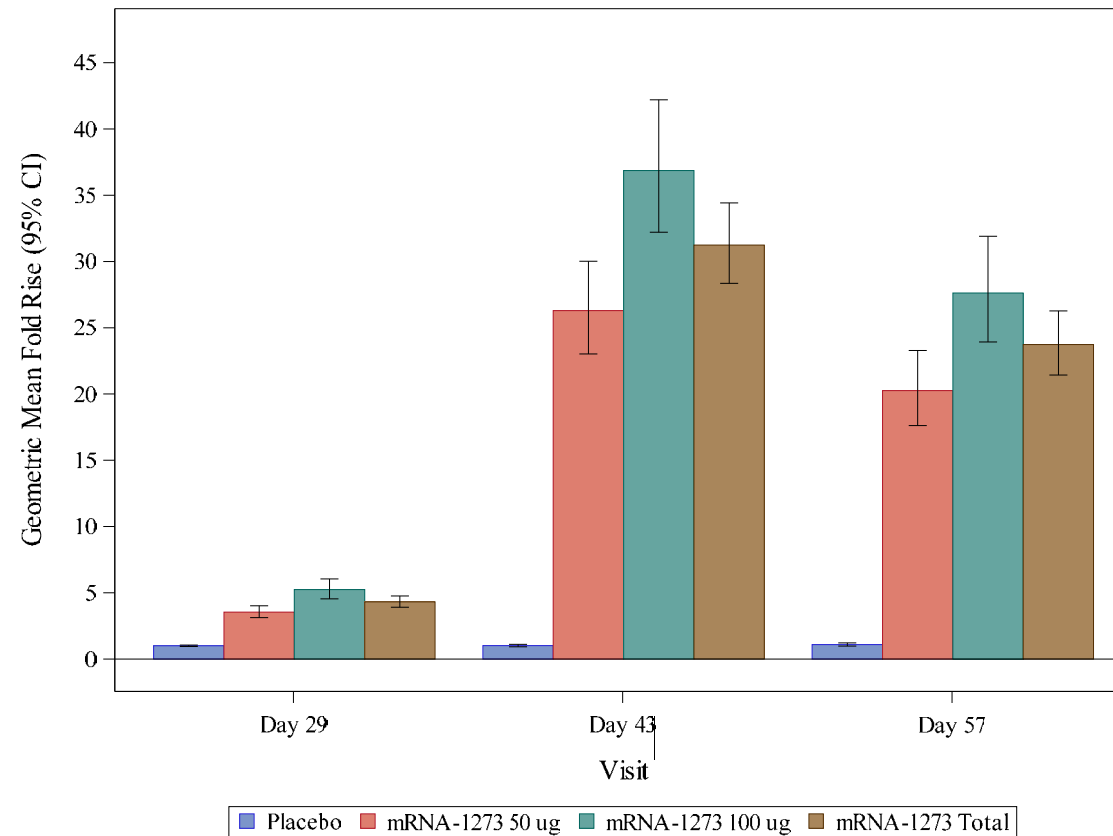
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

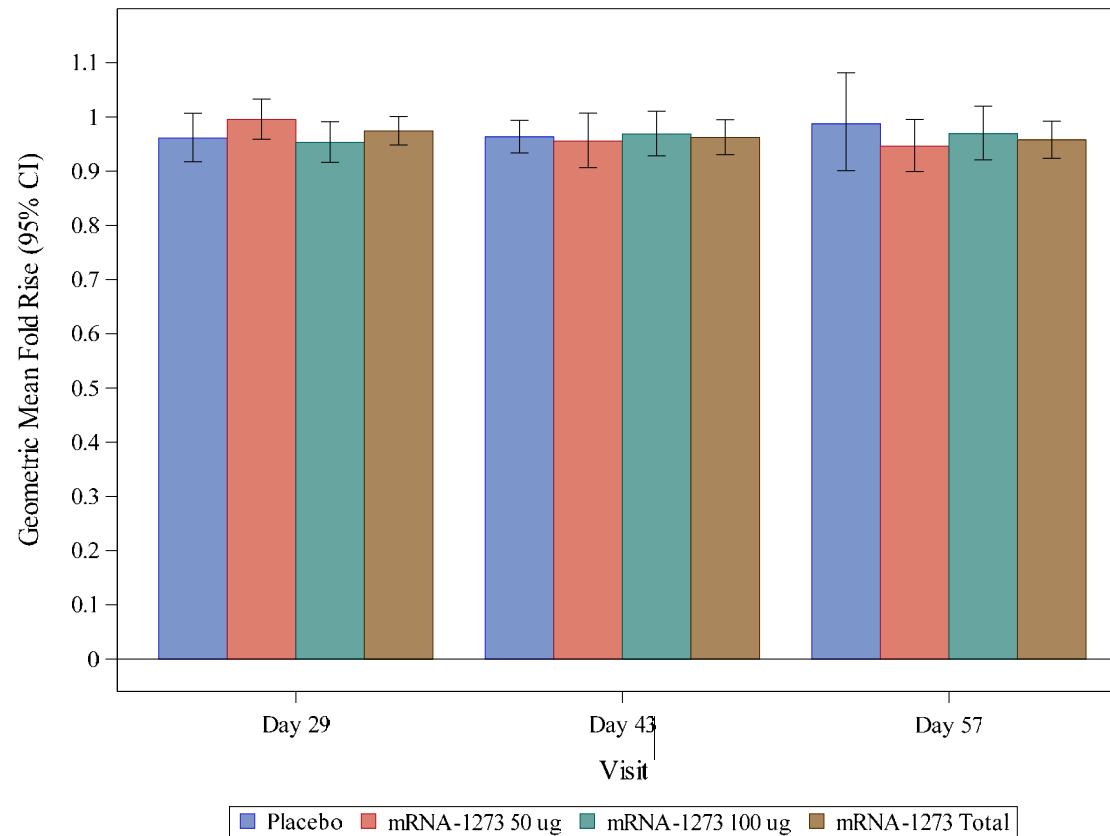
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)



Source table: T14.2.1.1.2

bAb = Binding antibody.

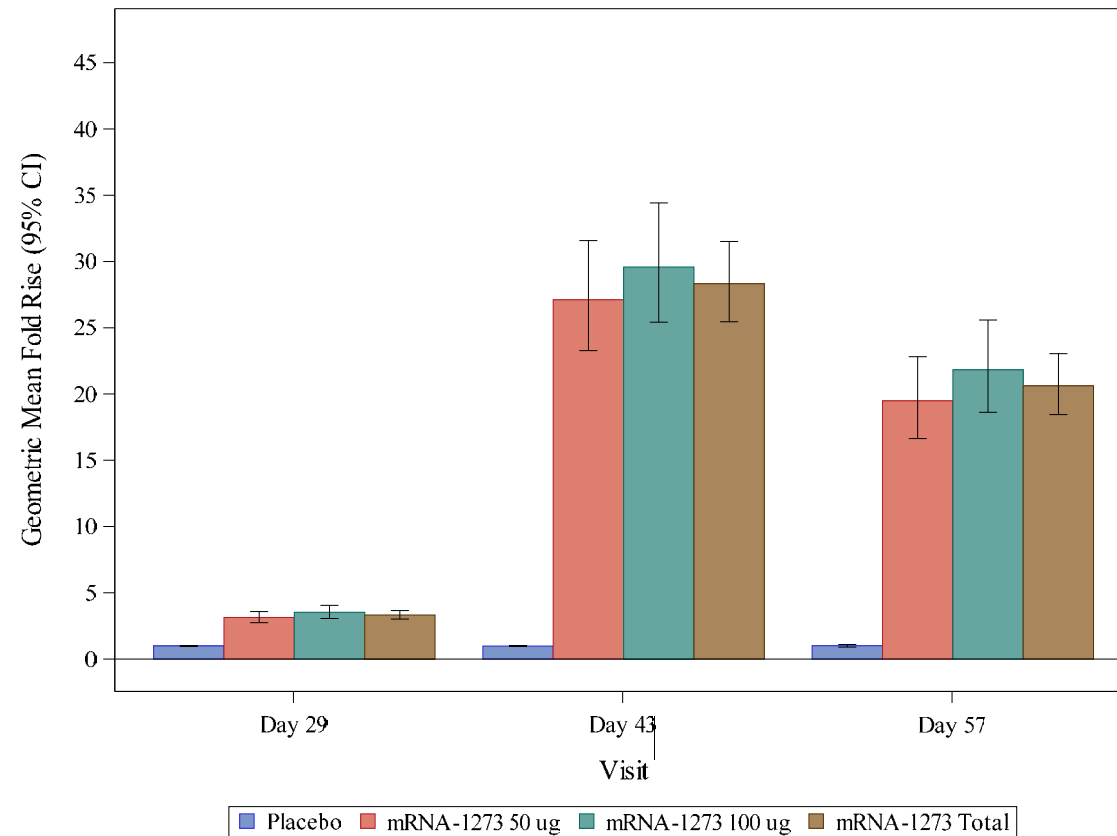
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.2.2
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)



Source table: T14.2.1.1.2

bAb = Binding antibody.

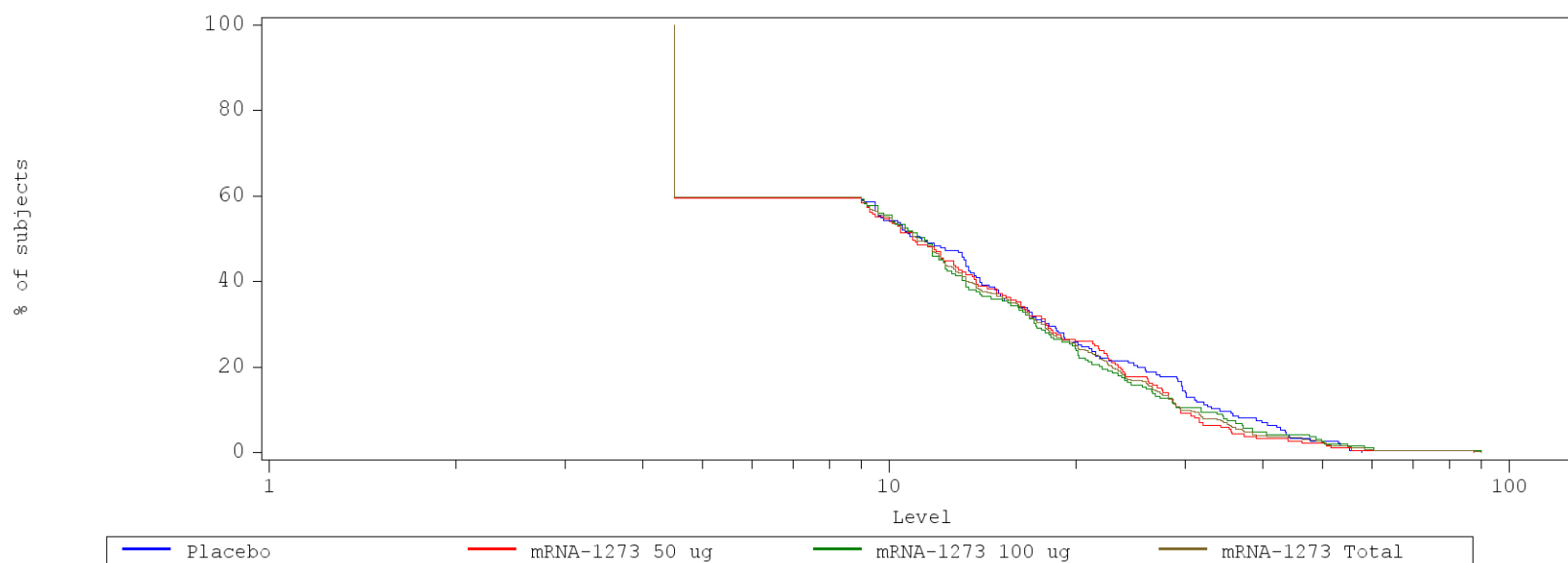
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020202.sas 19NOV2020 05:13 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

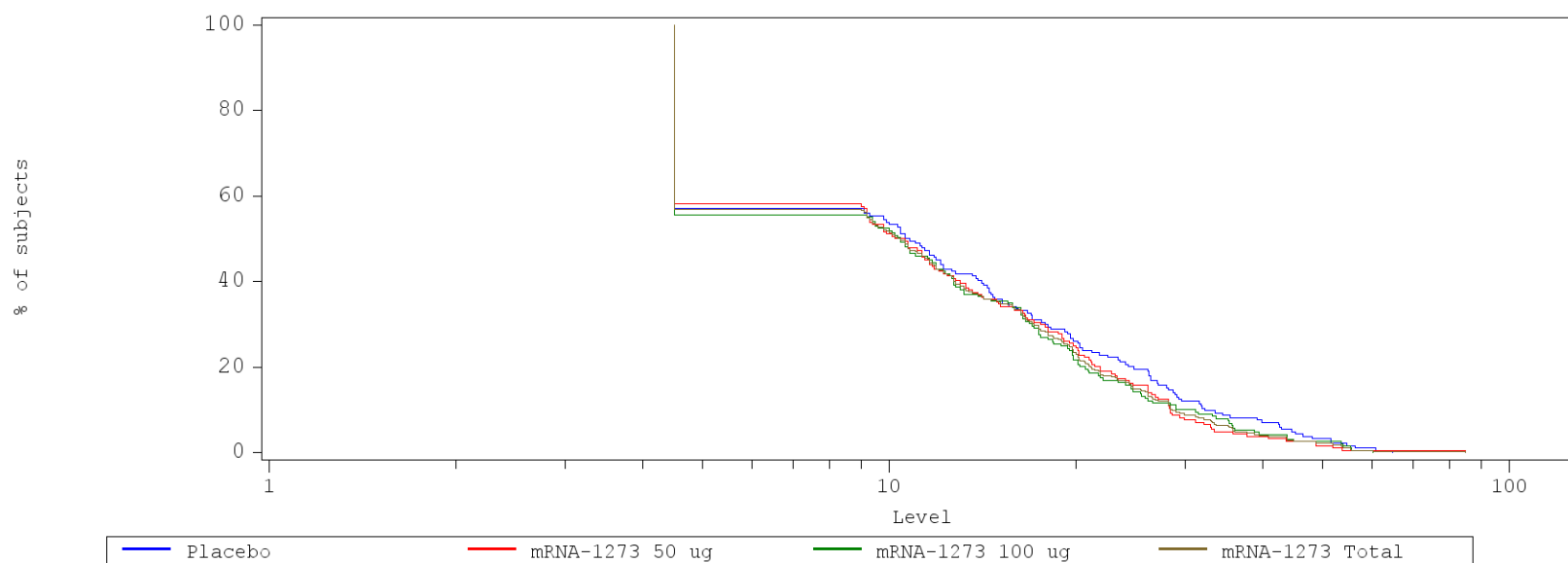
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

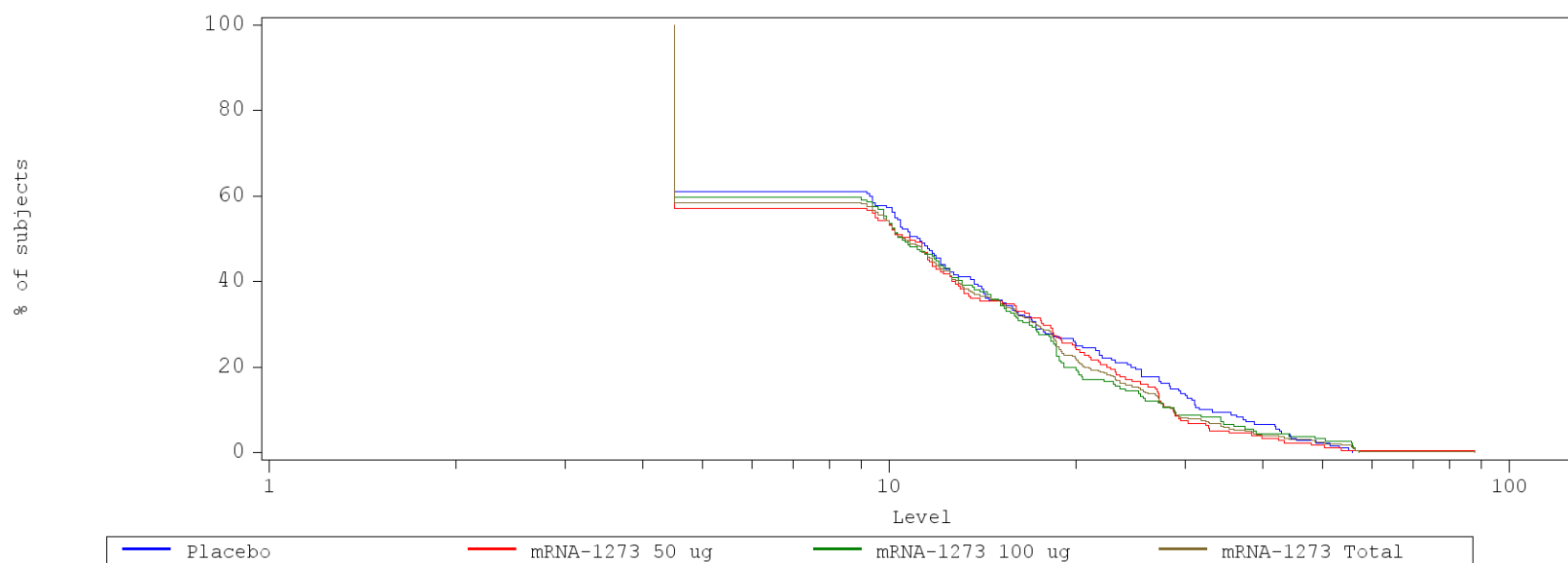
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

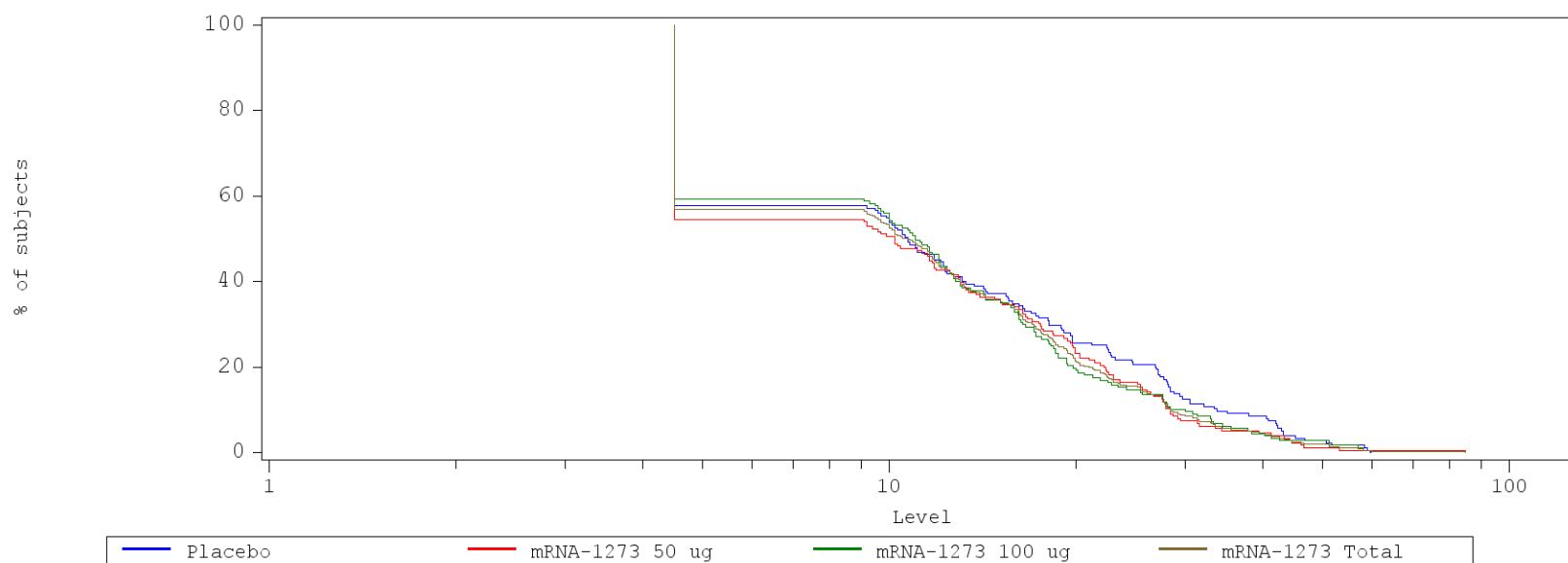
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

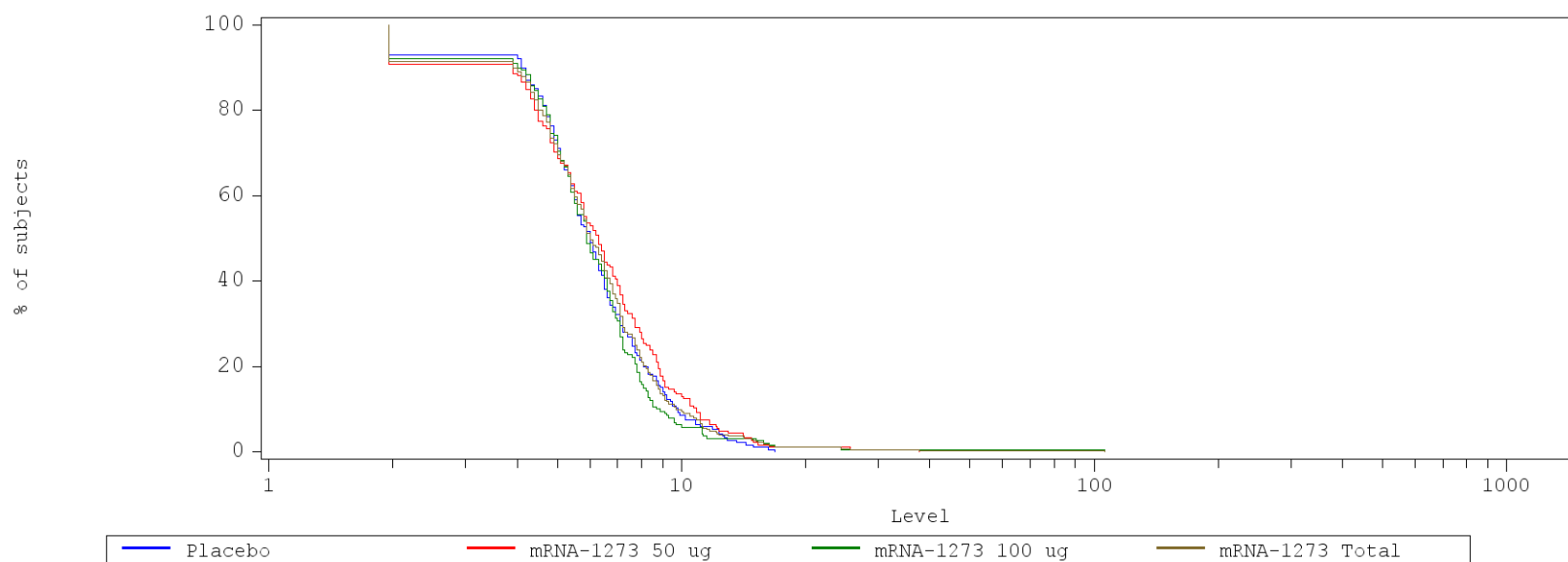
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

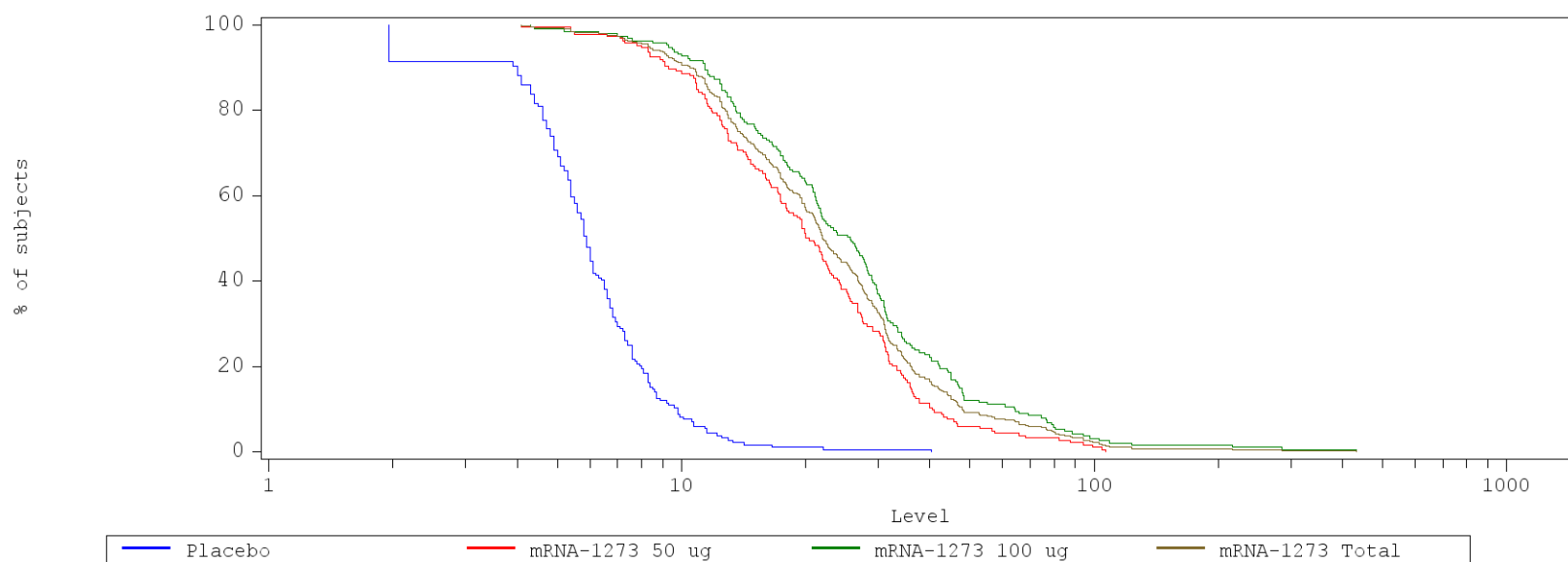
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

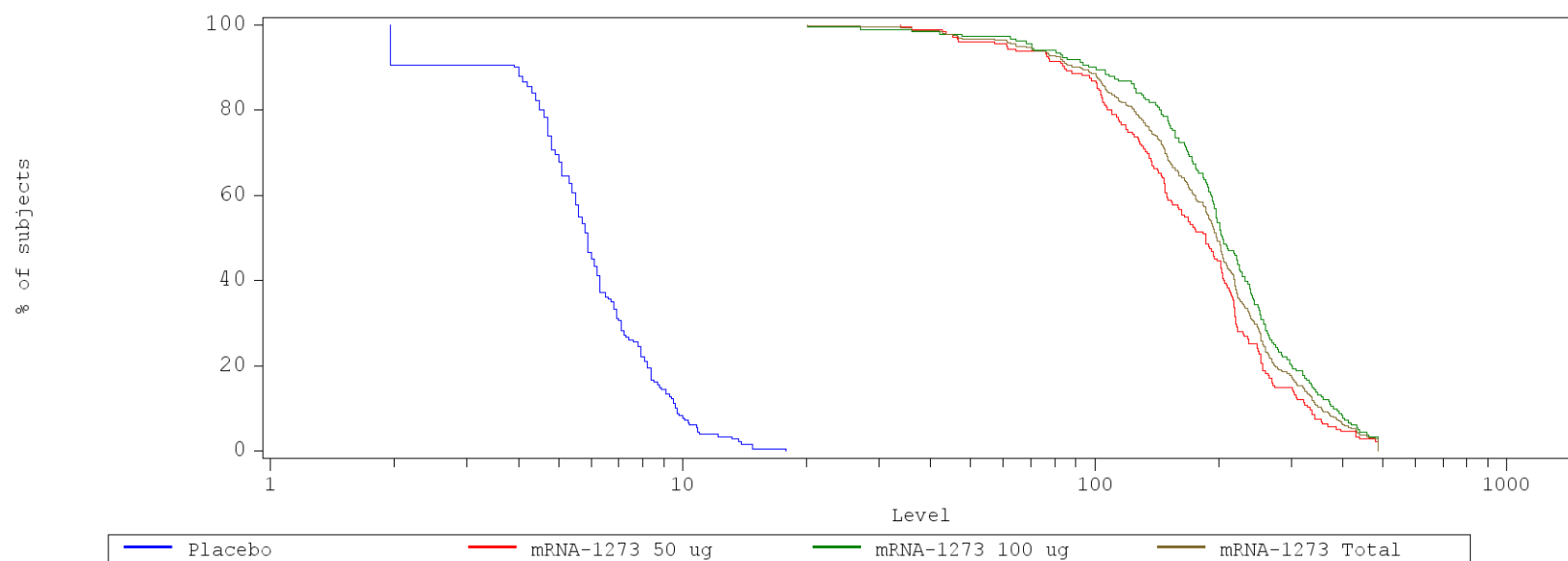
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

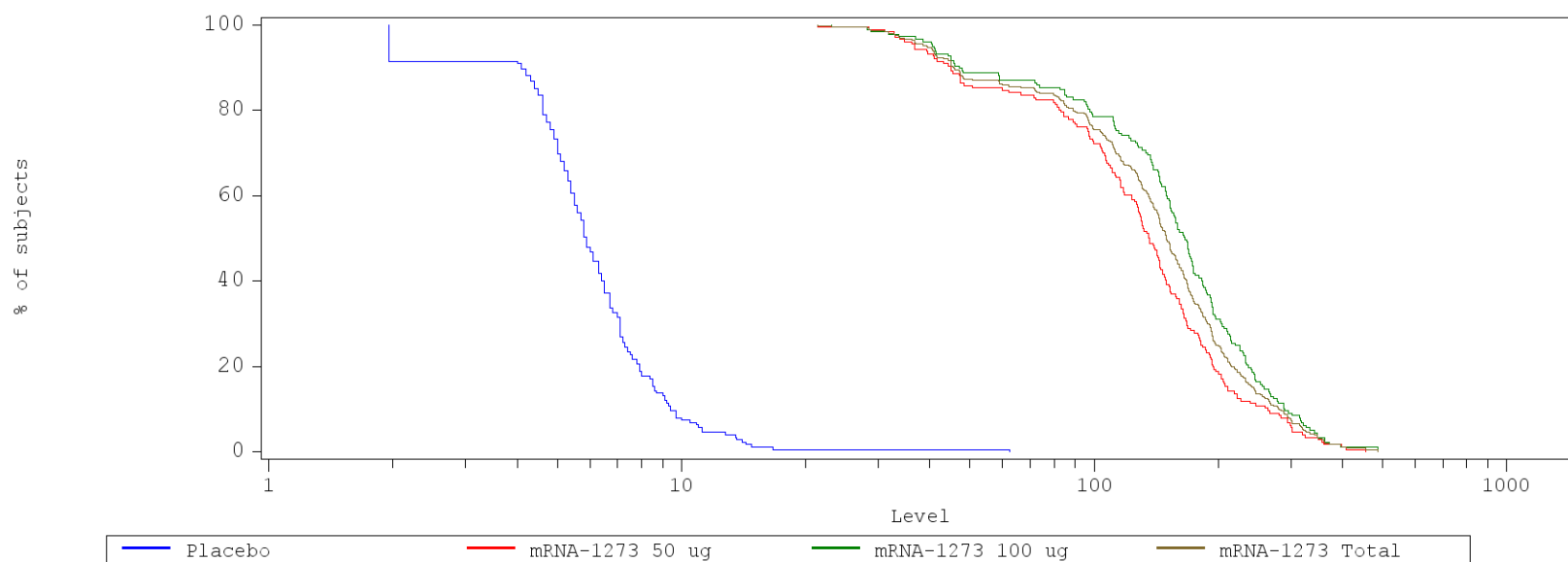
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

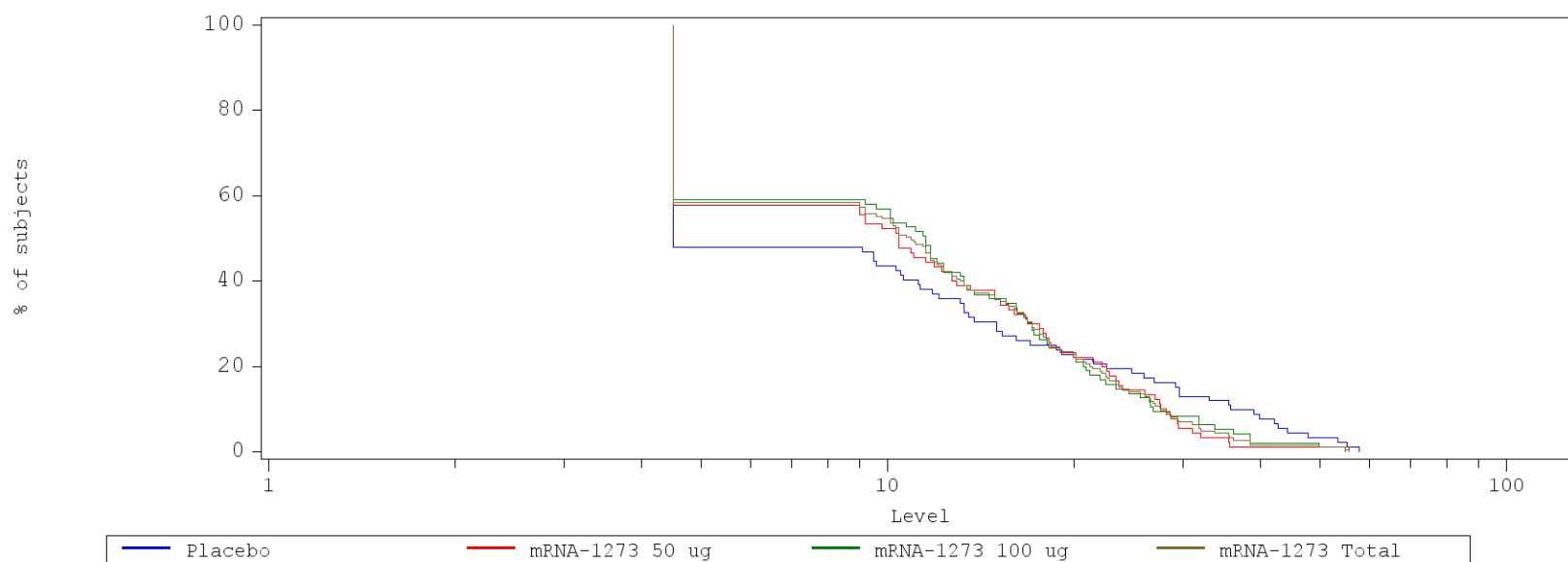
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

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Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

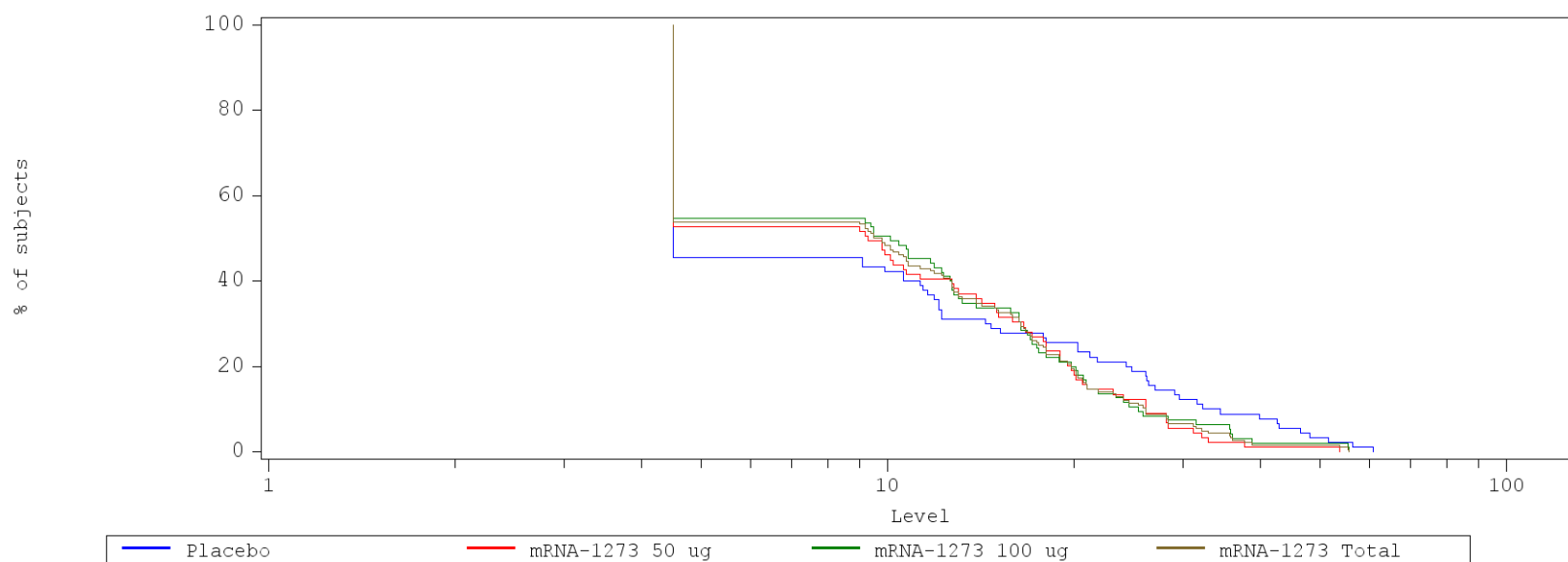
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

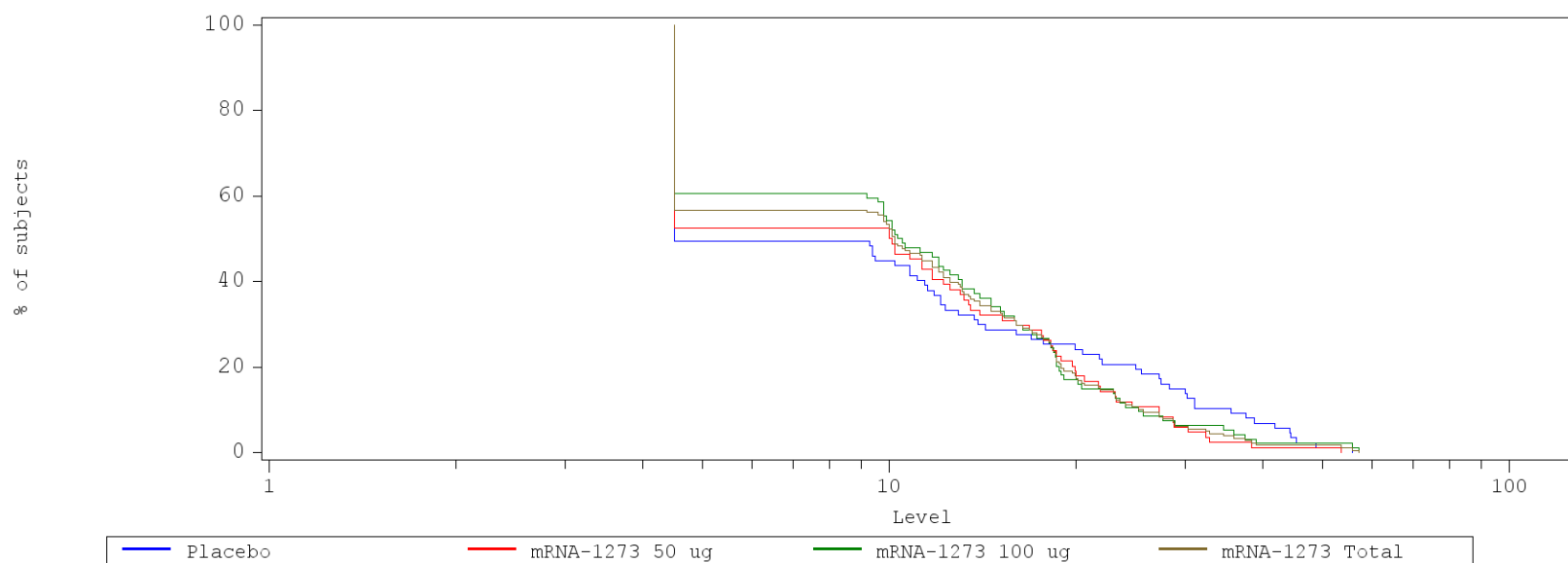
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

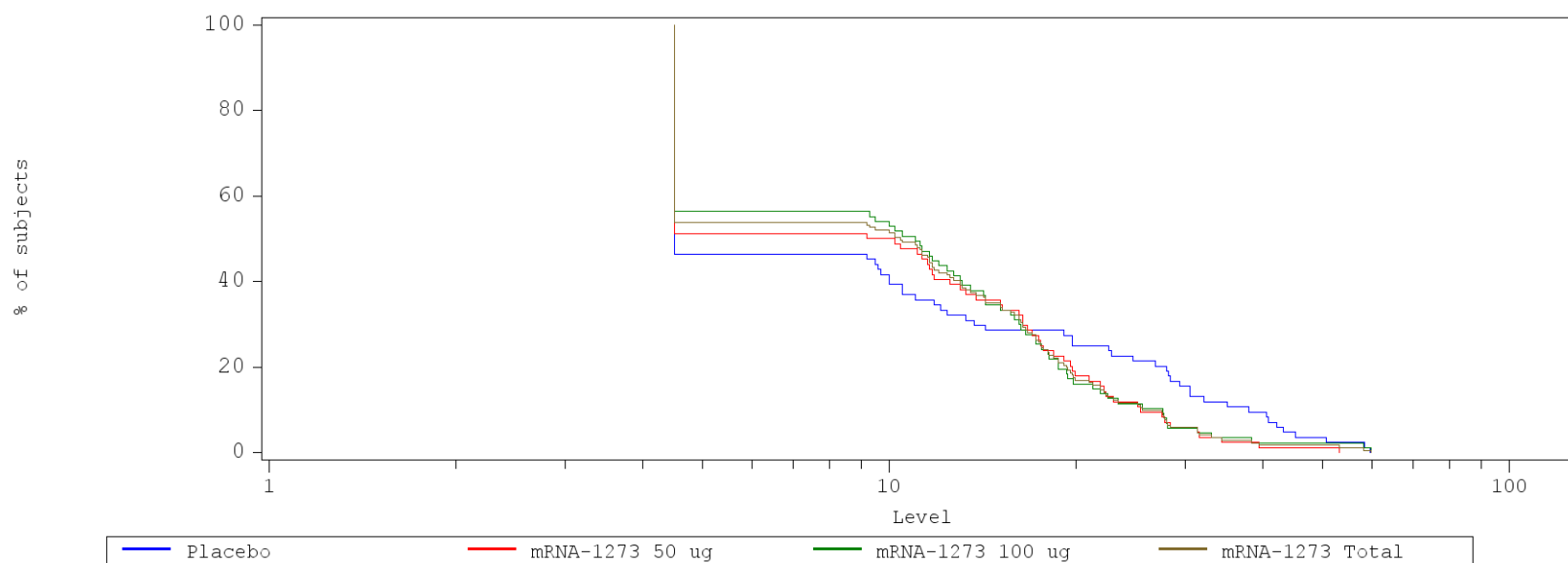
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

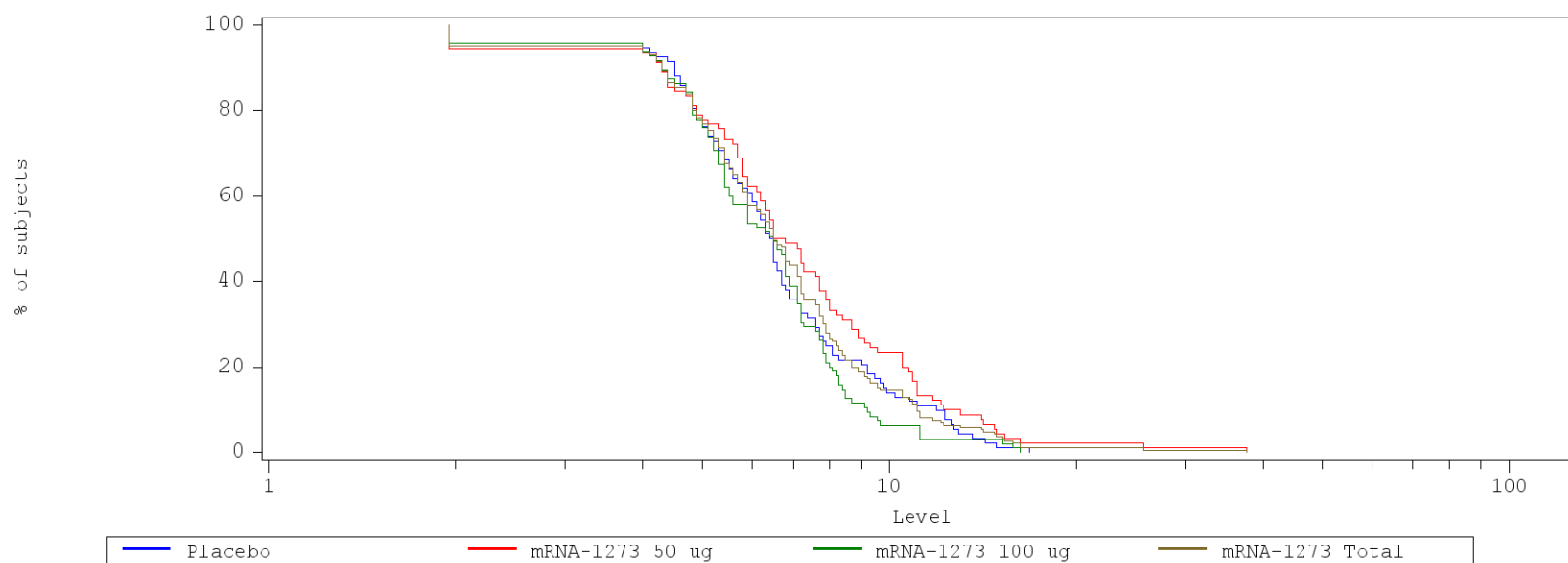
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

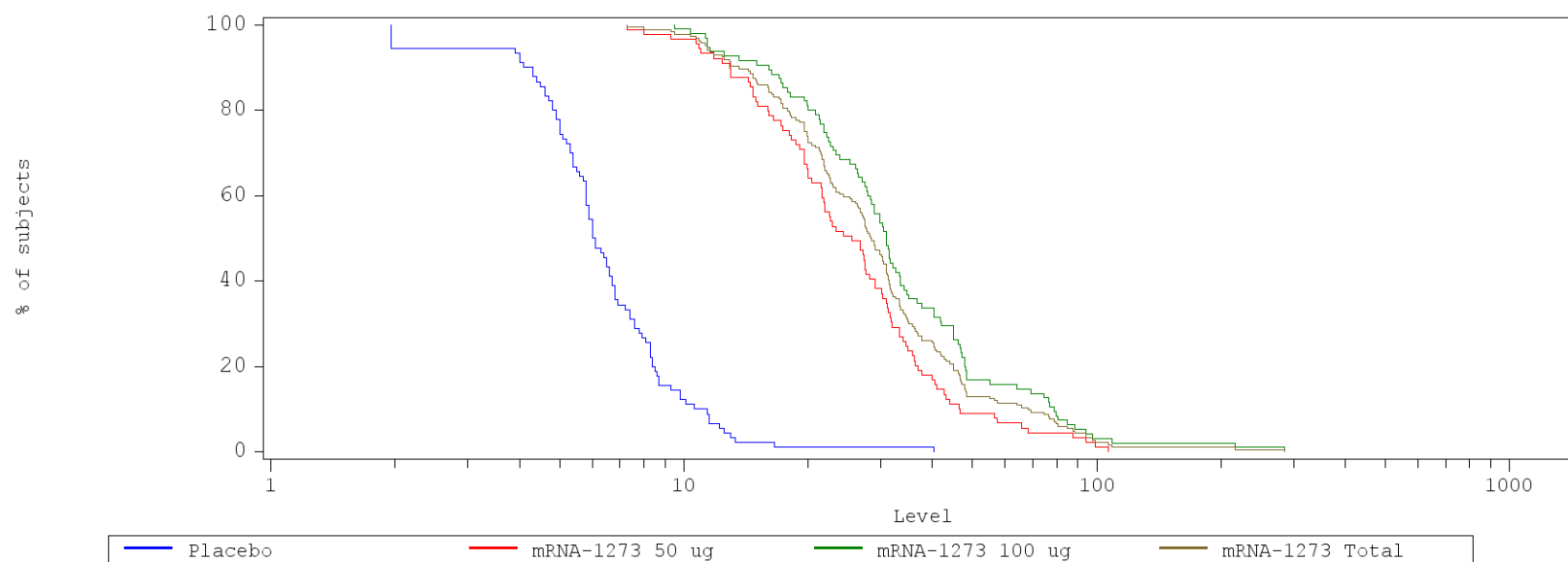
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

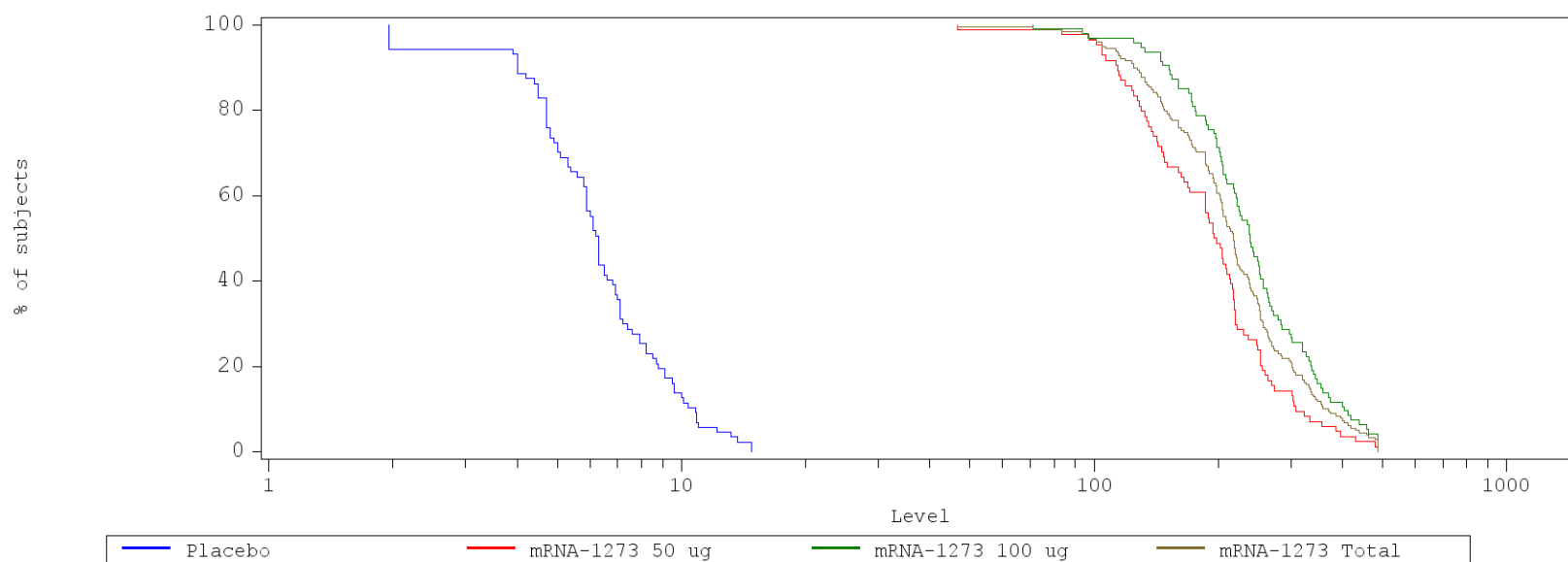
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

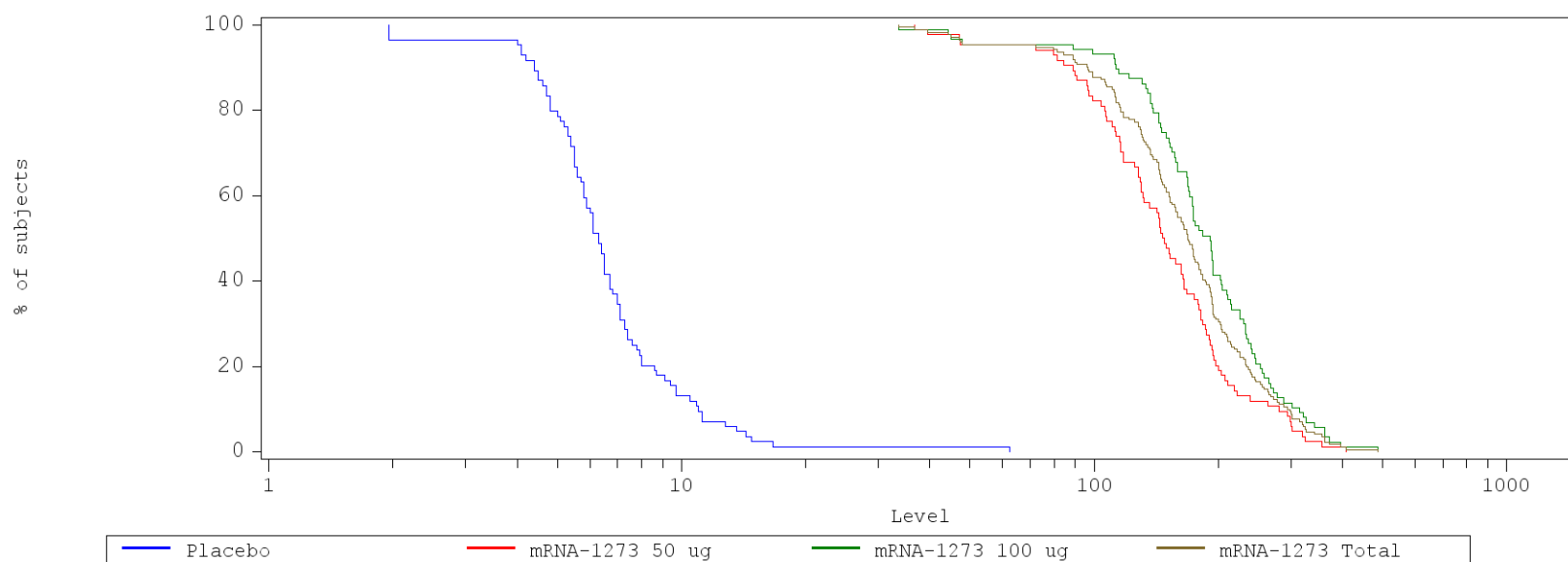
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

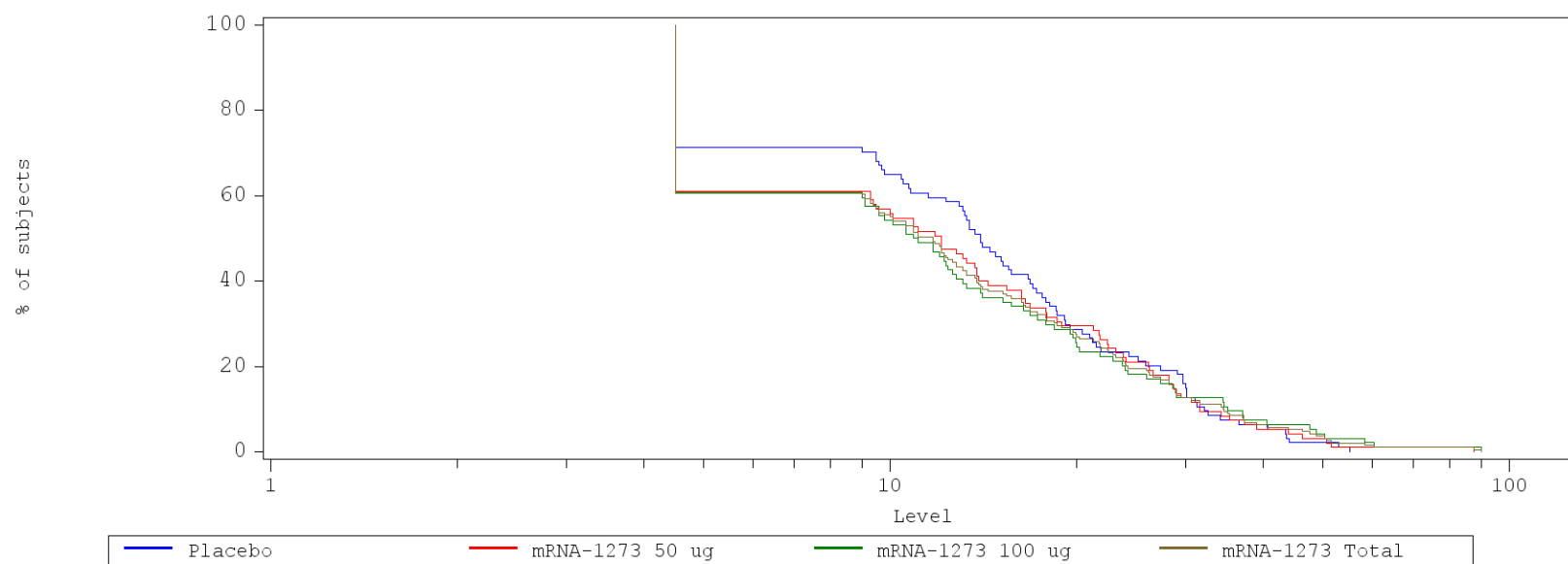
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

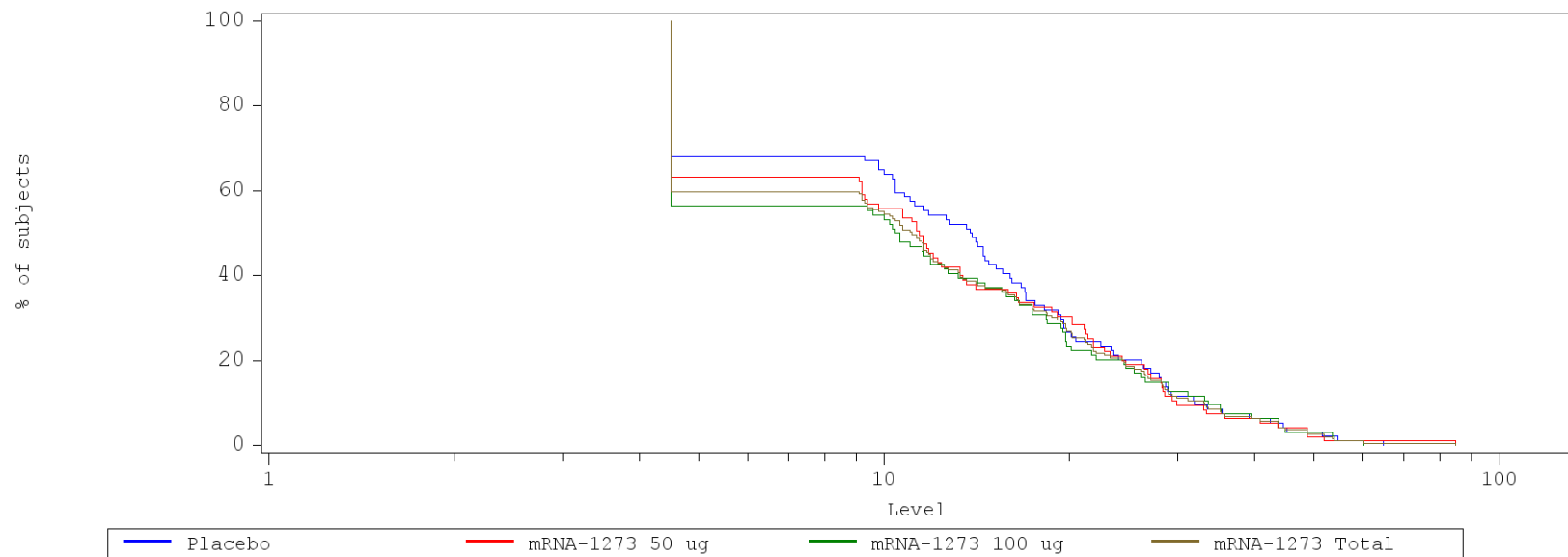
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

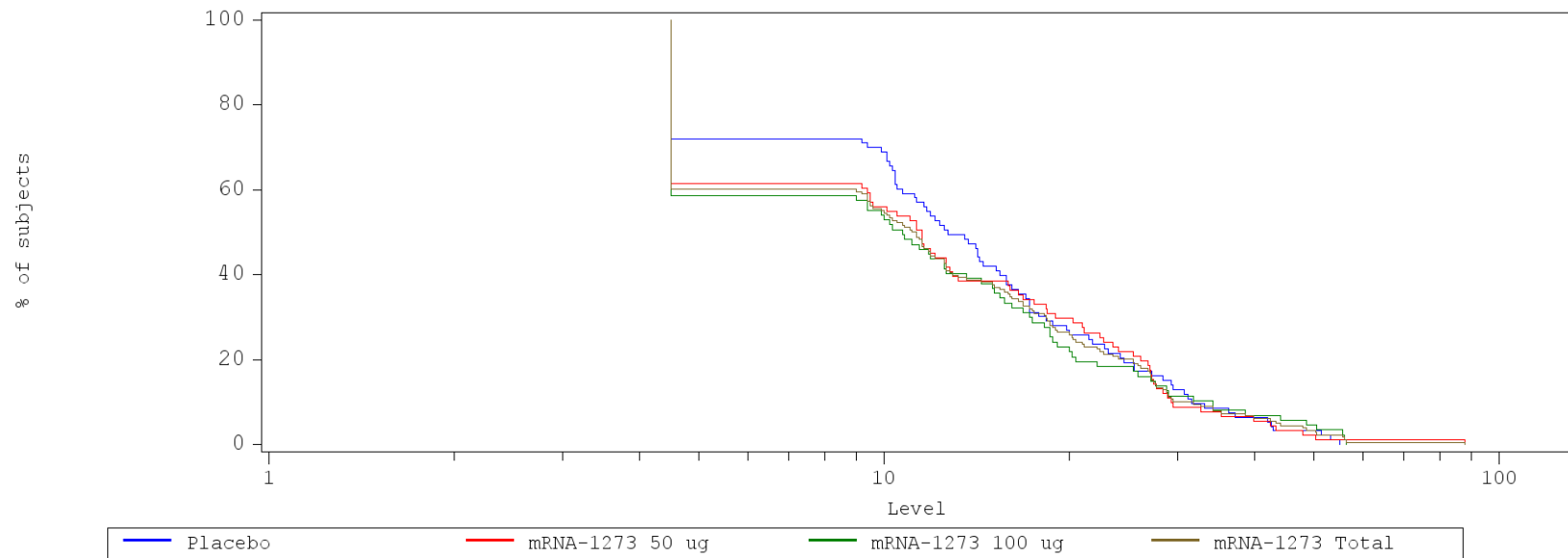
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\f14020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

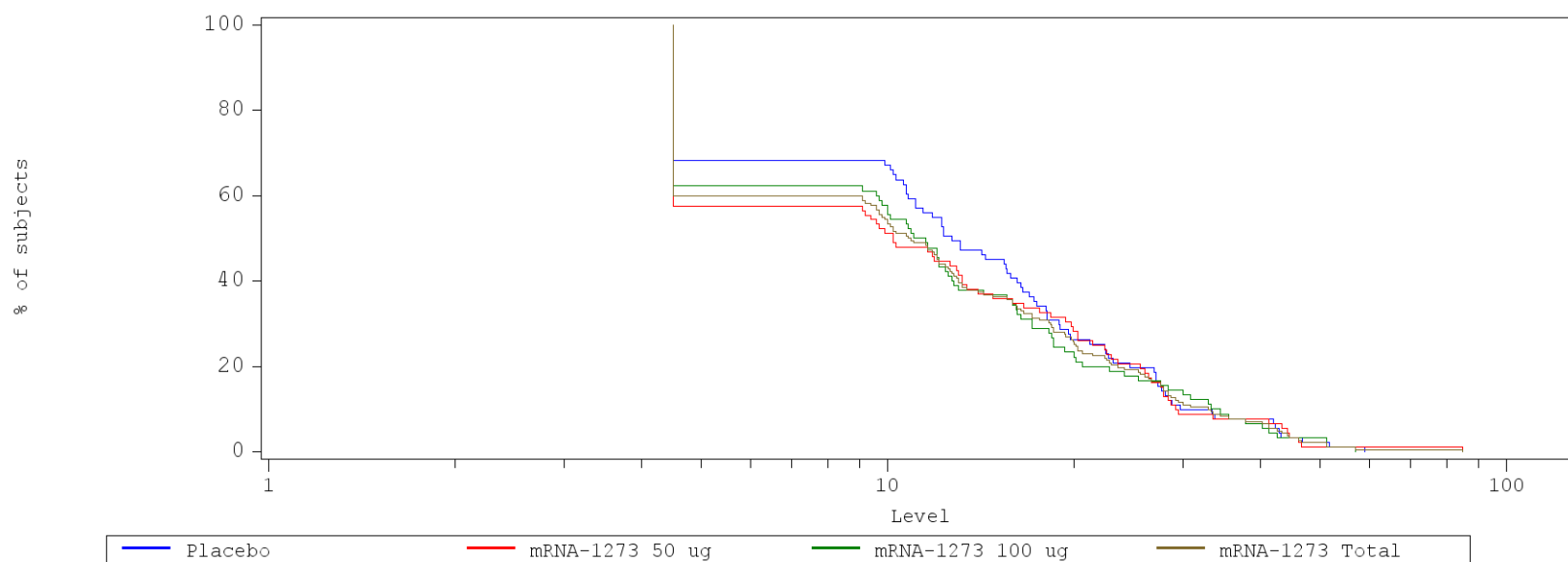
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\f14020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

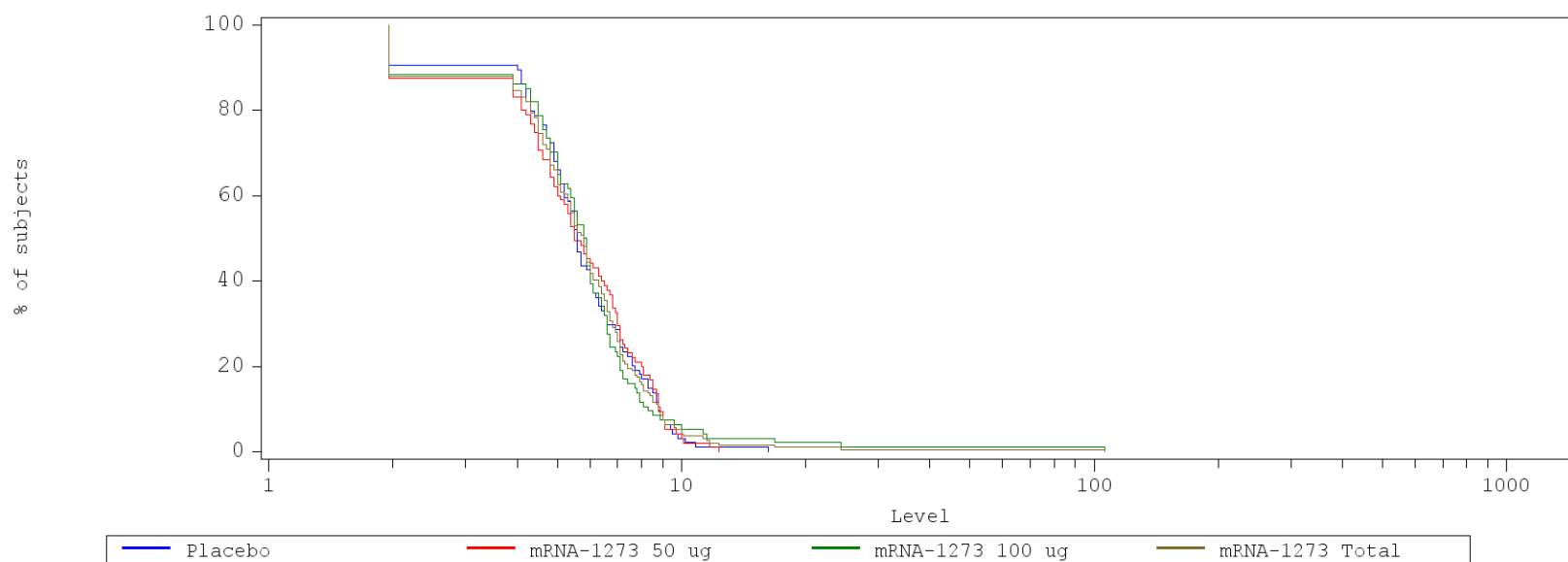
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

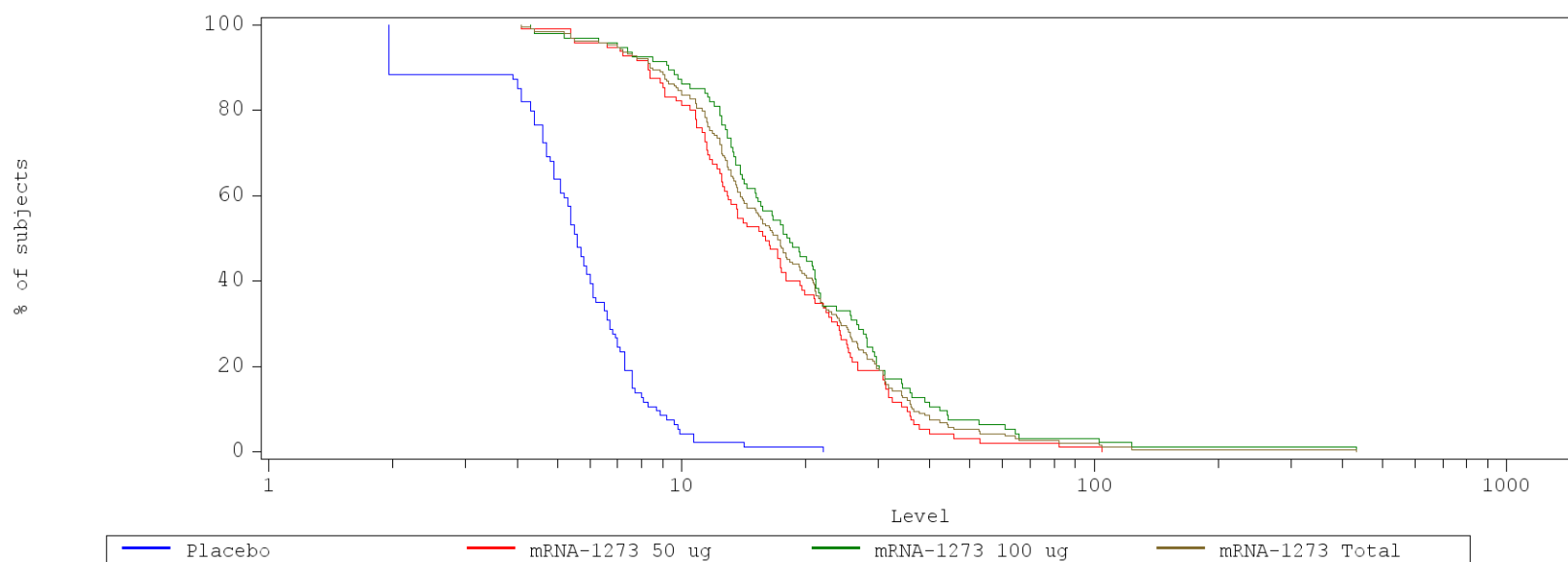
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

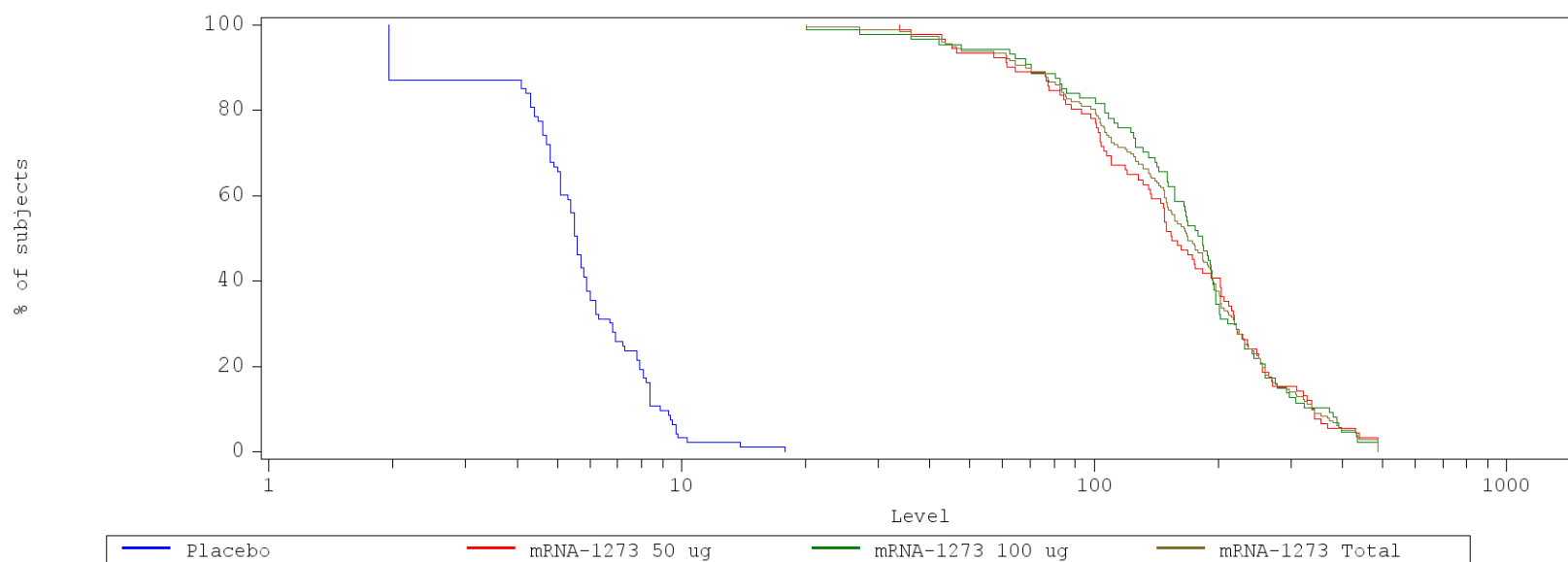
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

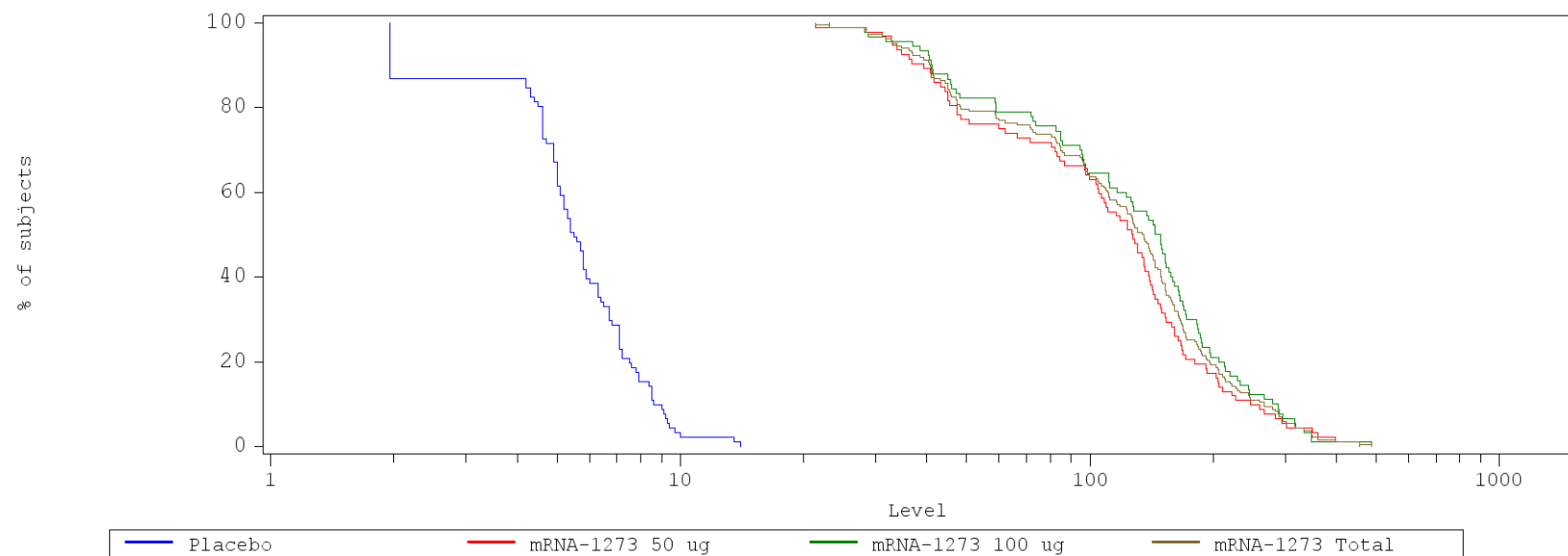
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

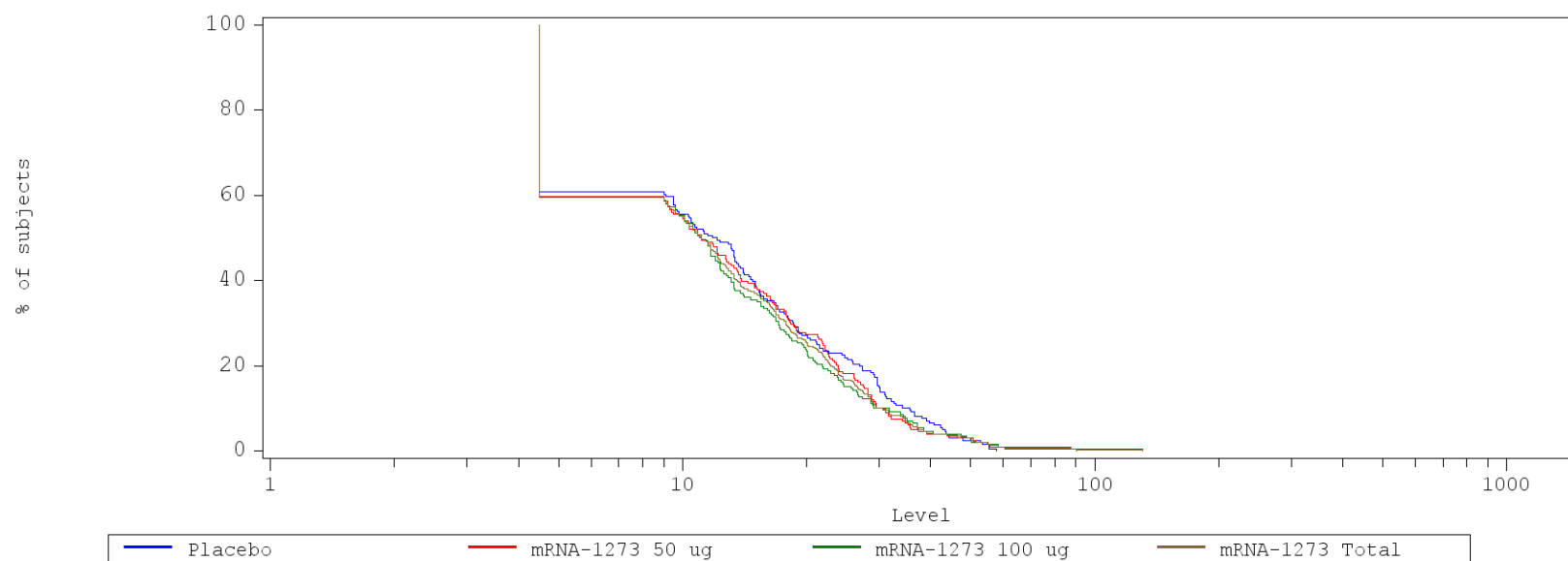
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020301.sas 19NOV2020 00:07 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

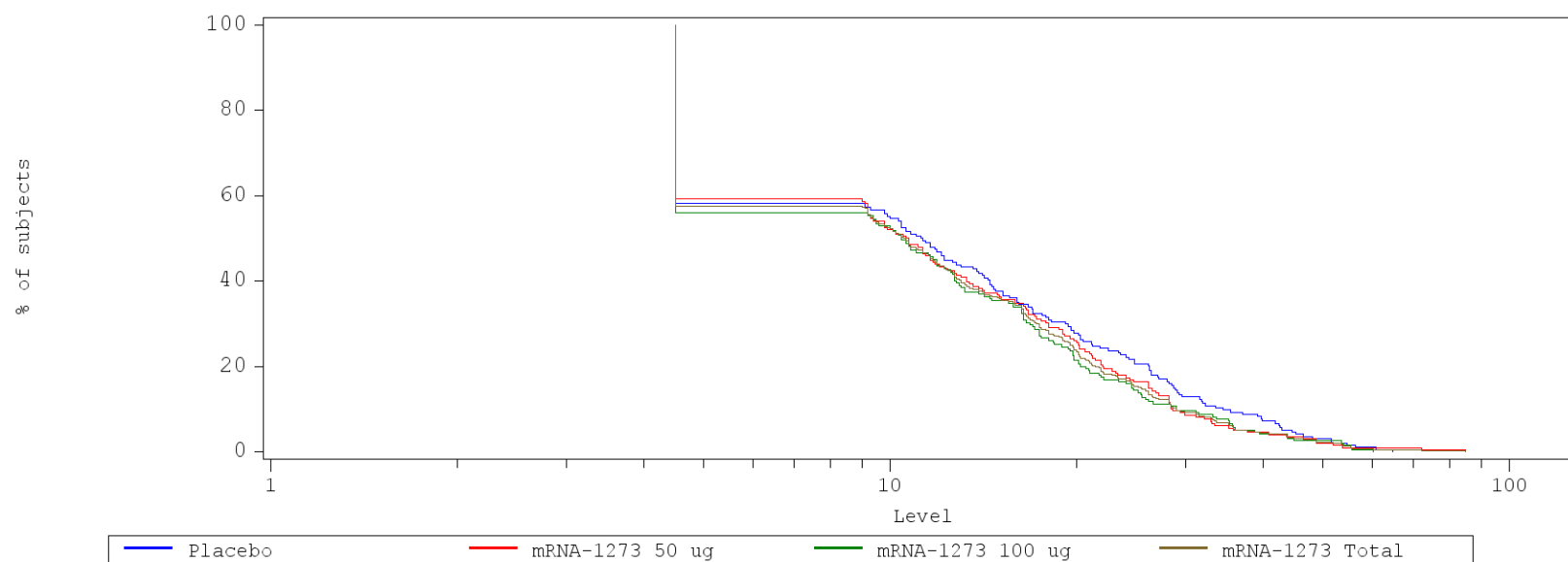
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

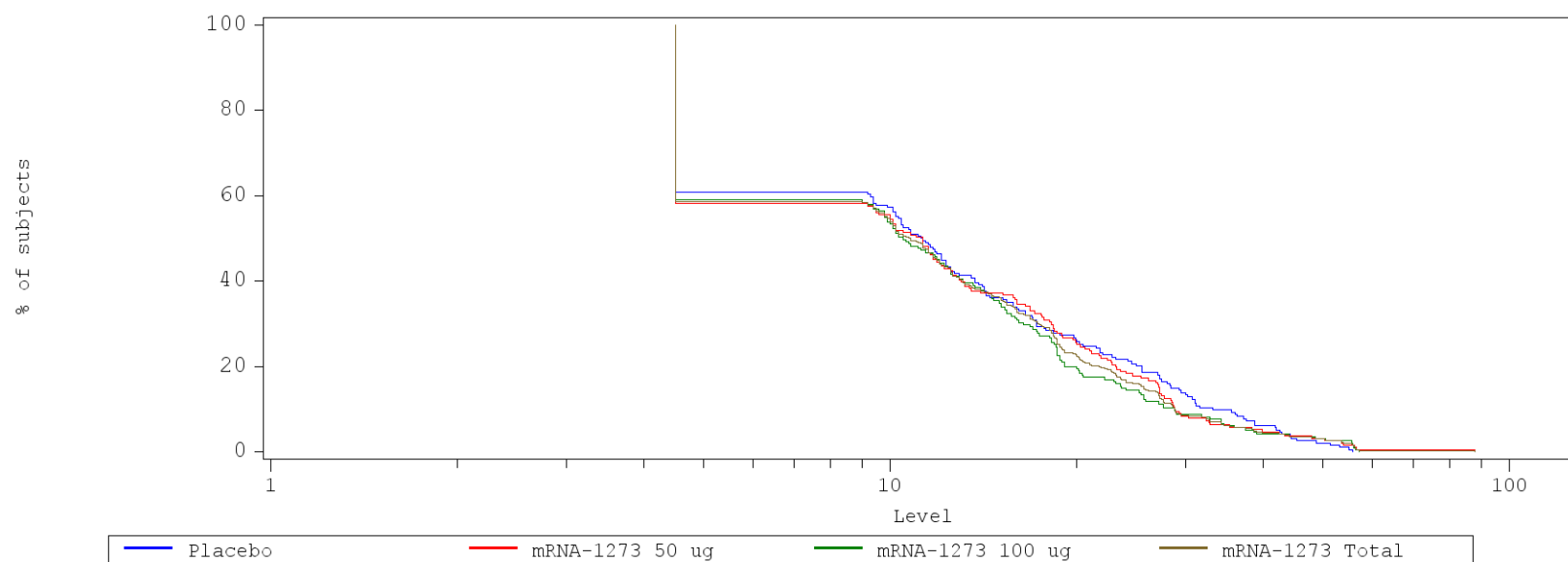
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

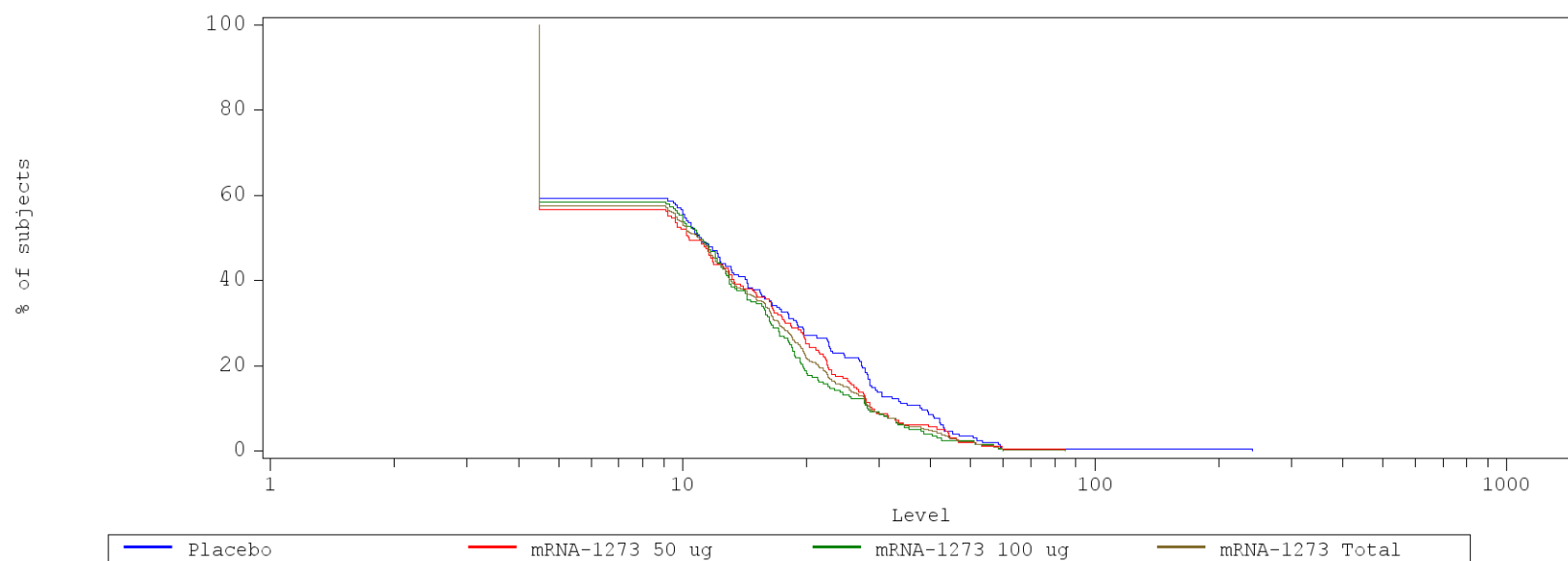
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

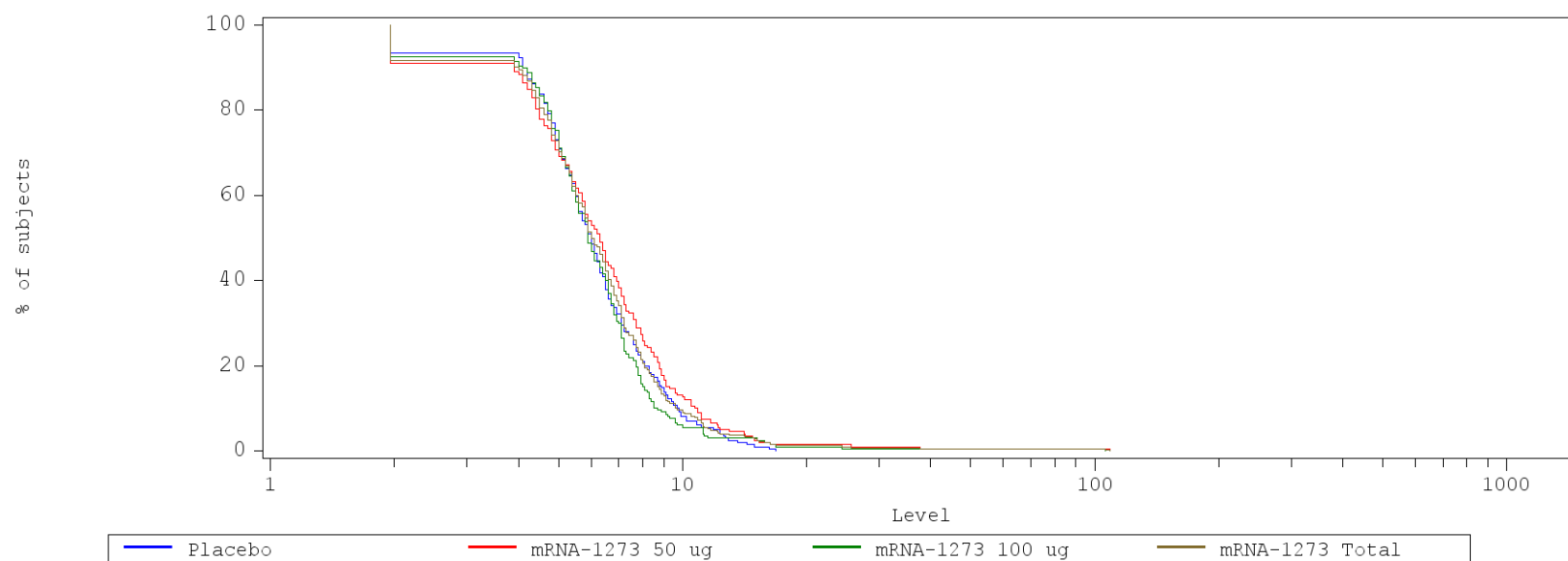
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

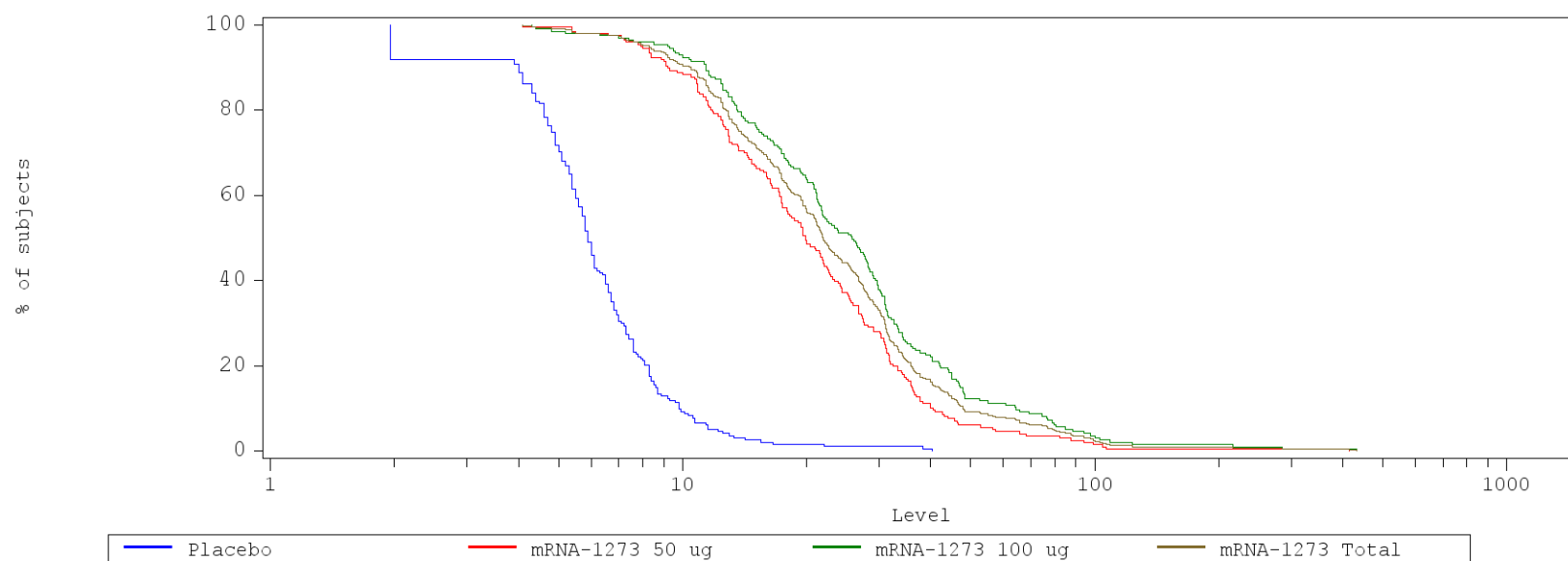
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

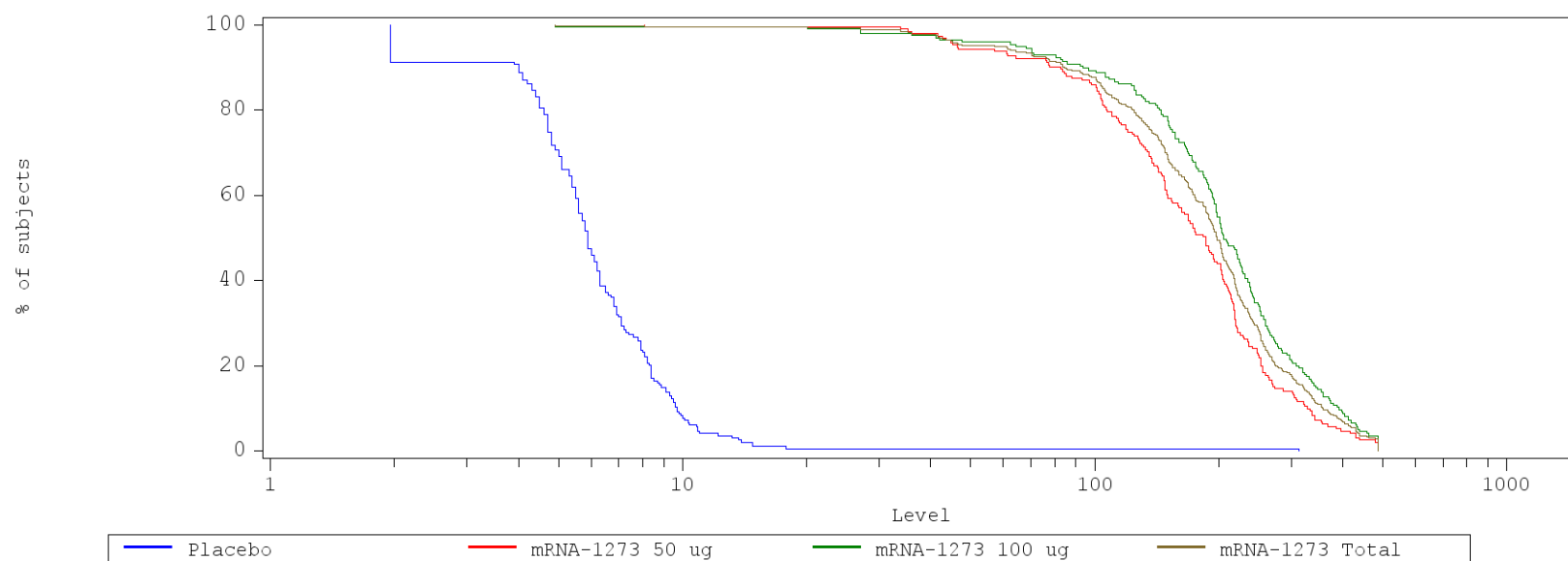
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

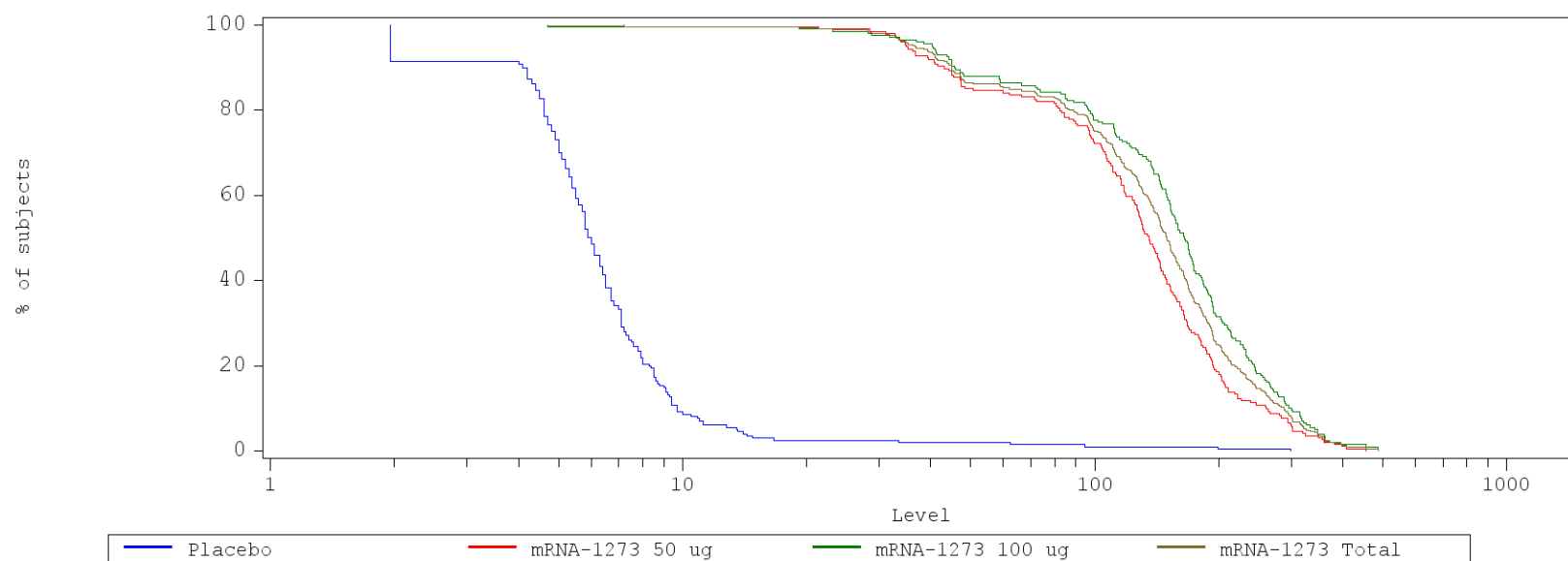
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

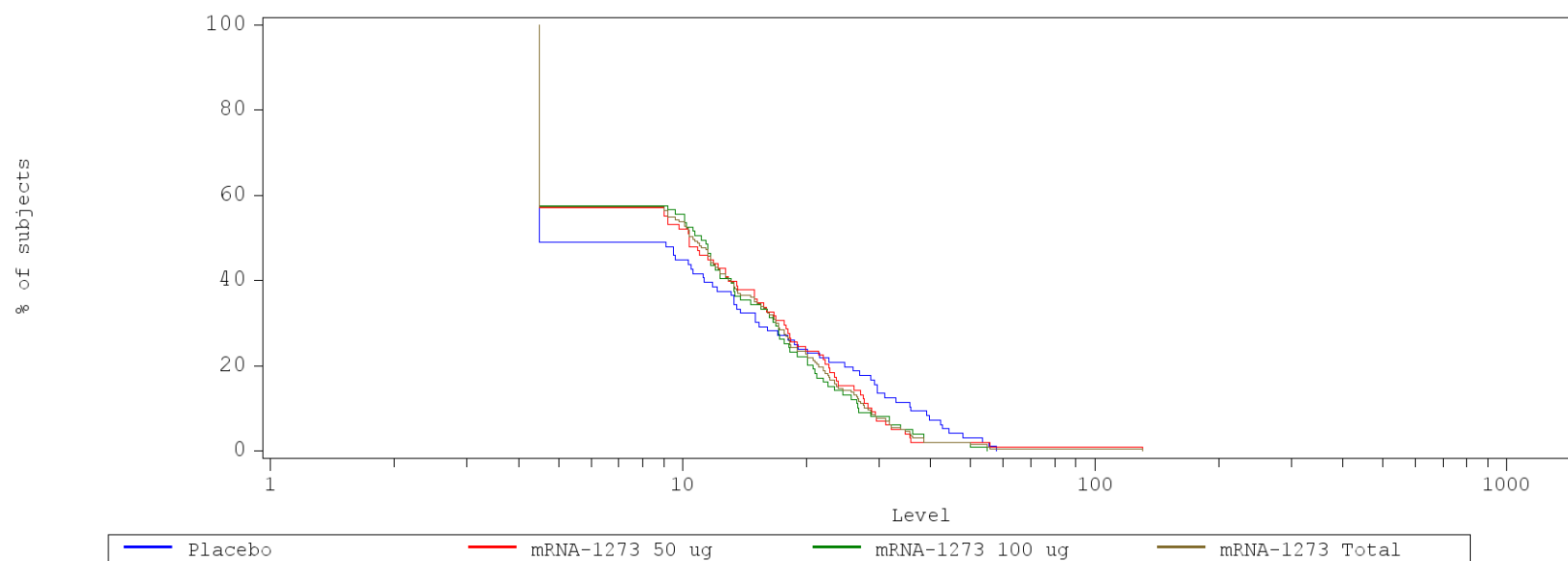
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

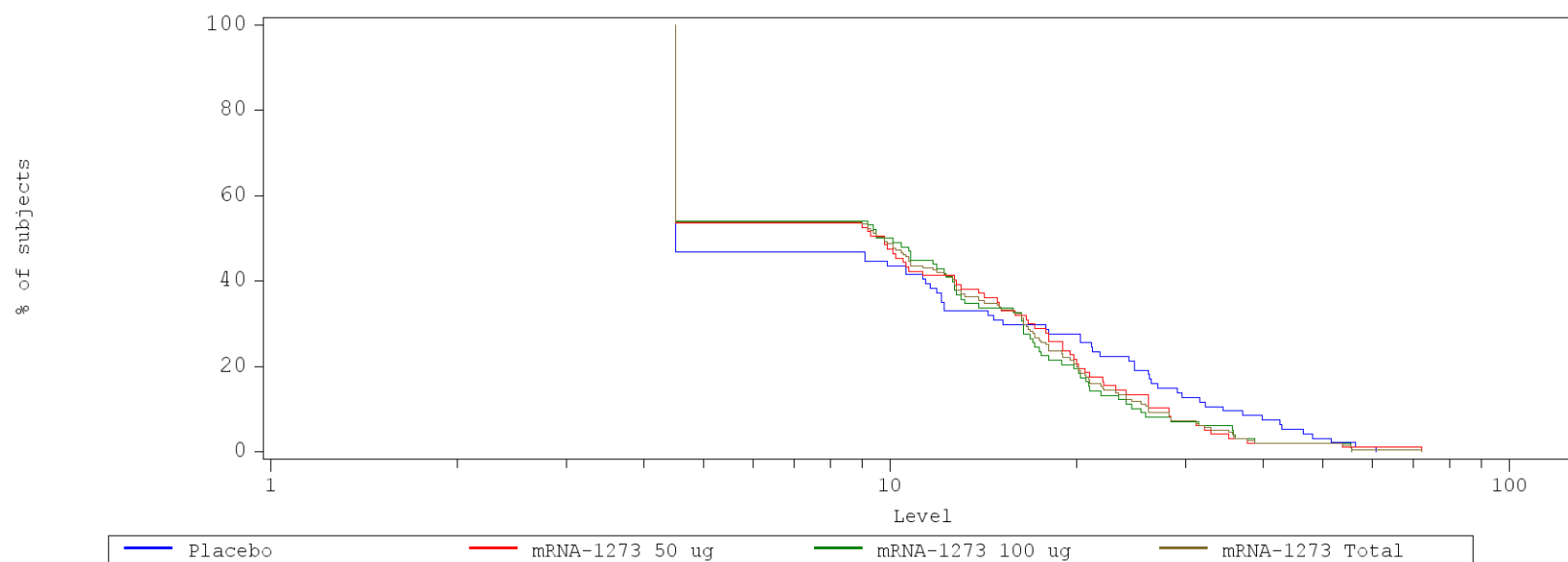
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

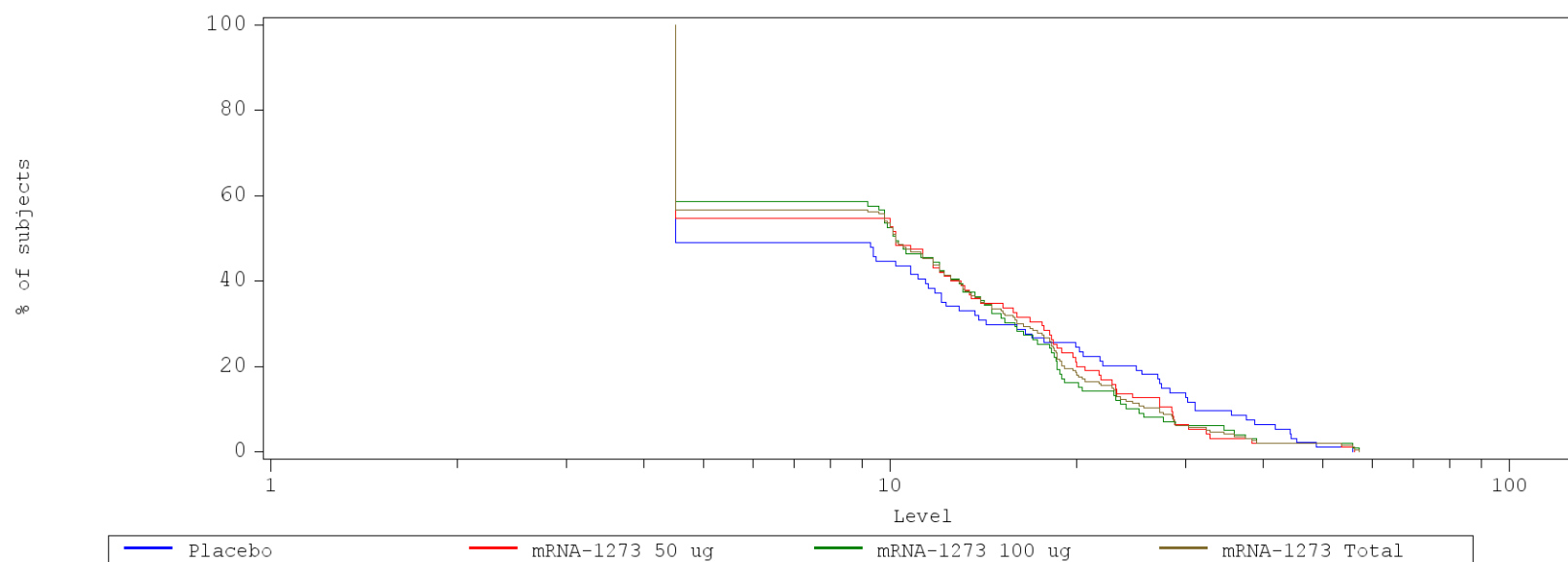
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

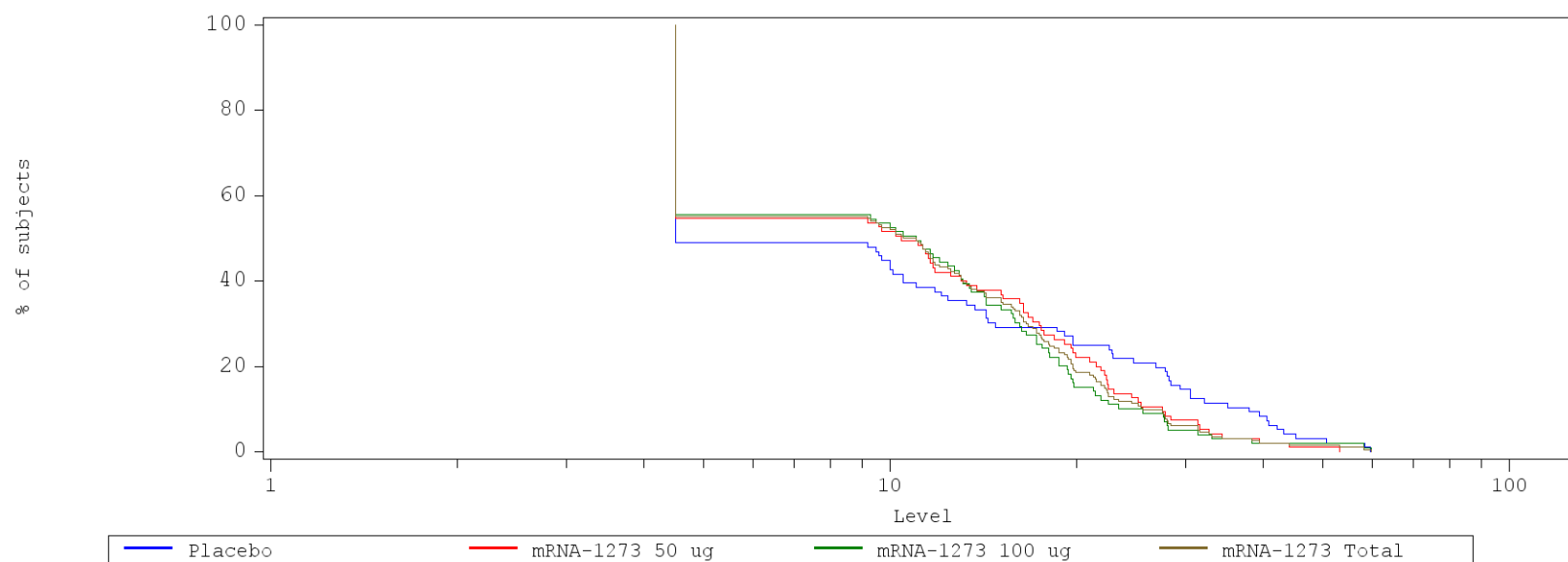
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

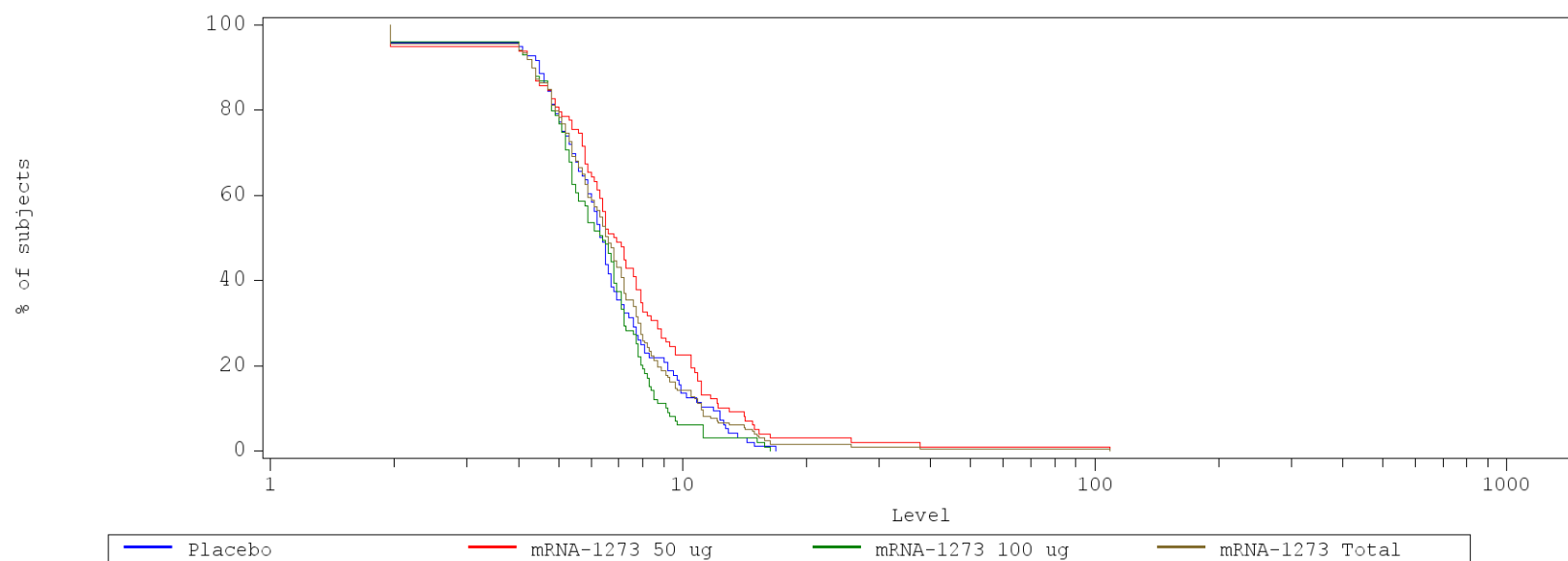
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

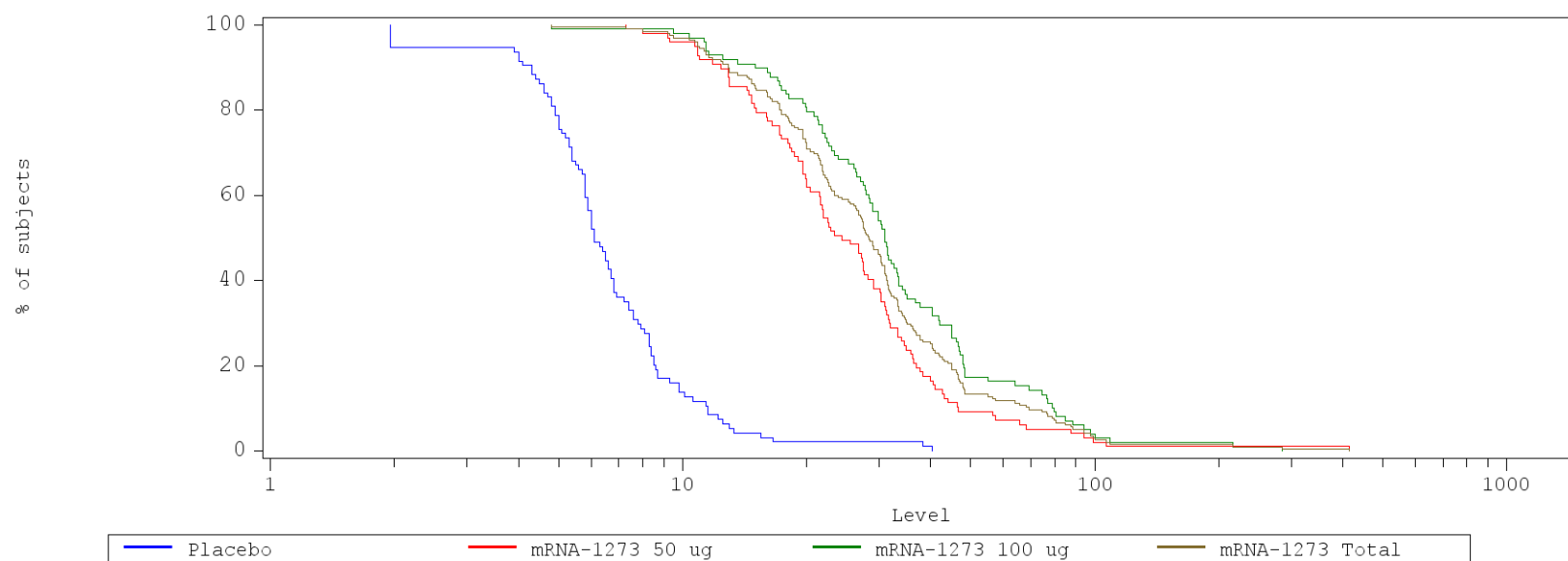
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

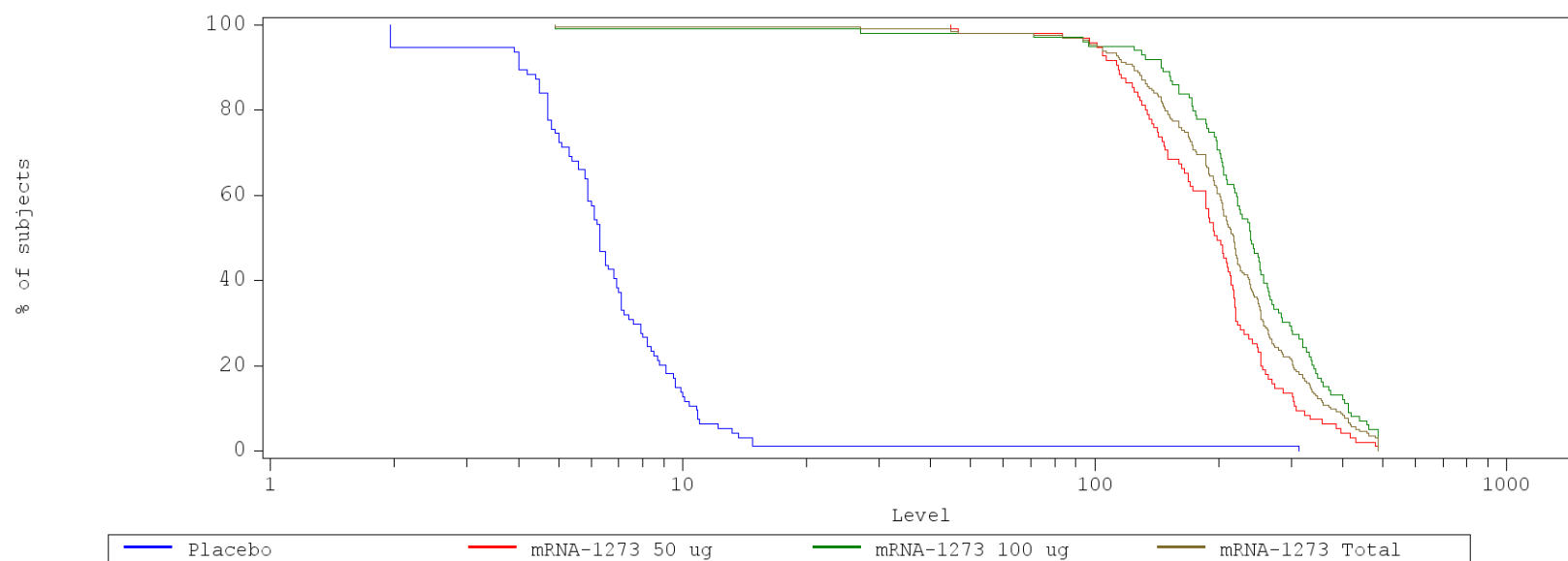
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

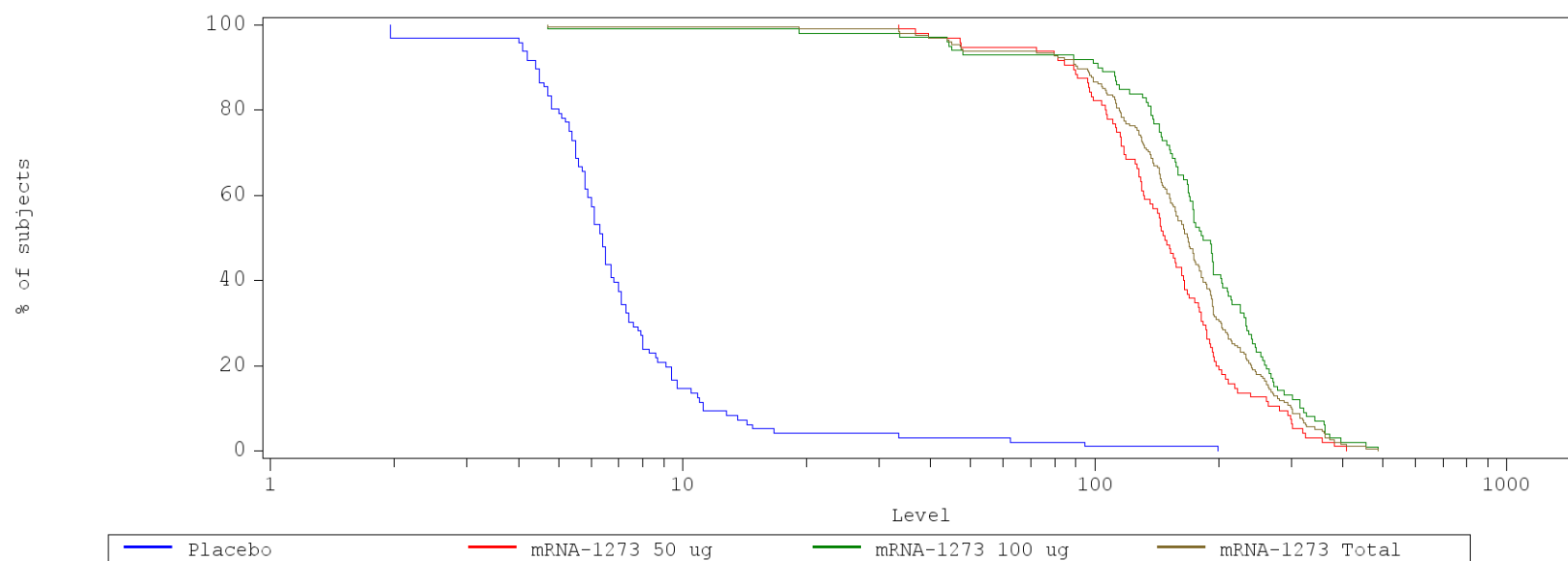
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (≥ 18 and < 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

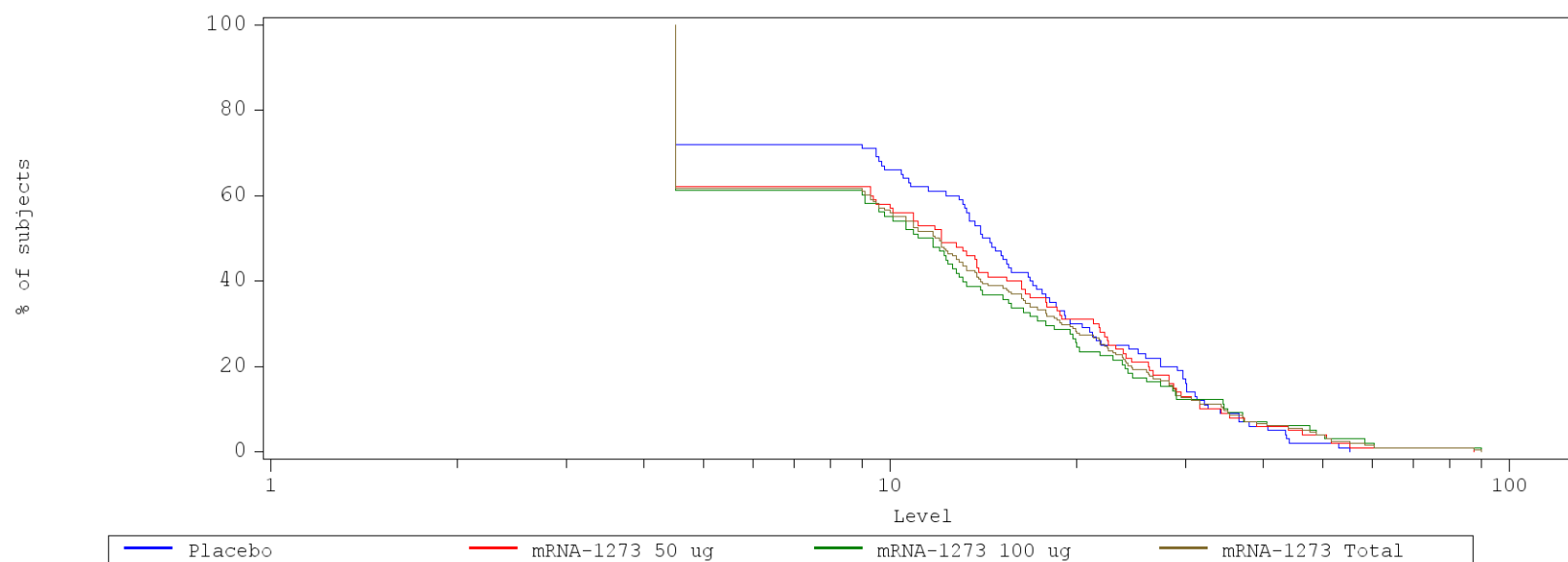
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Baseline



bAb = Binding antibody.

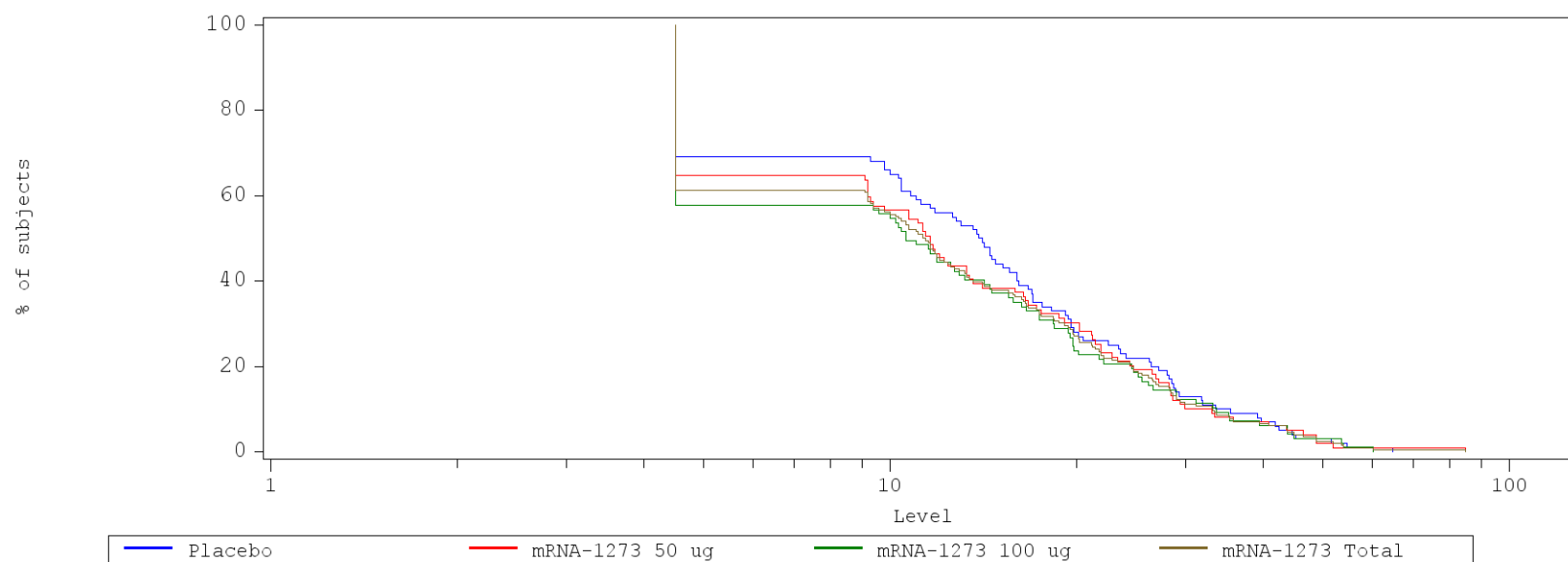
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 29



bAb = Binding antibody.

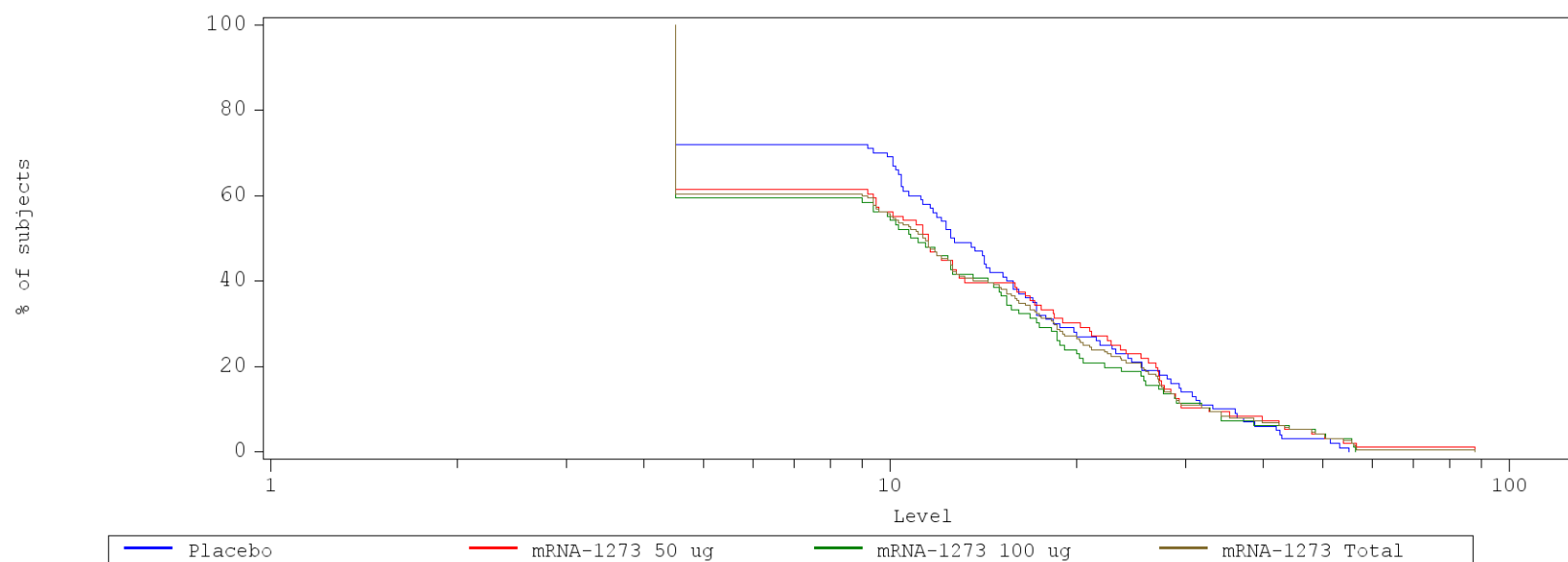
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\f14020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 43



bAb = Binding antibody.

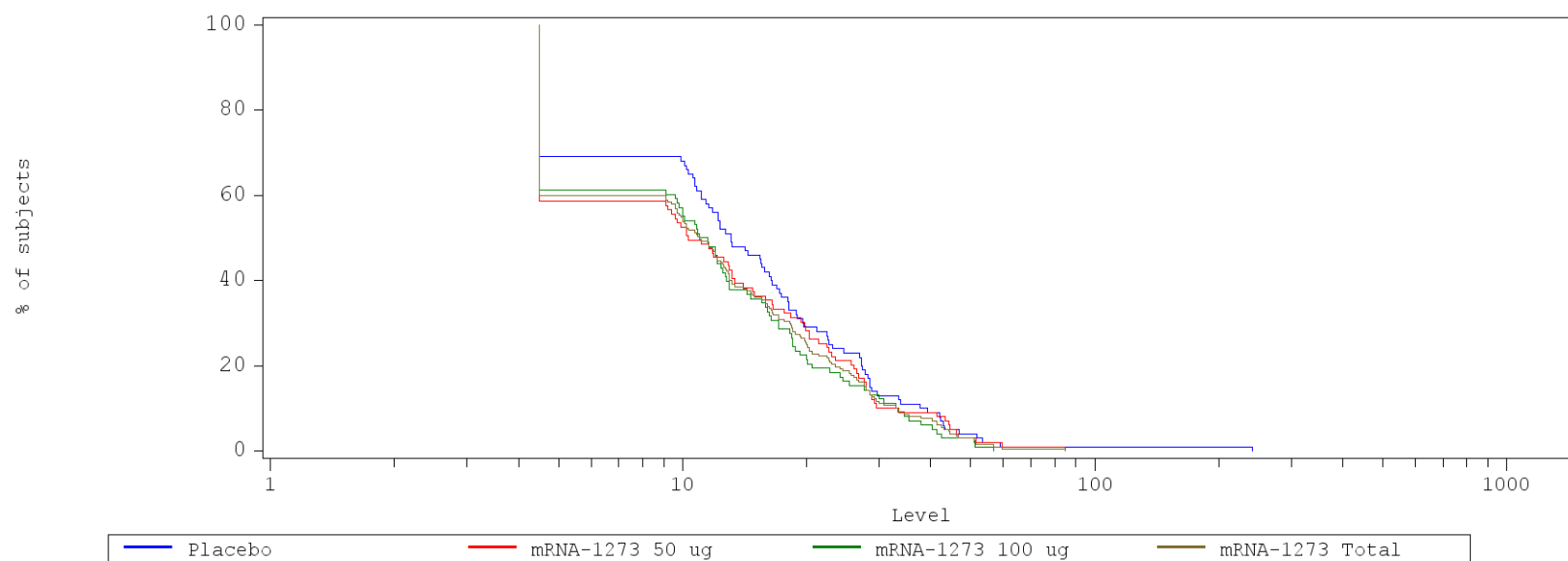
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/ml) (LLOQ: 9, ULOQ: 33000)
Day 57



bAb = Binding antibody.

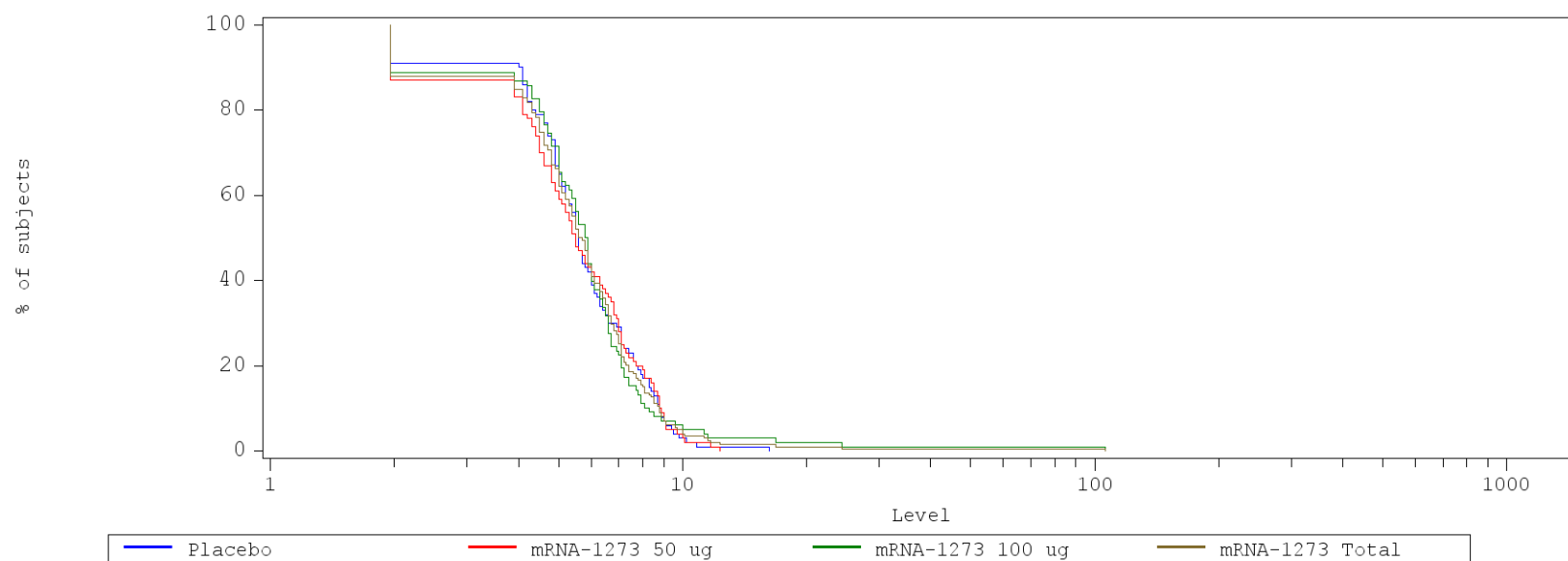
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Baseline



bAb = Binding antibody.

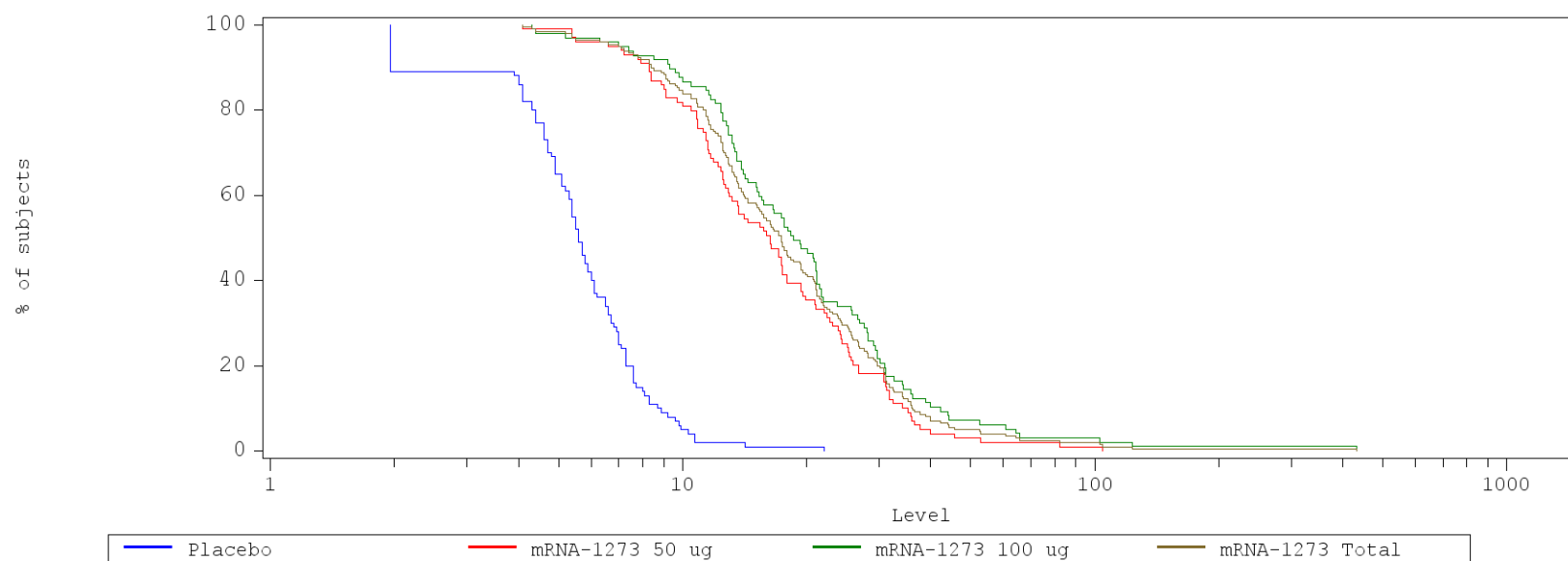
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 29



bAb = Binding antibody.

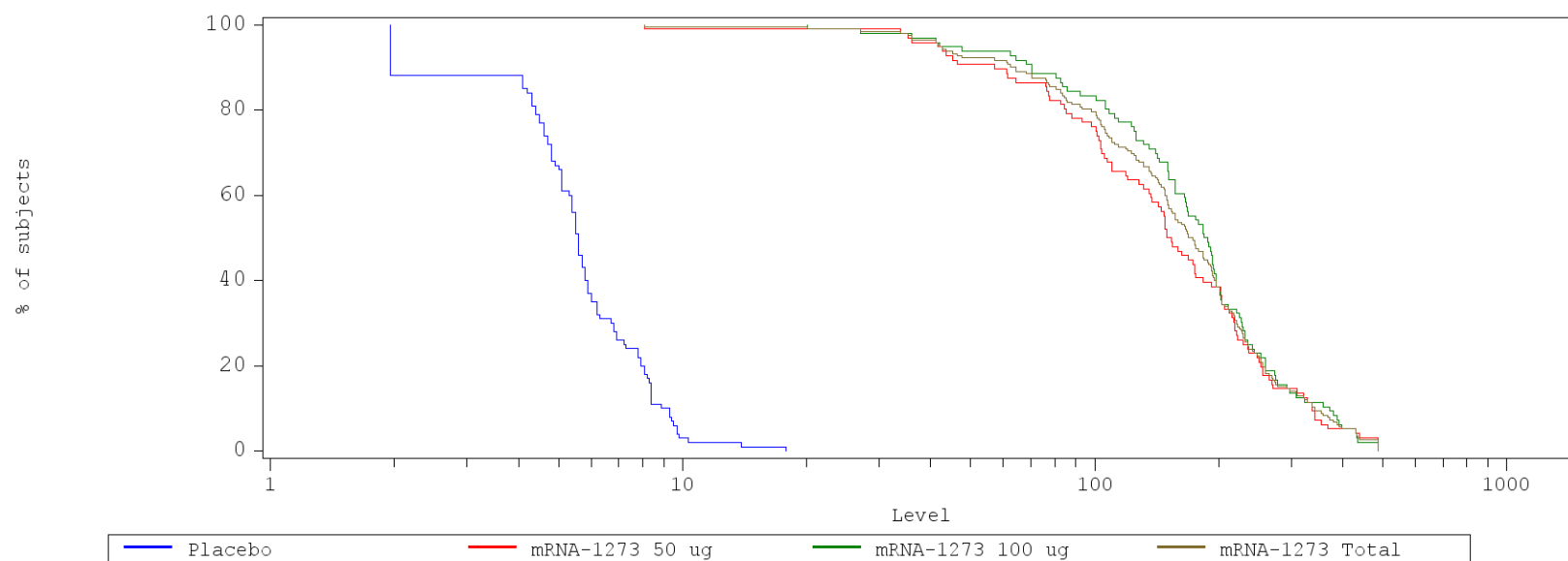
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 43



bAb = Binding antibody.

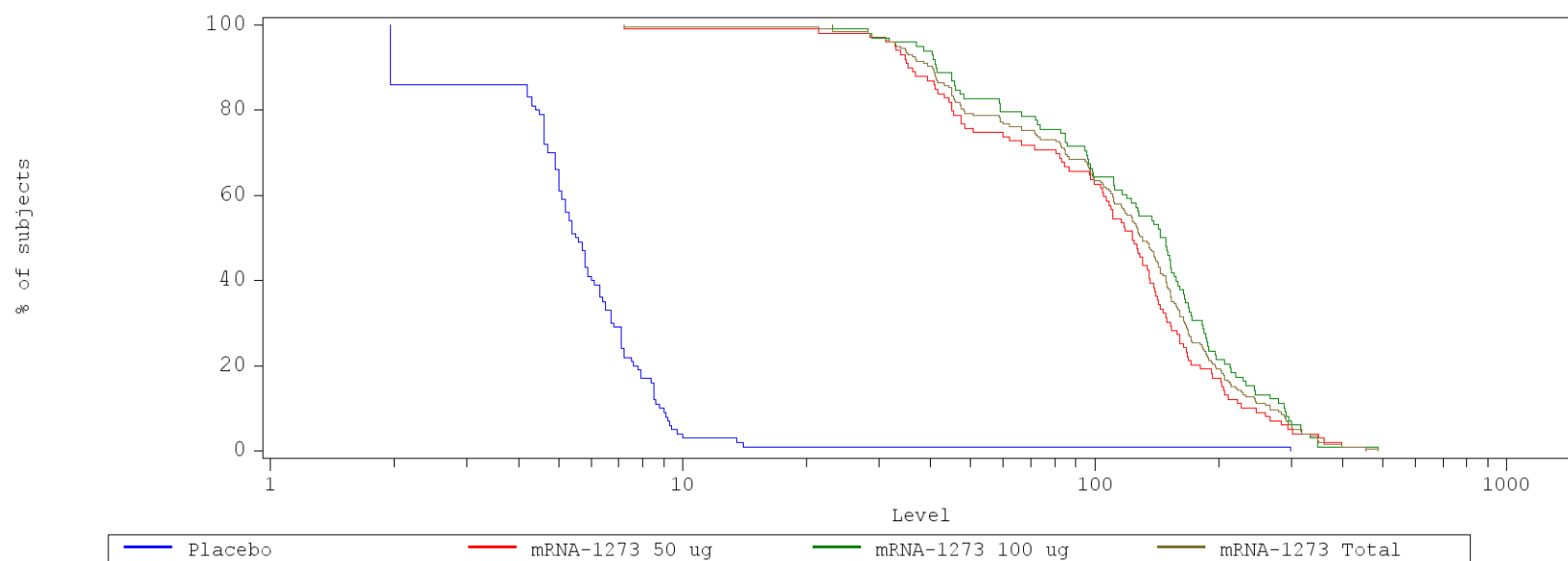
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.3.2
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (≥ 55 Years)
Antibody: VAC58 Spike IgG Antibody (ug/ml) (LLOQ: 3.9, ULOQ: 487)
Day 57



bAb = Binding antibody.

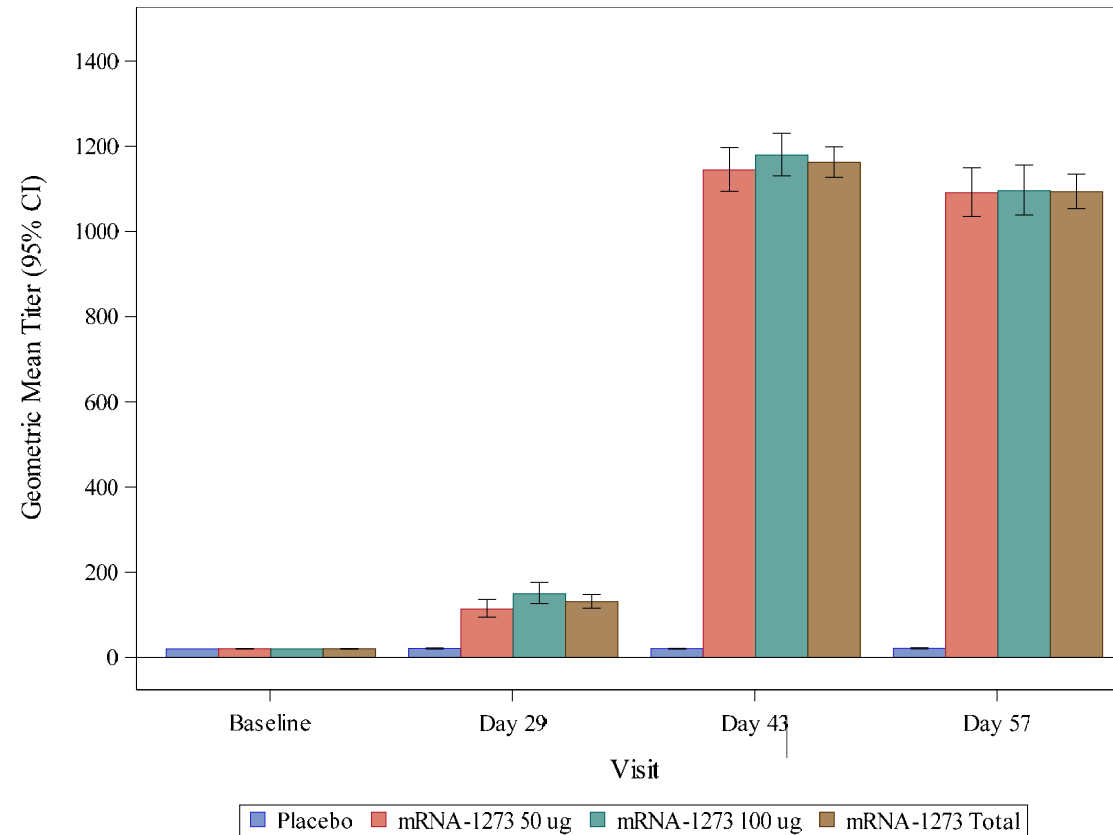
Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific bAb with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020302.sas 19NOV2020 04:39 Database Lock Date: 05NOV2020

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

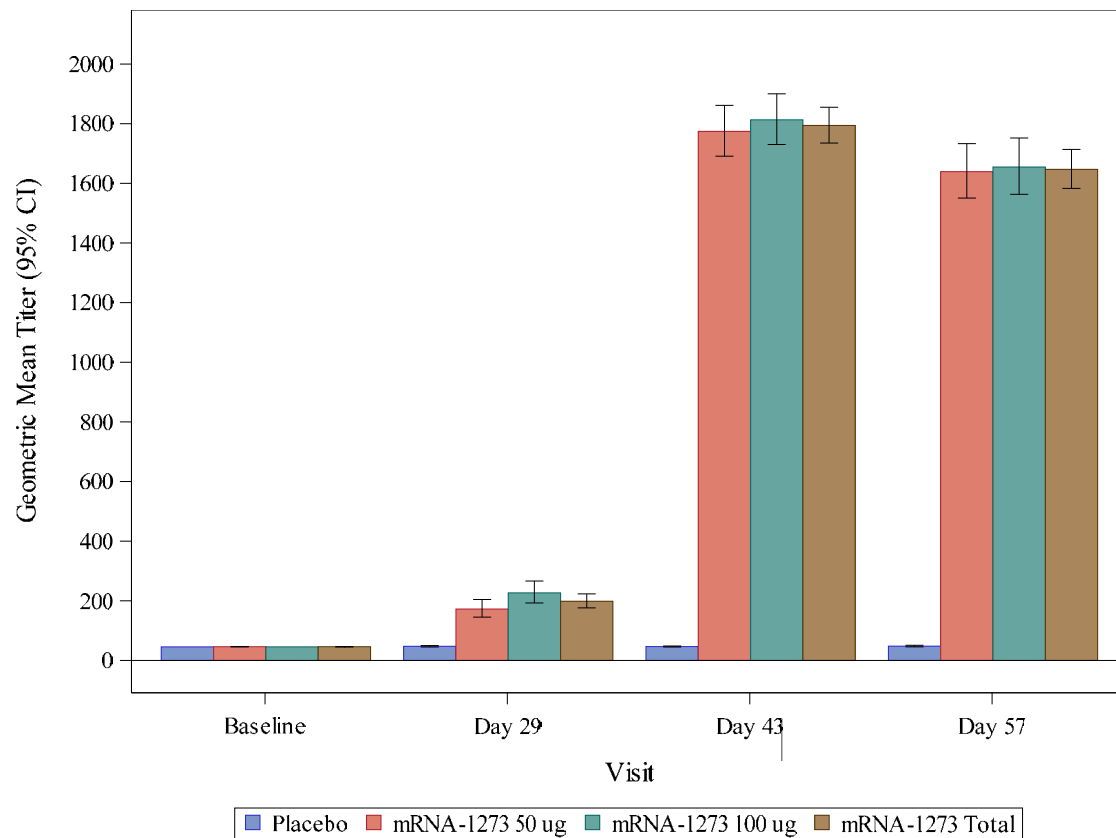
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

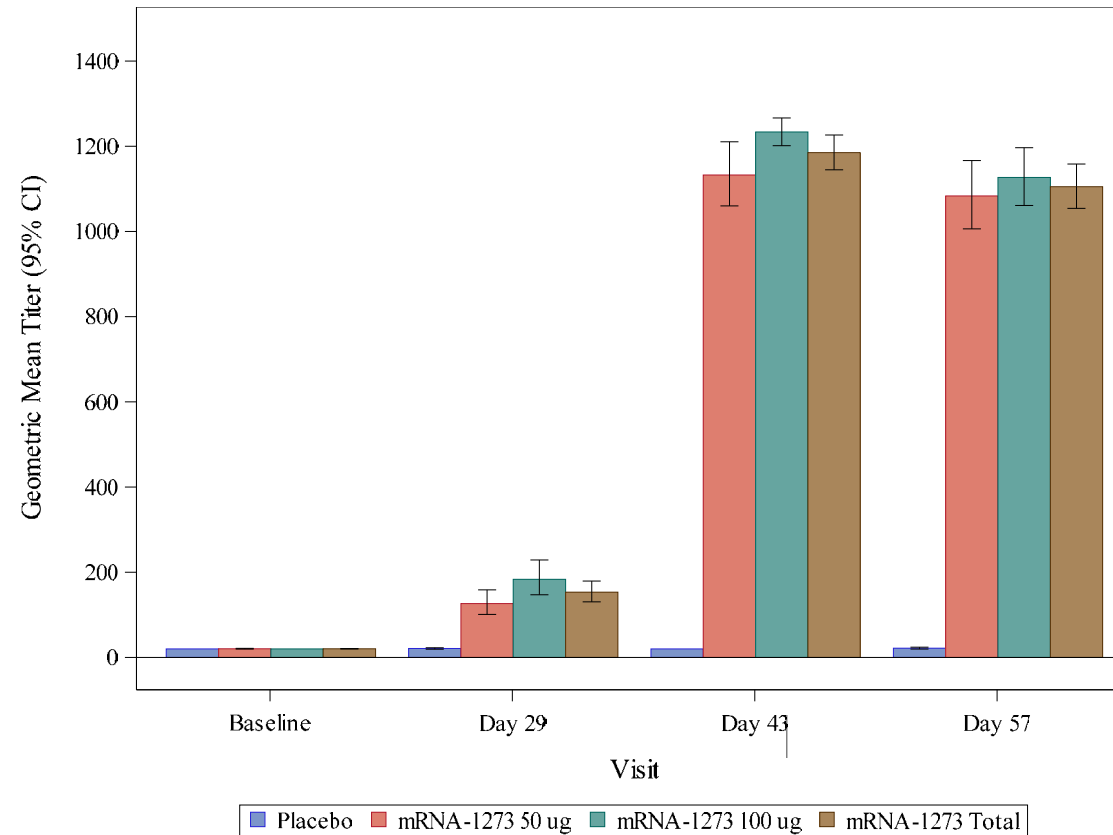
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

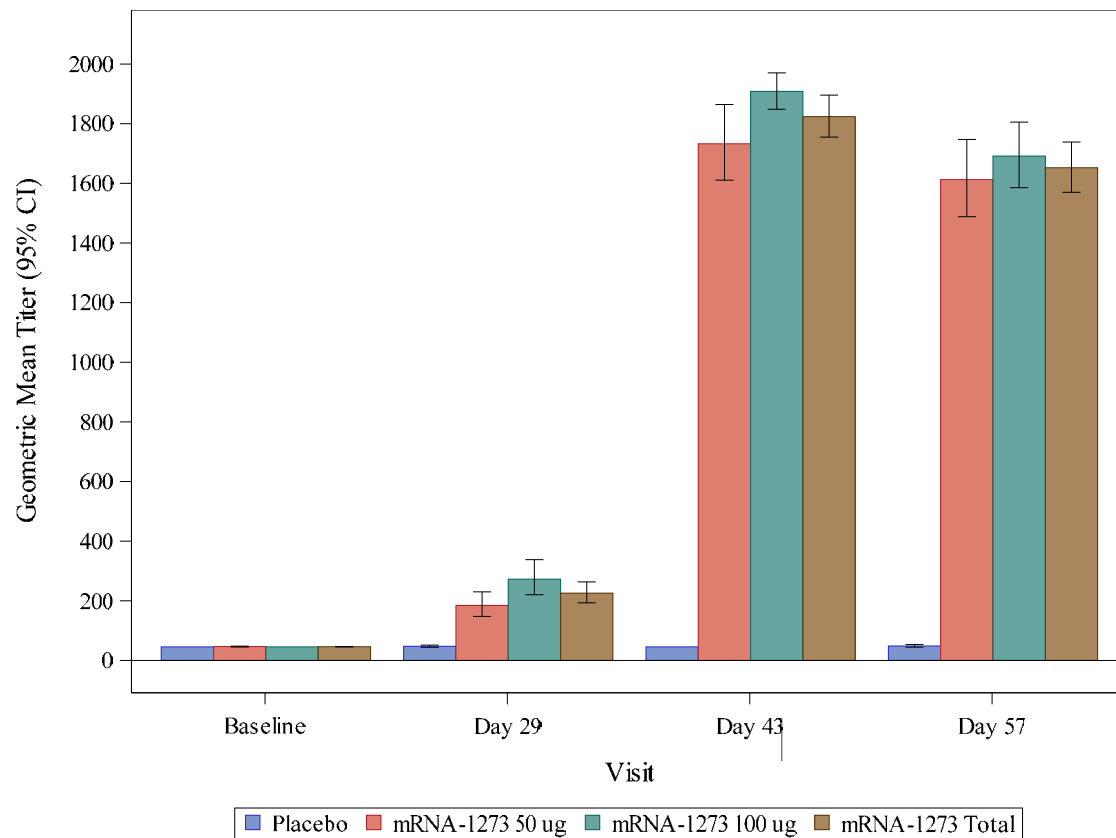
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

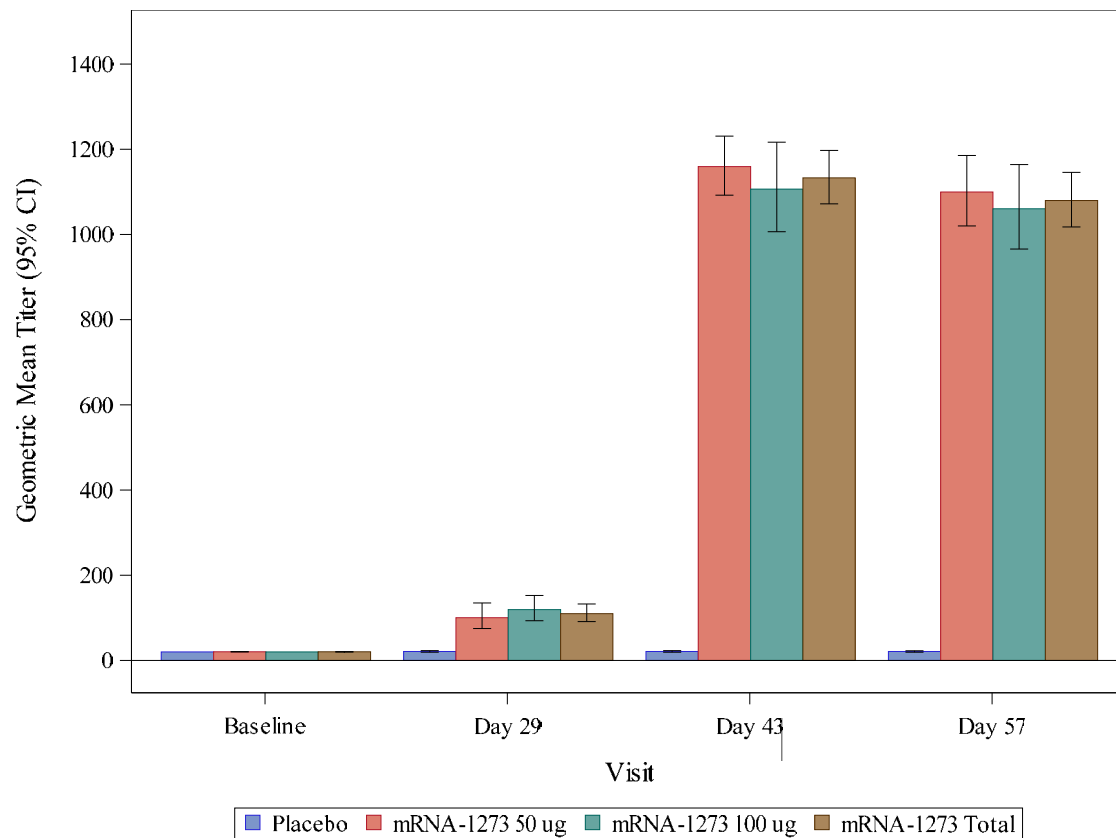
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

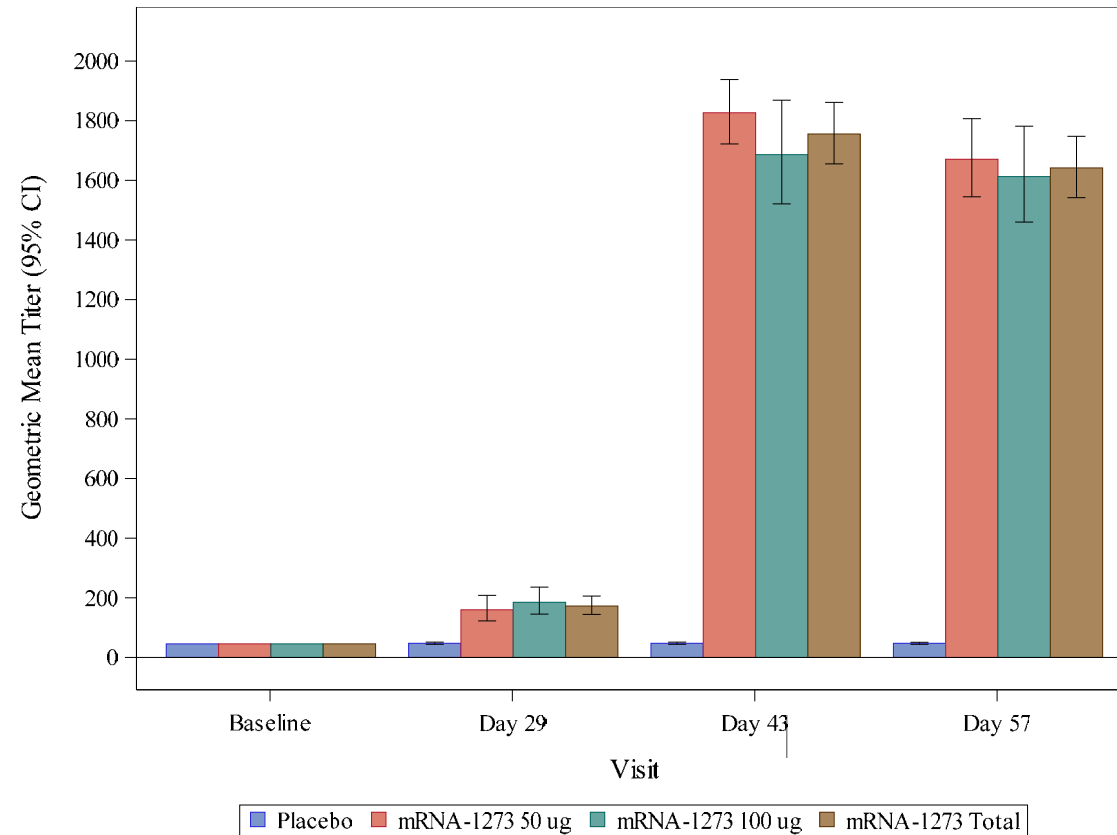
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

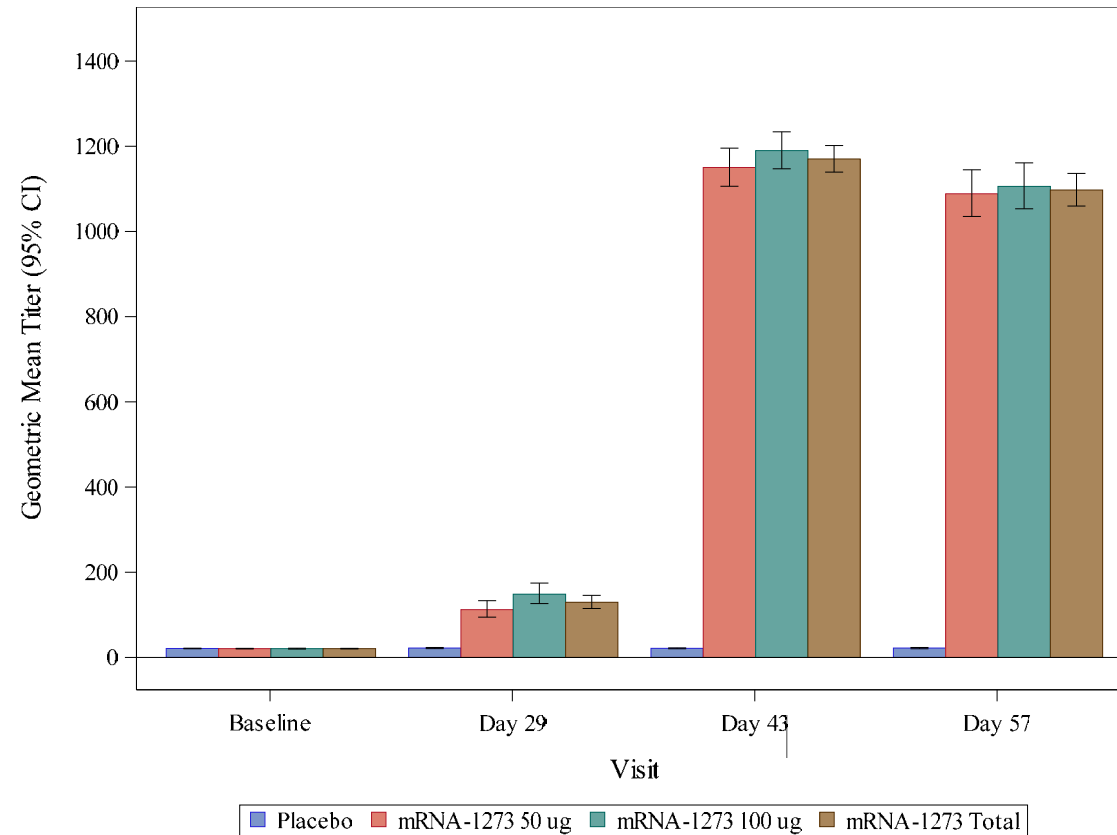
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

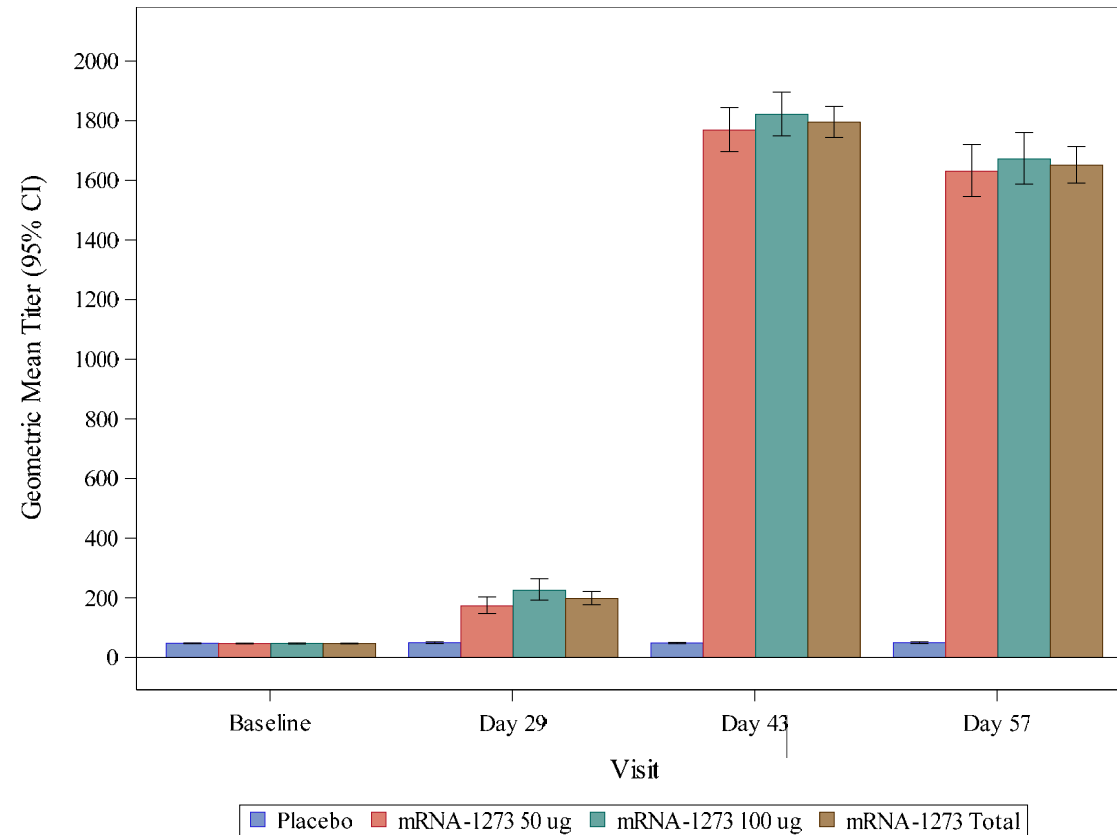
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

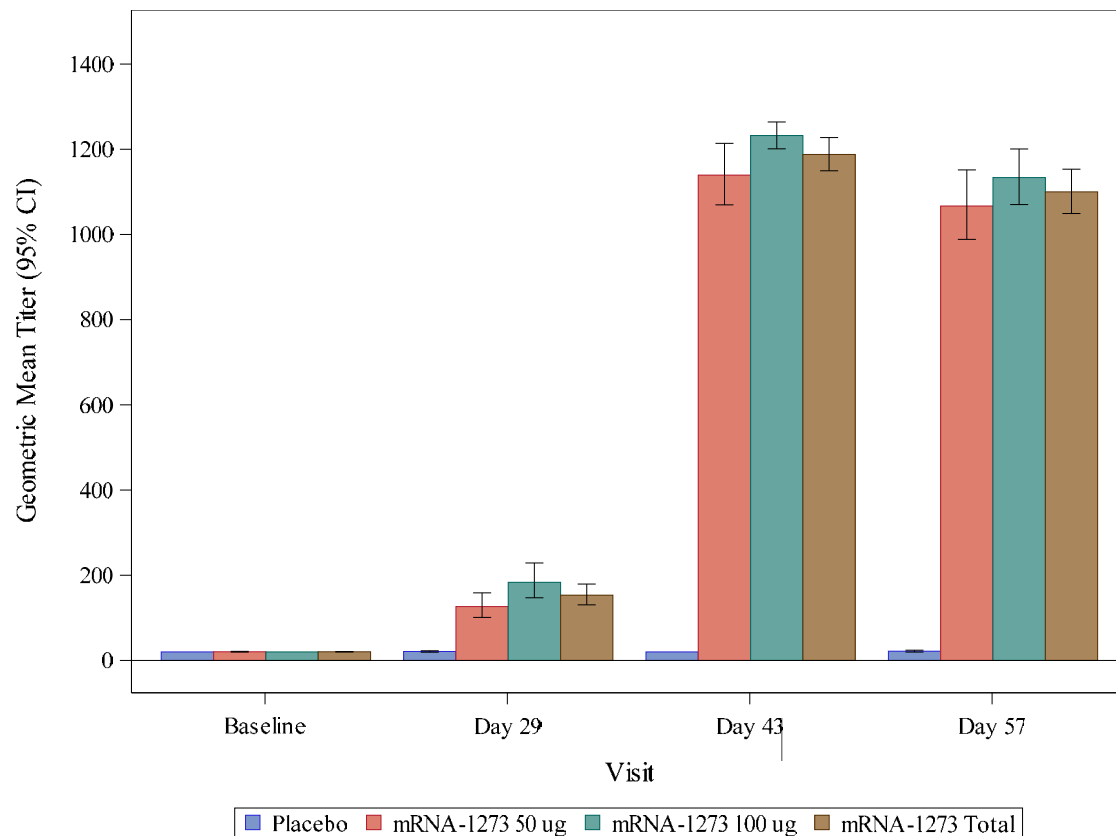
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

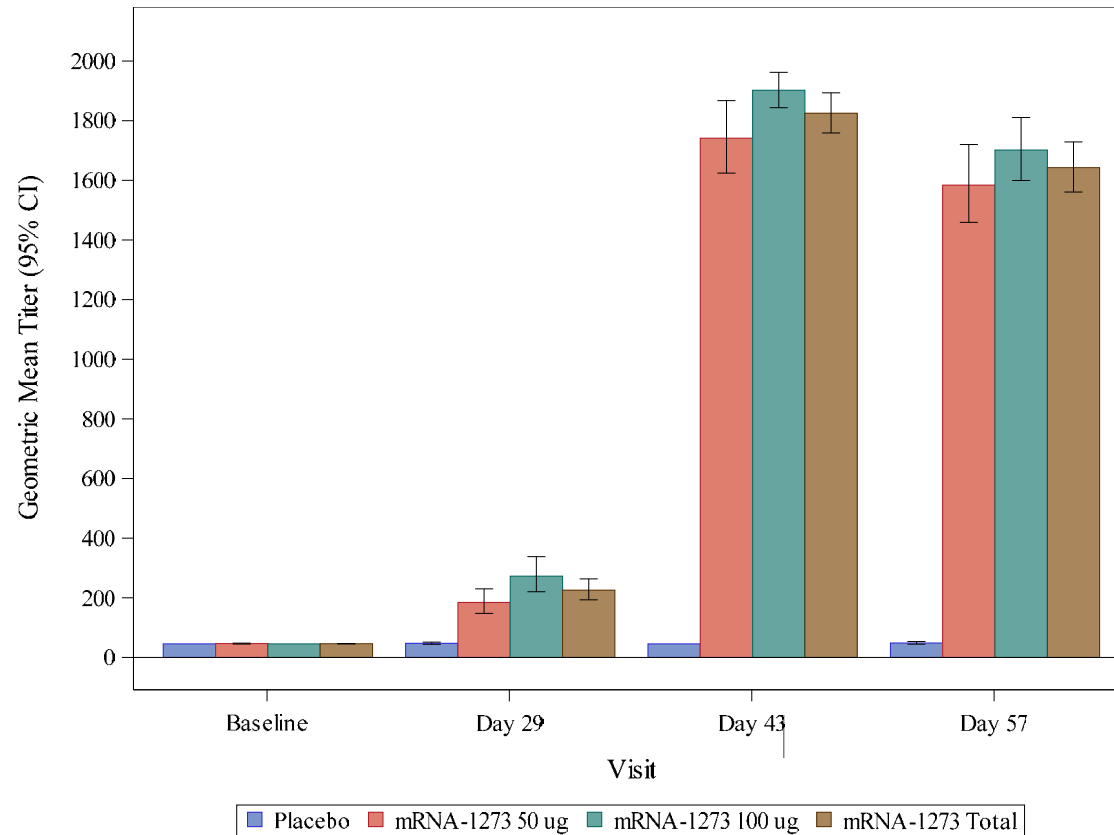
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

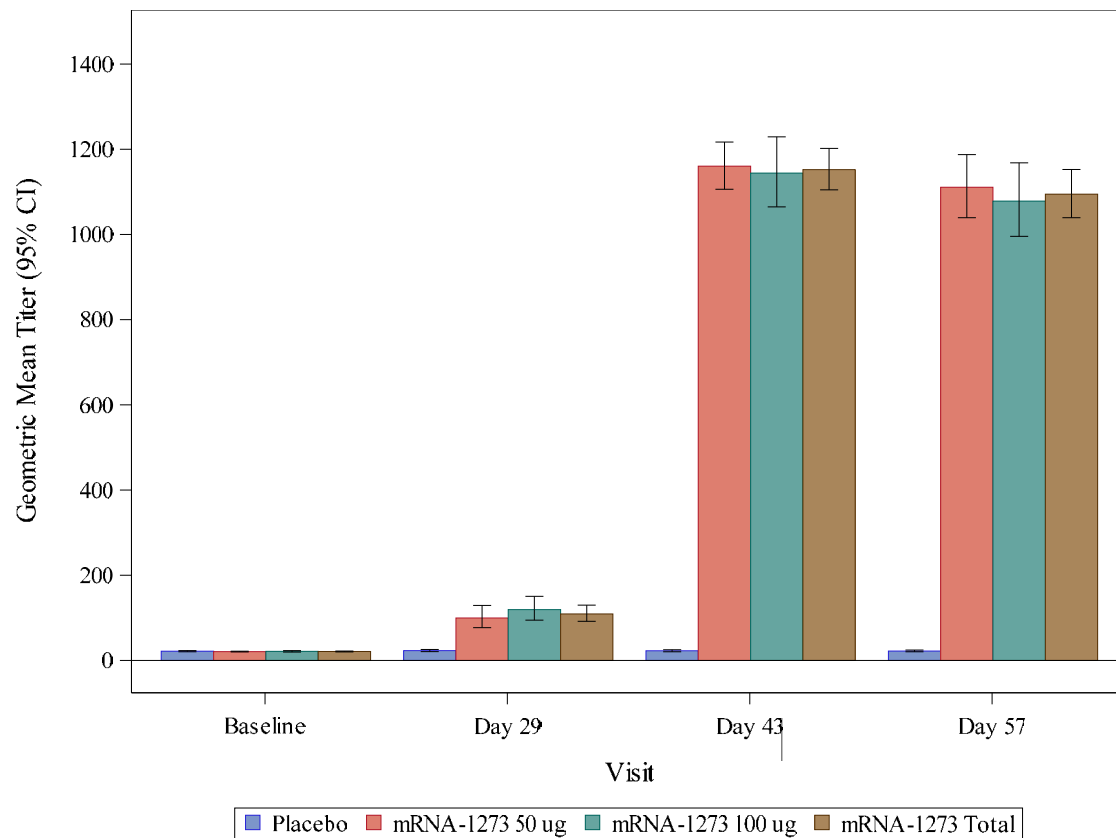
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

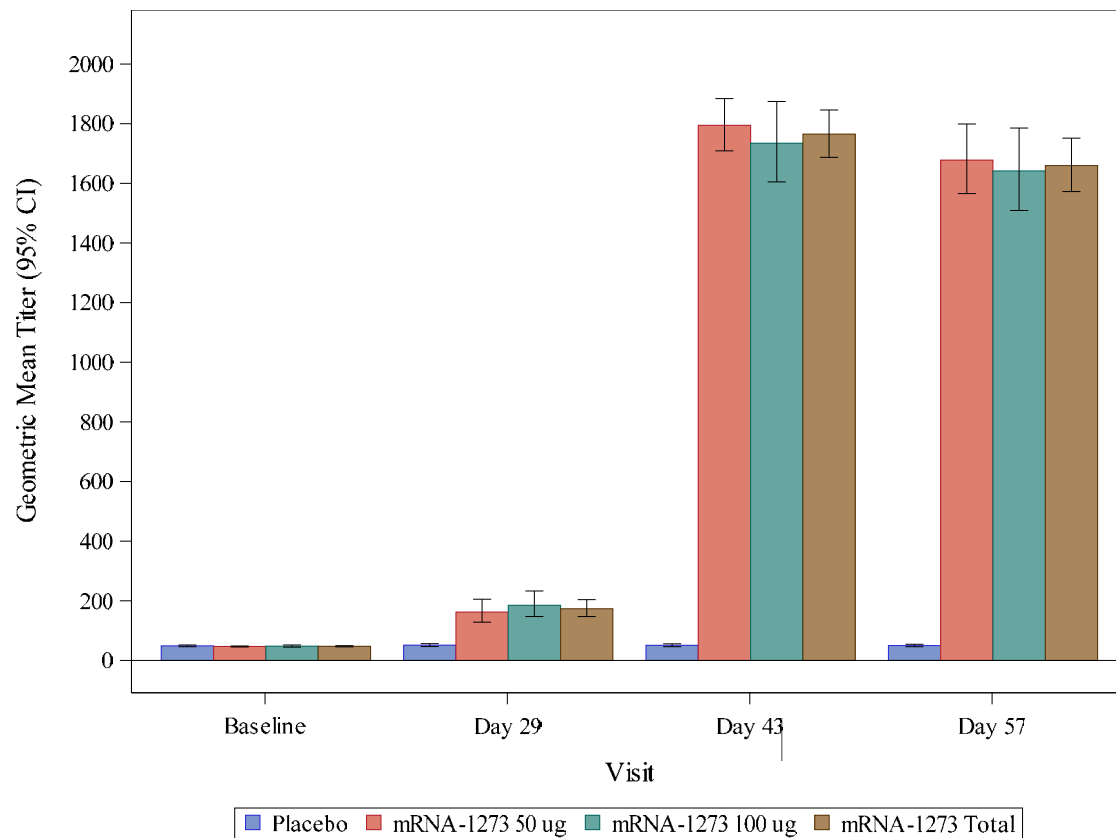
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

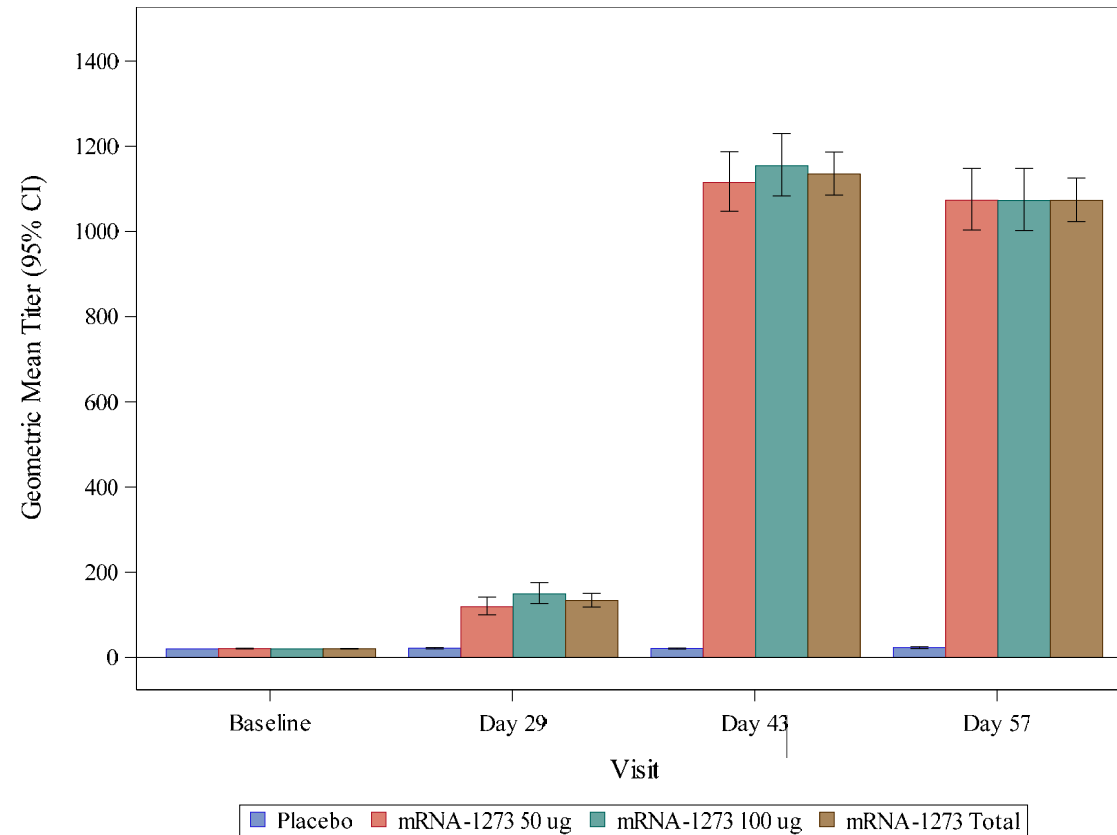
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

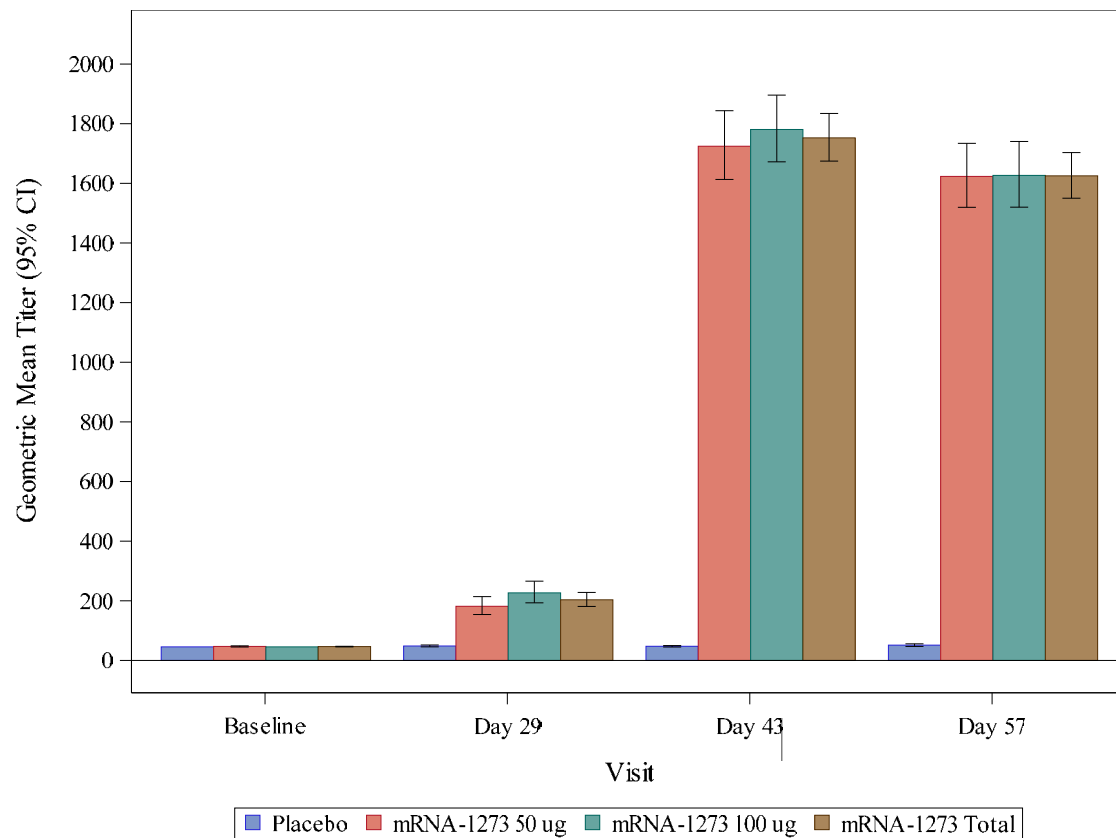
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

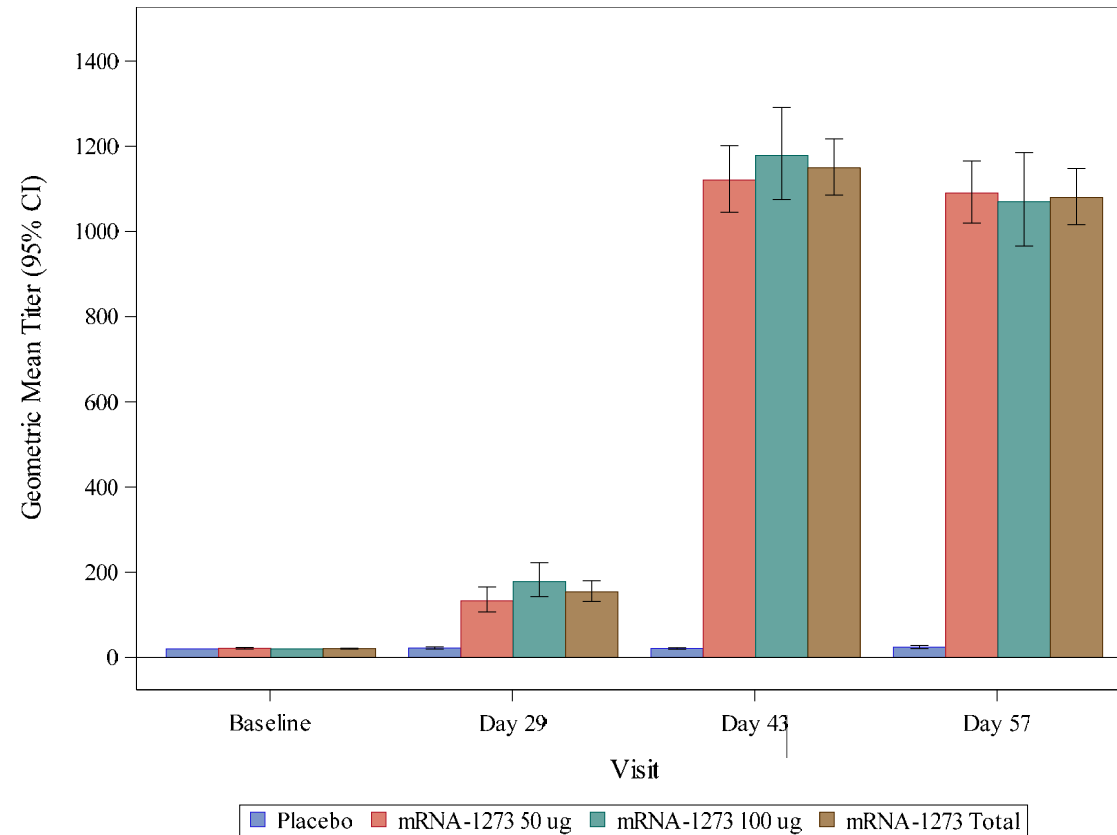
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

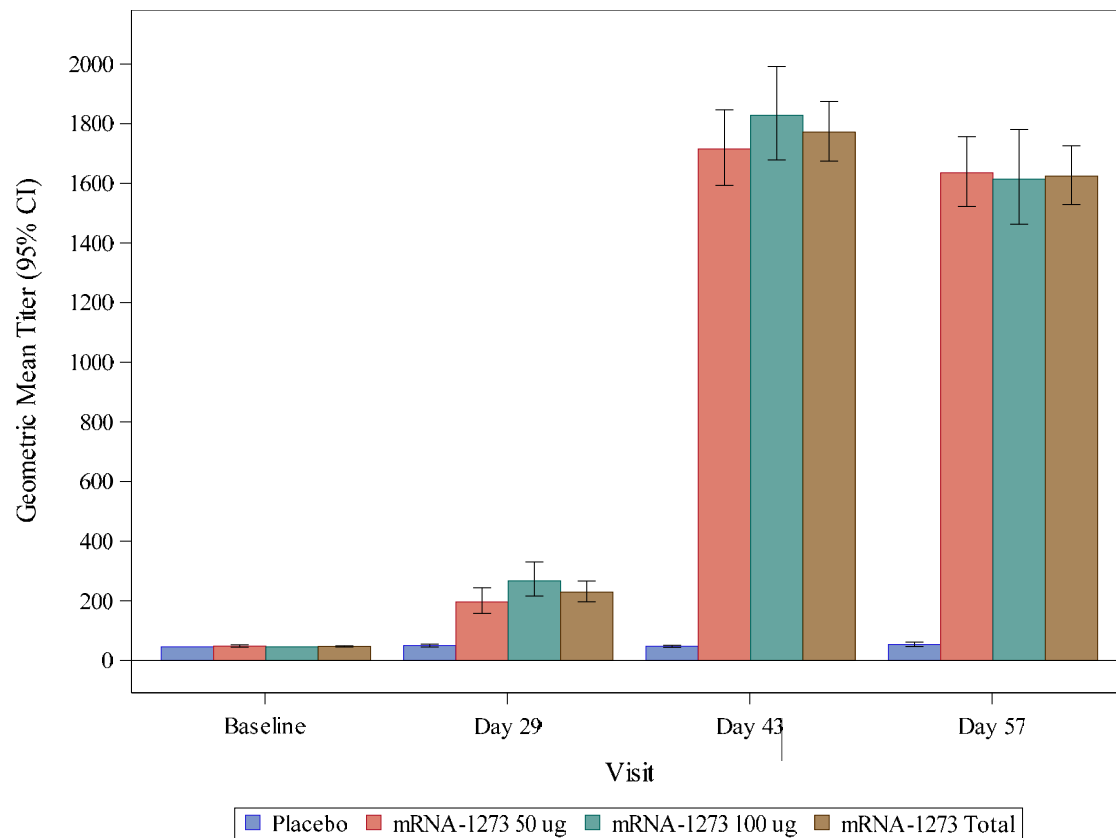
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

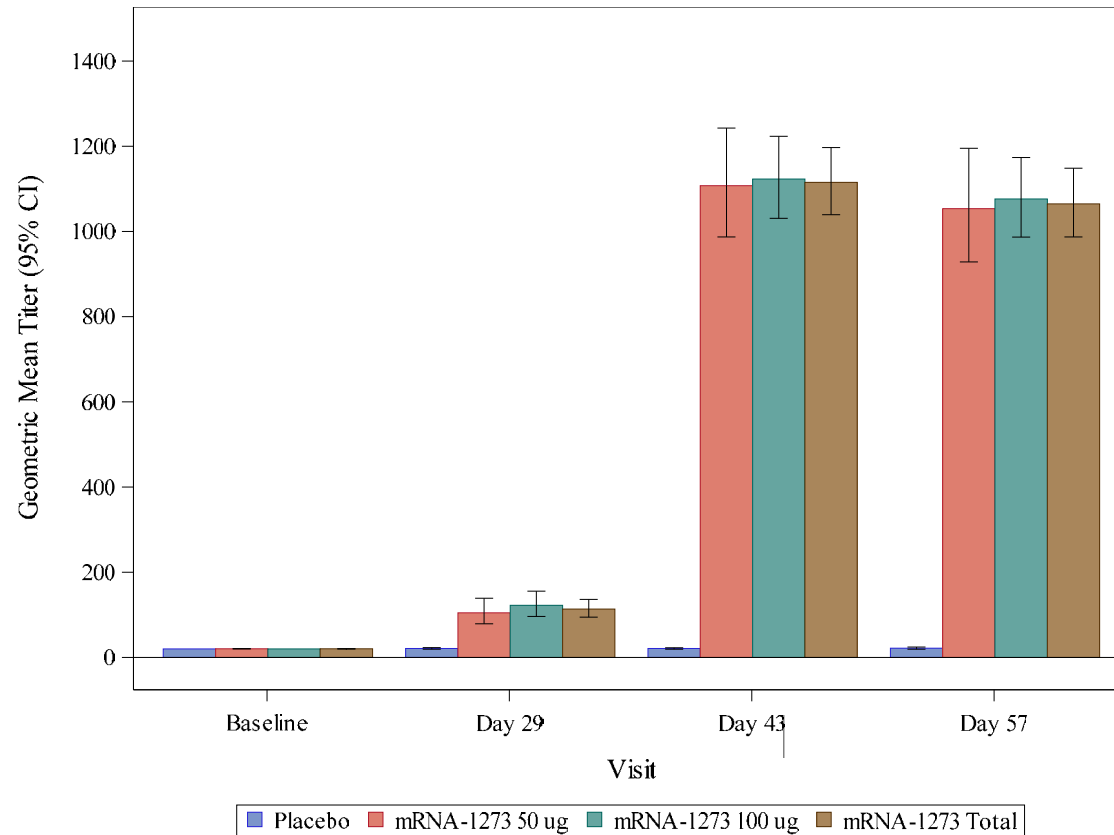
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

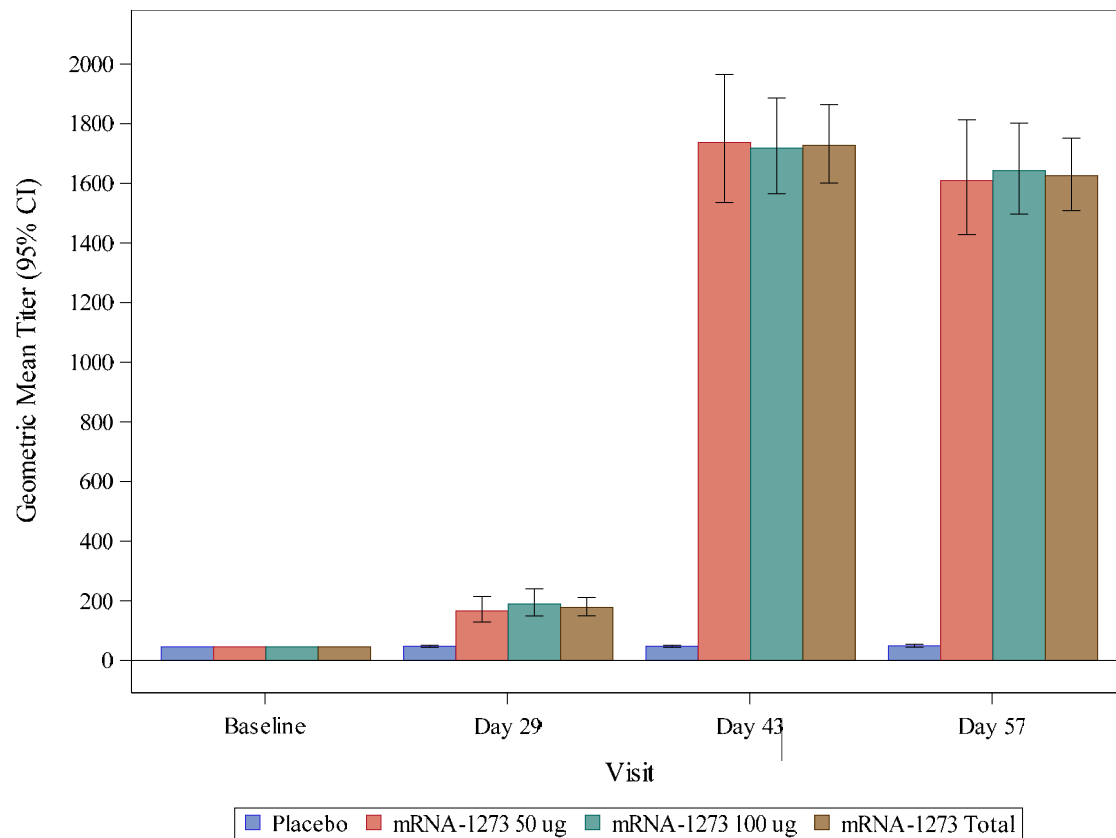
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

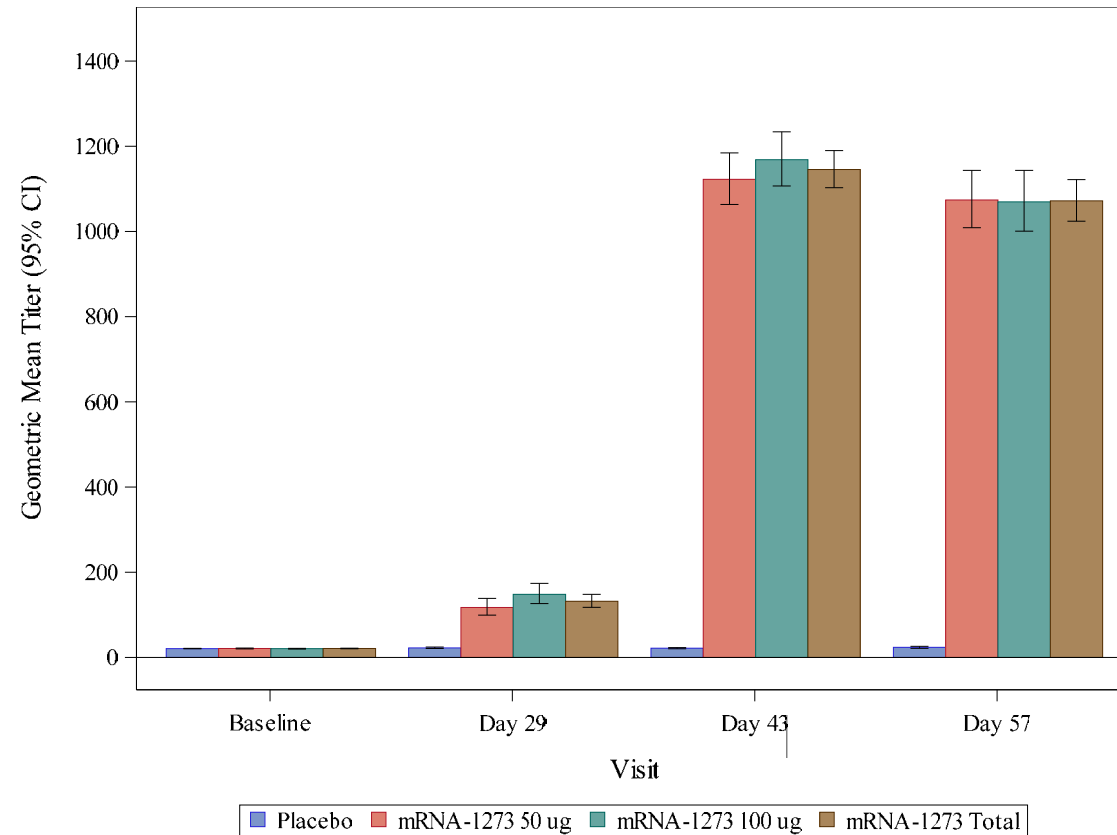
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

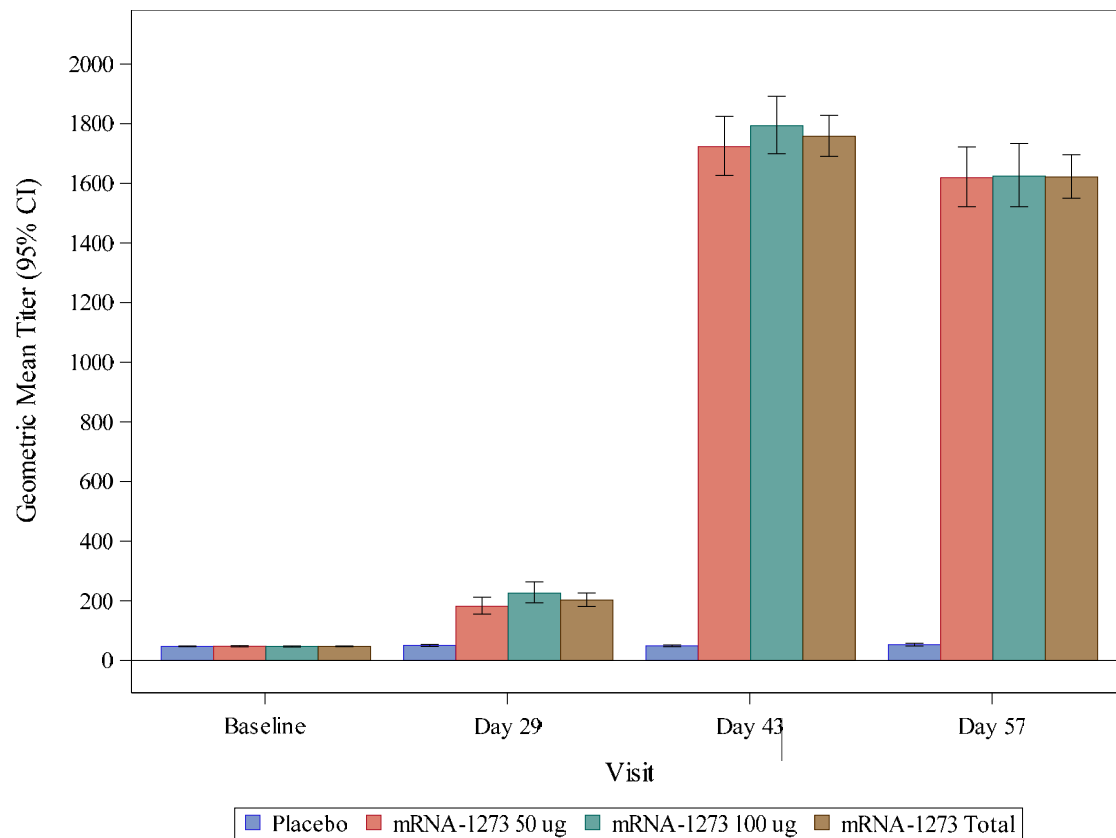
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

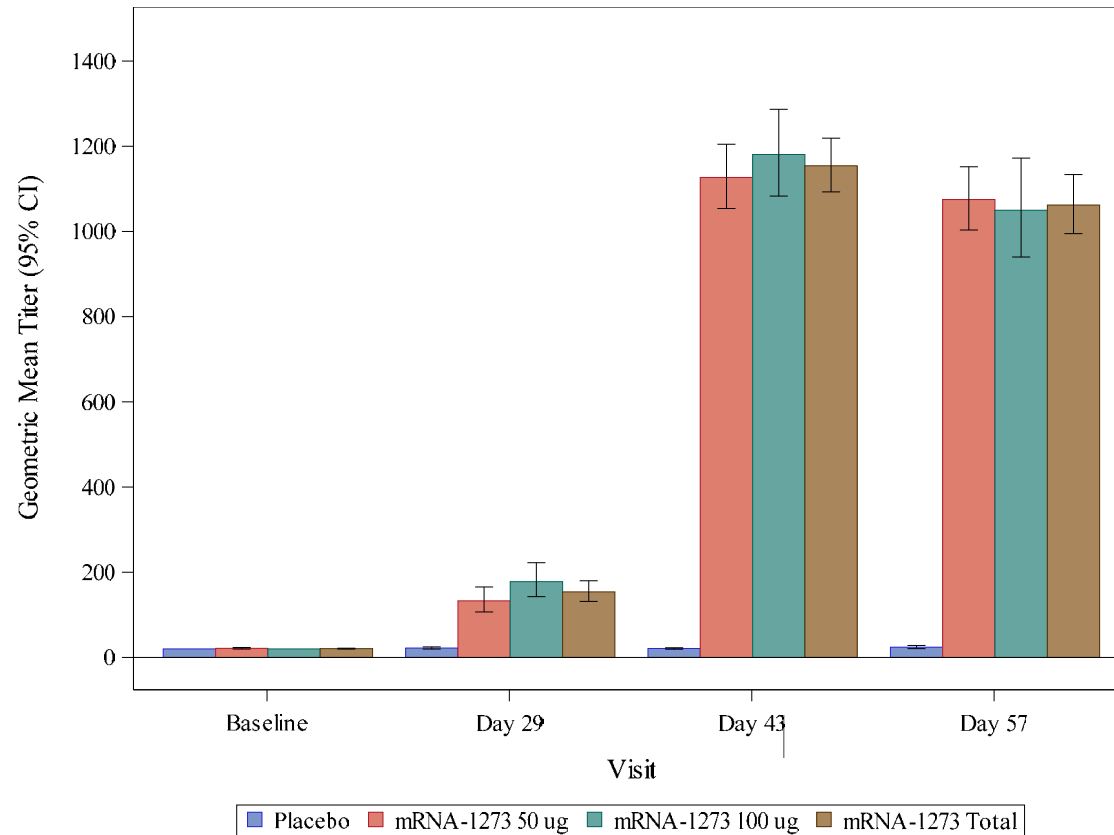
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

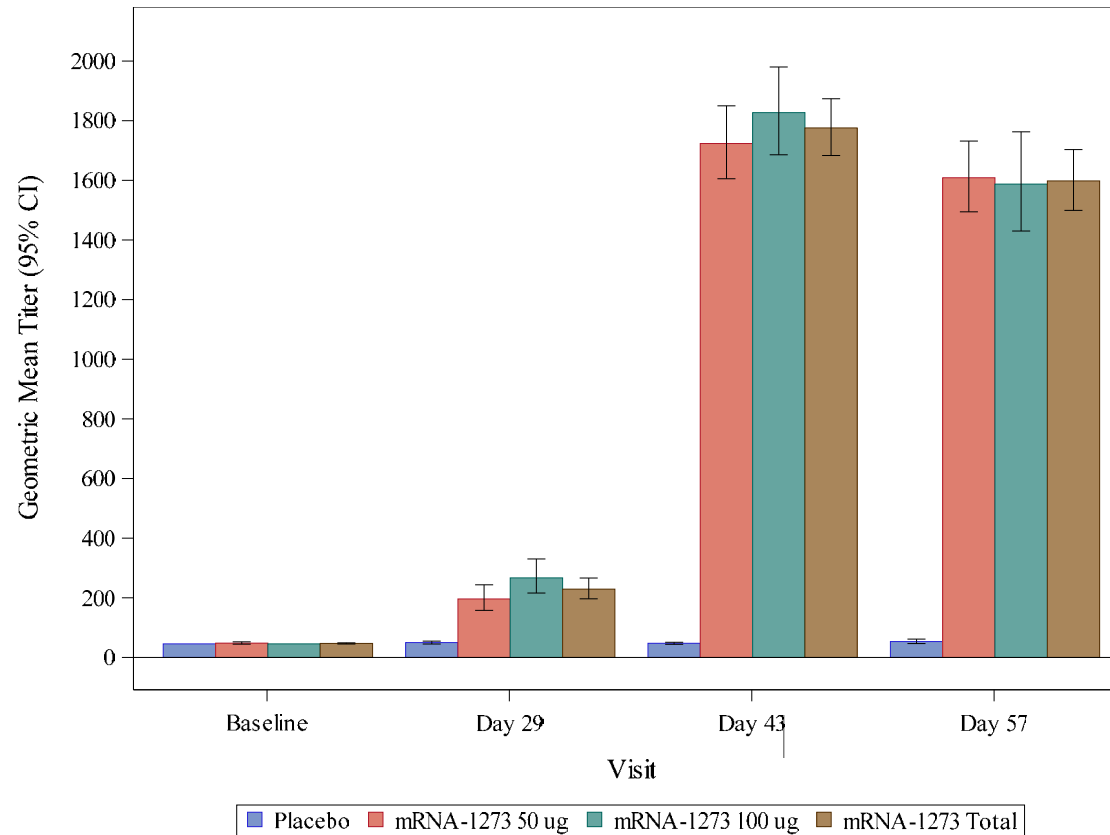
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

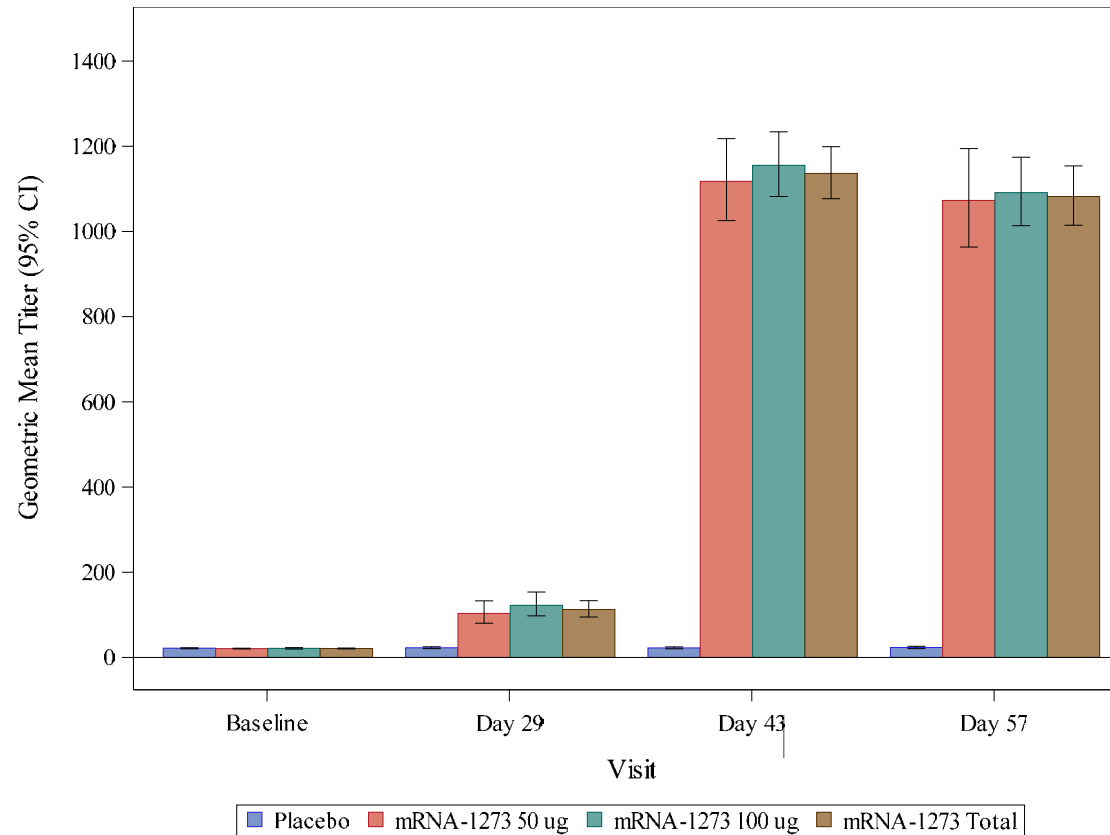
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

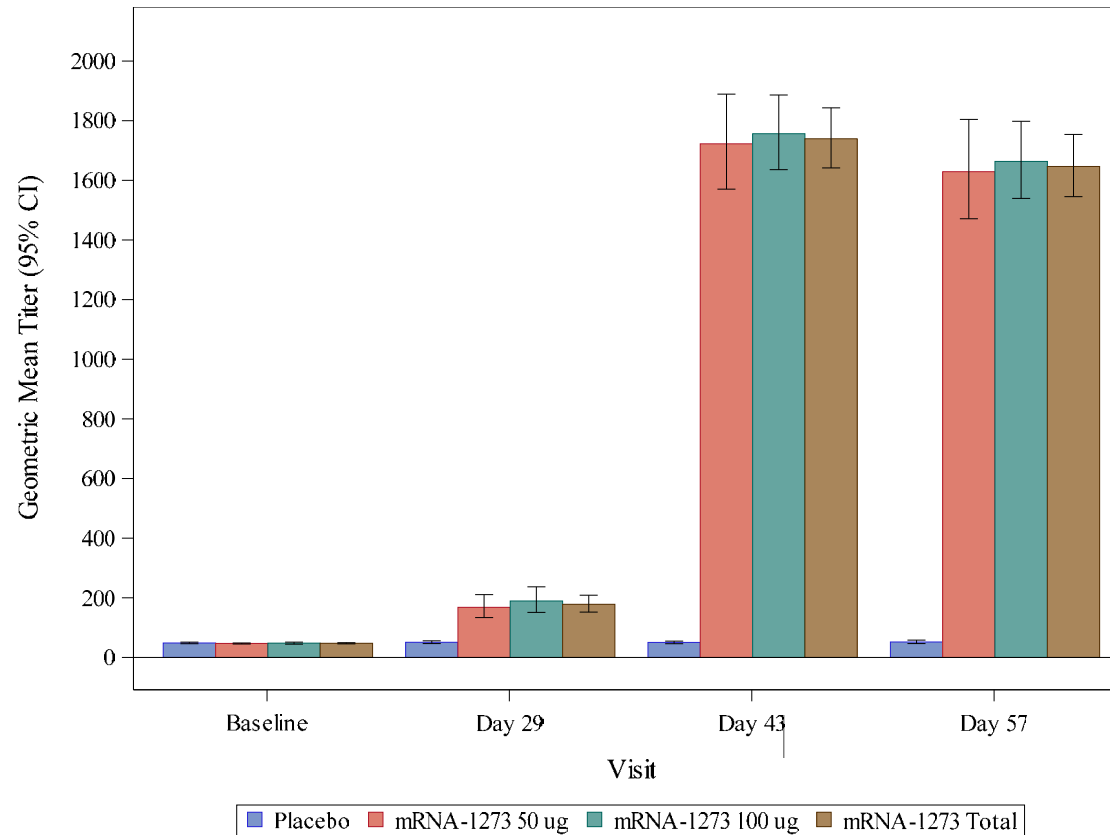
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.4.2.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

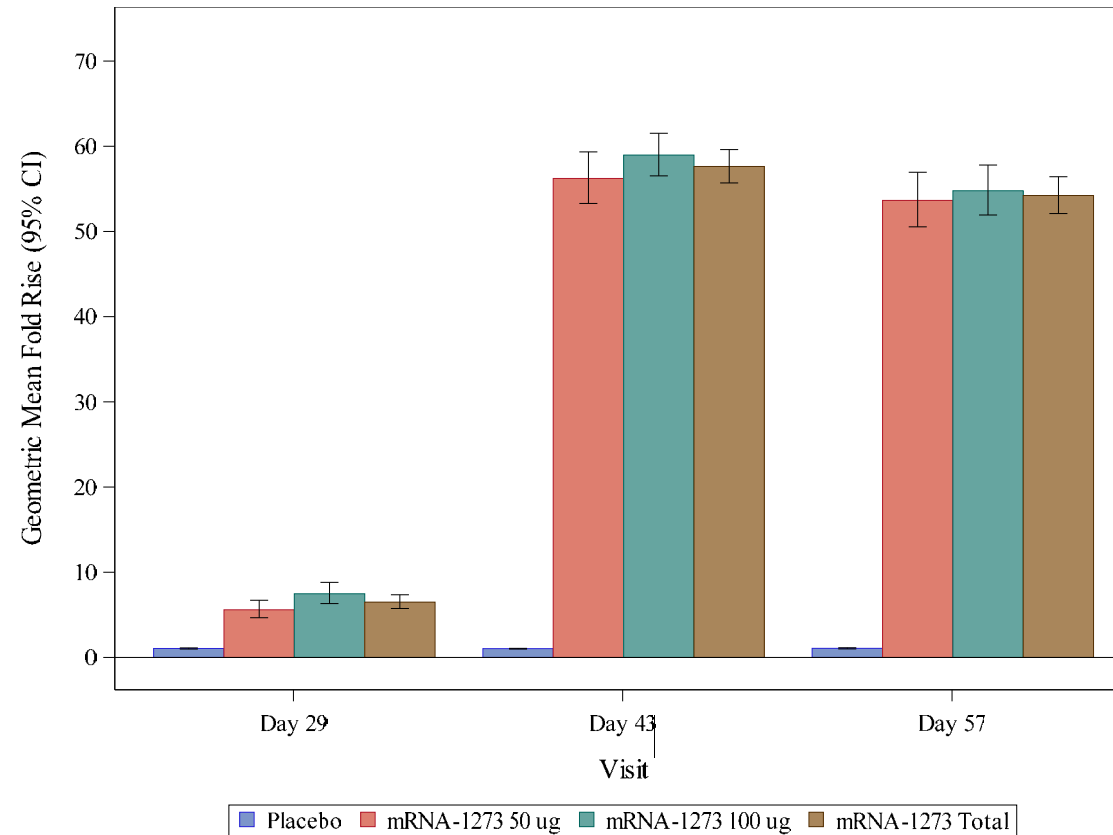
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

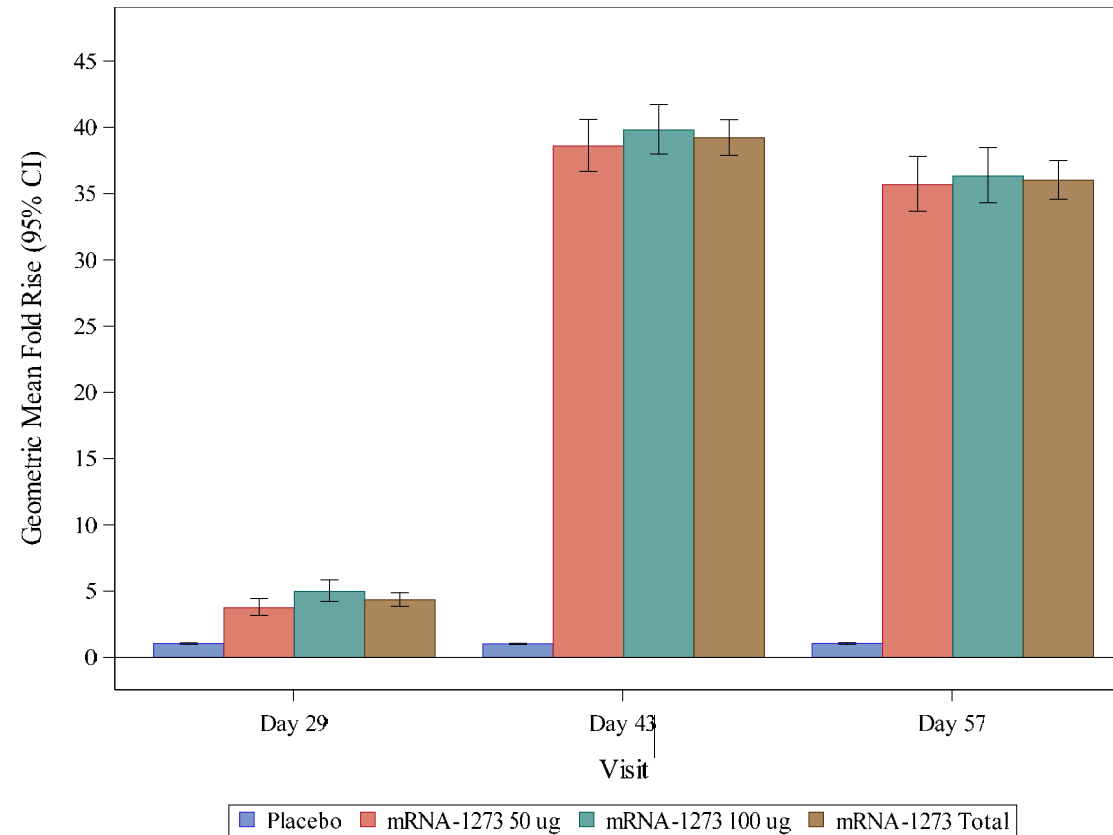
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

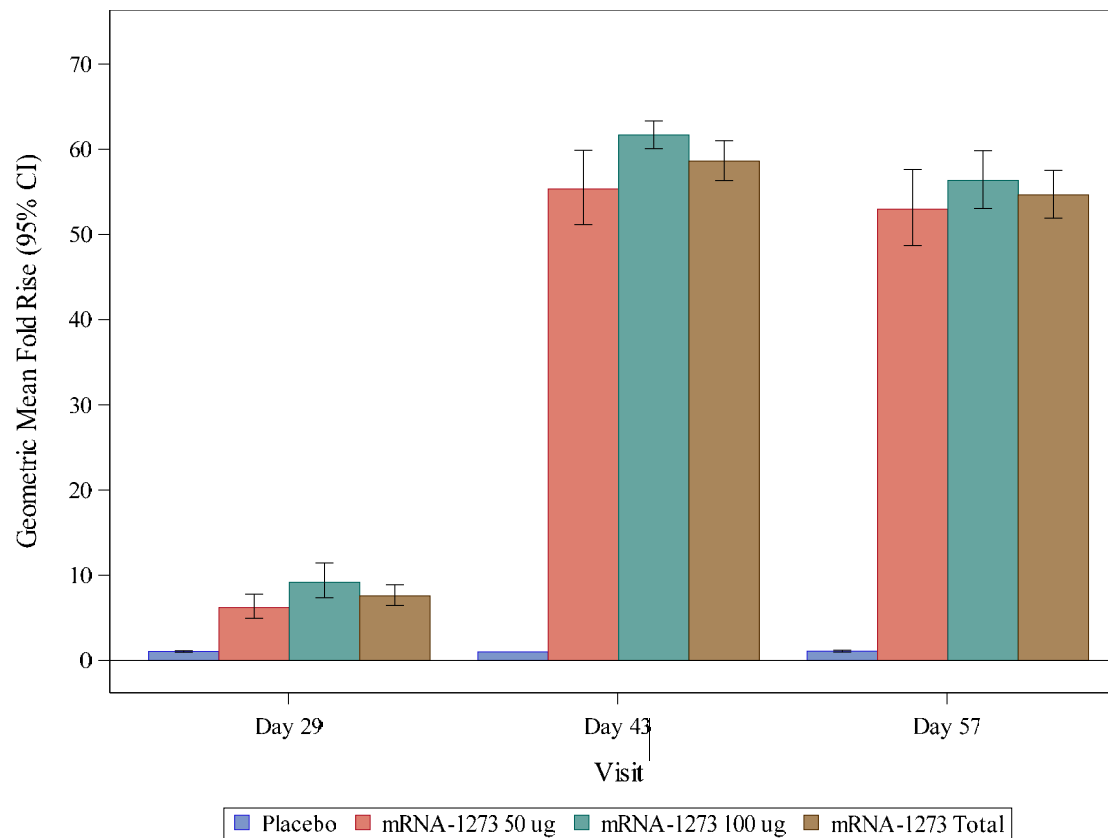
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

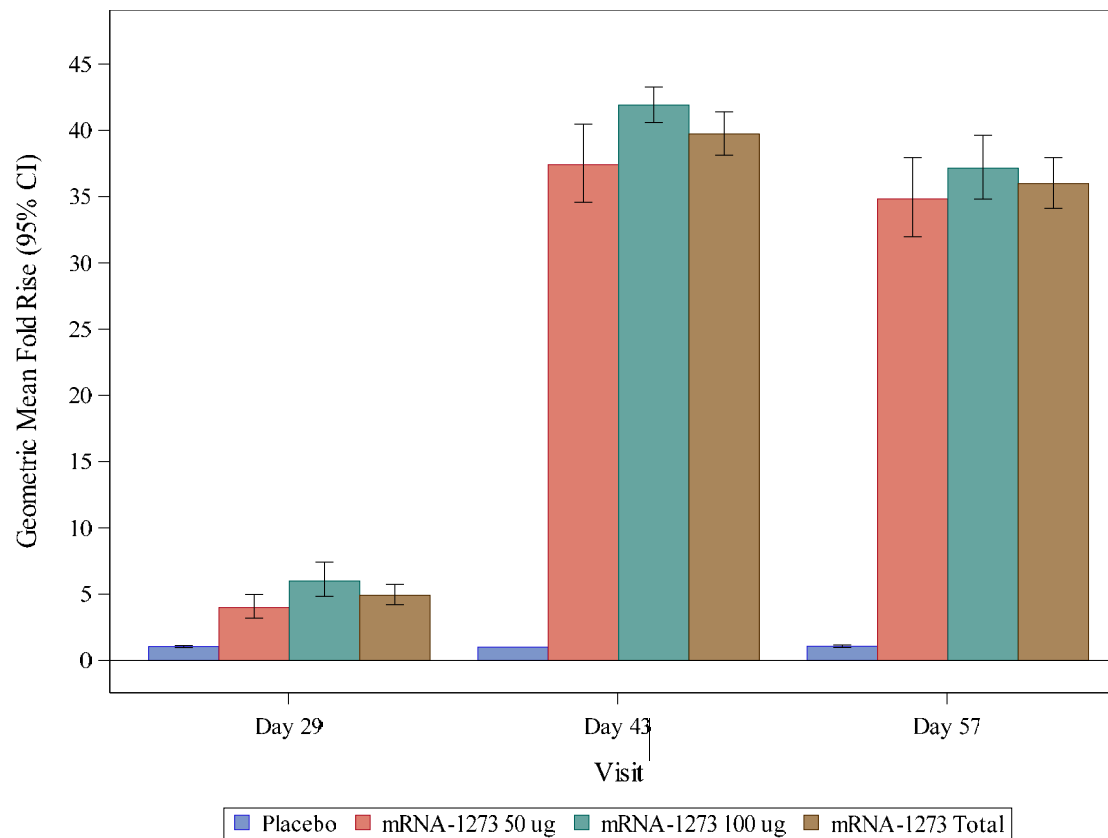
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

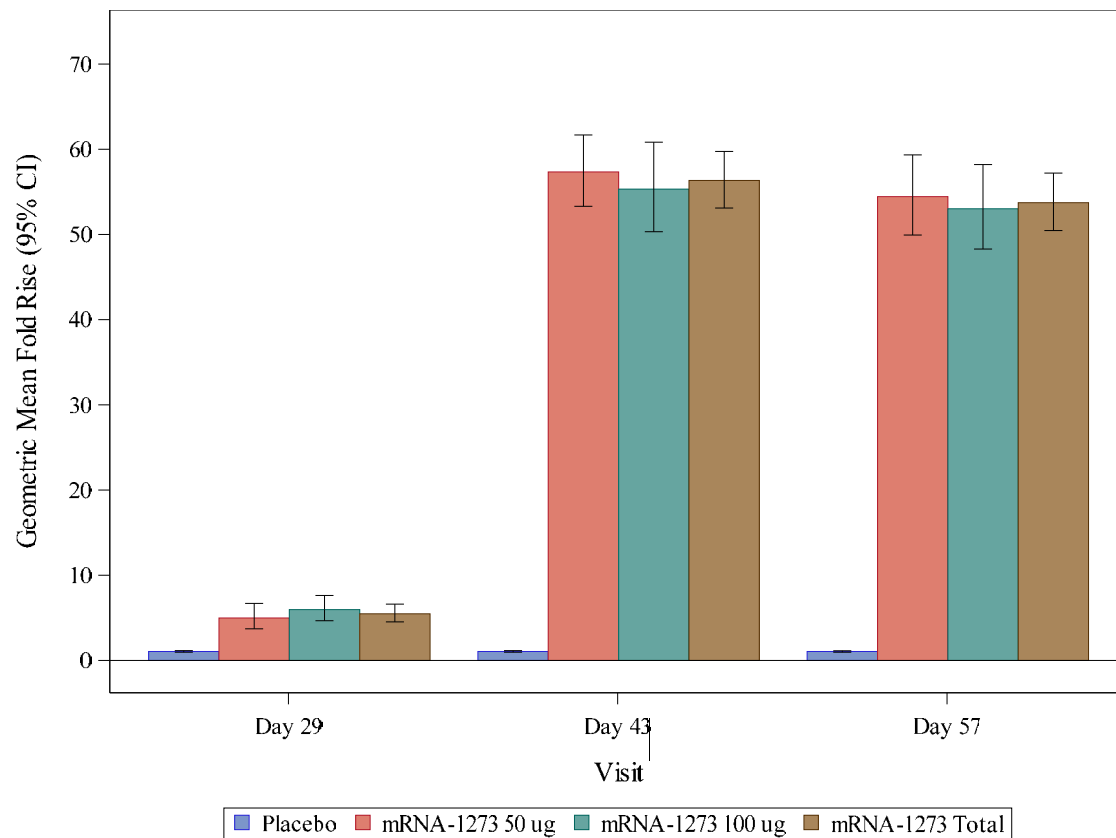
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

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Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

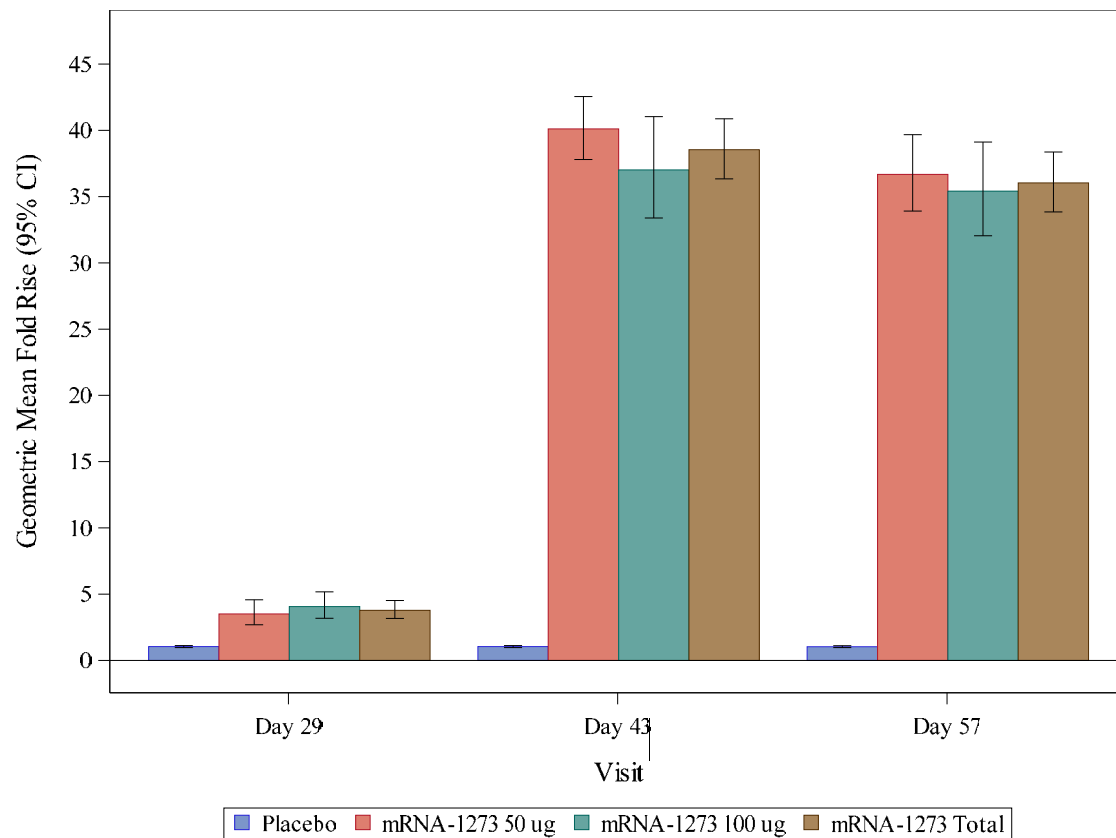
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.5.1.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

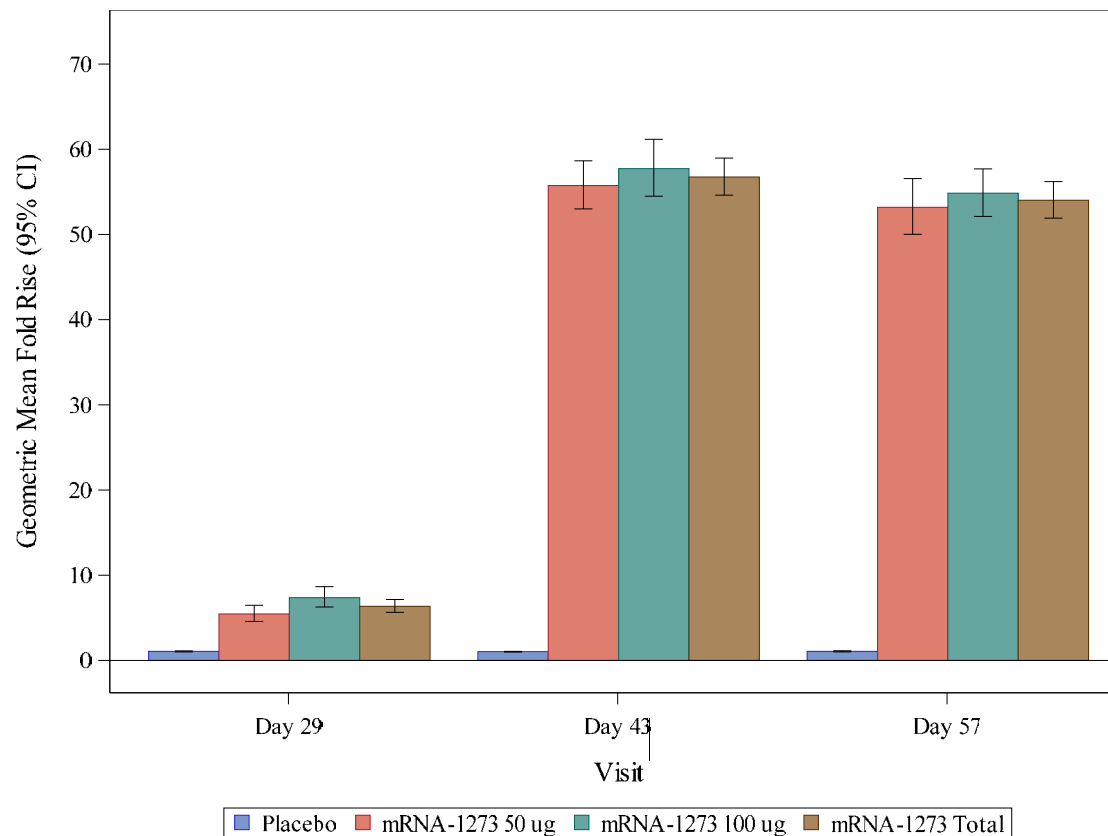
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050101.sas 19NOV2020 04:19 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

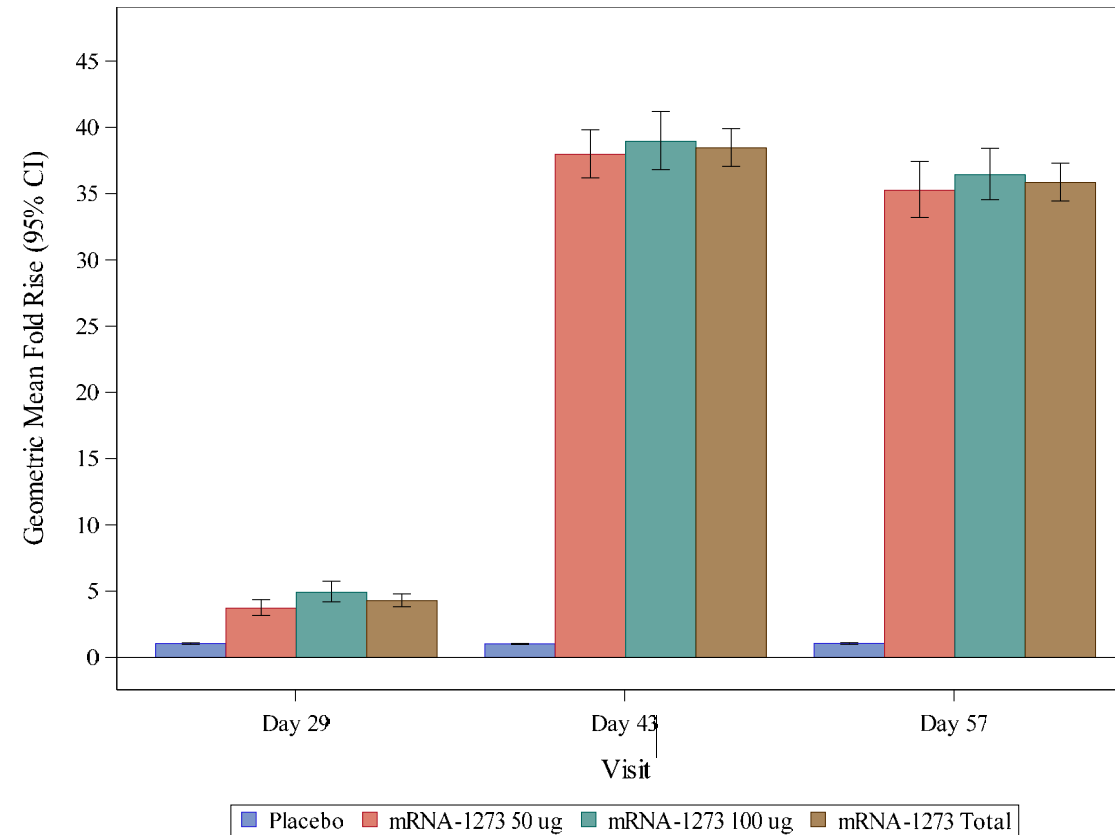
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

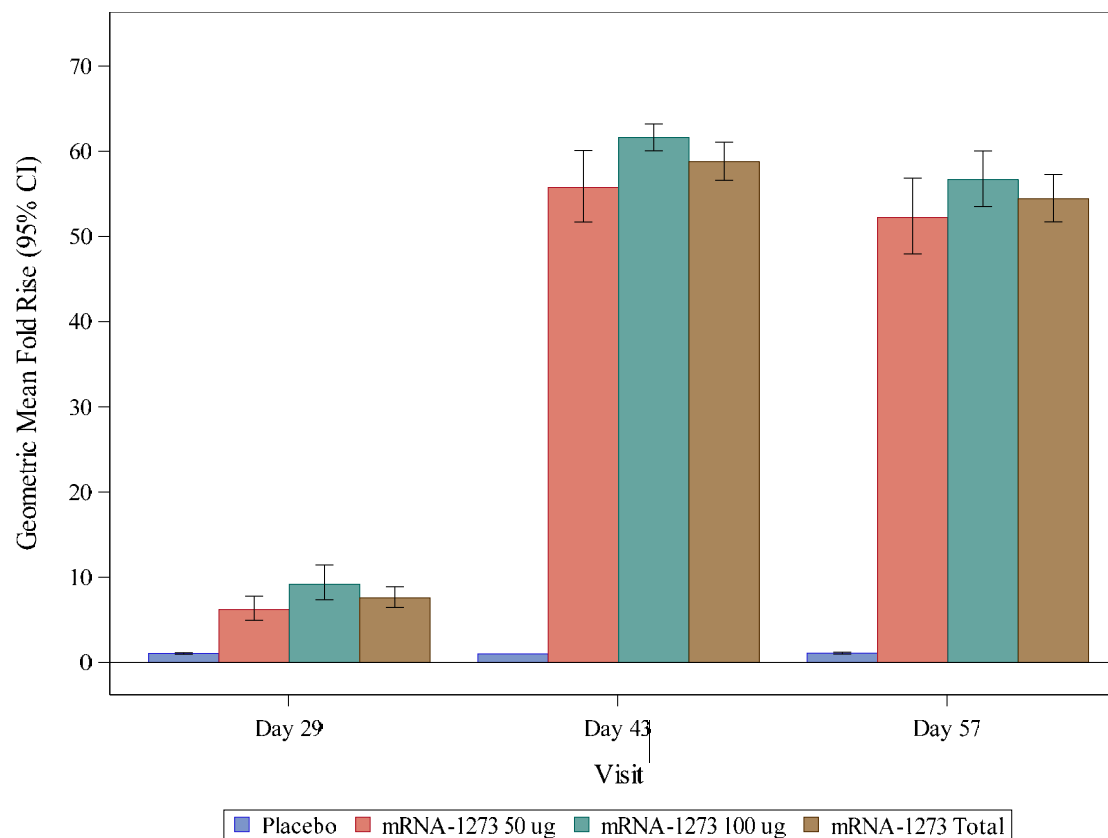
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

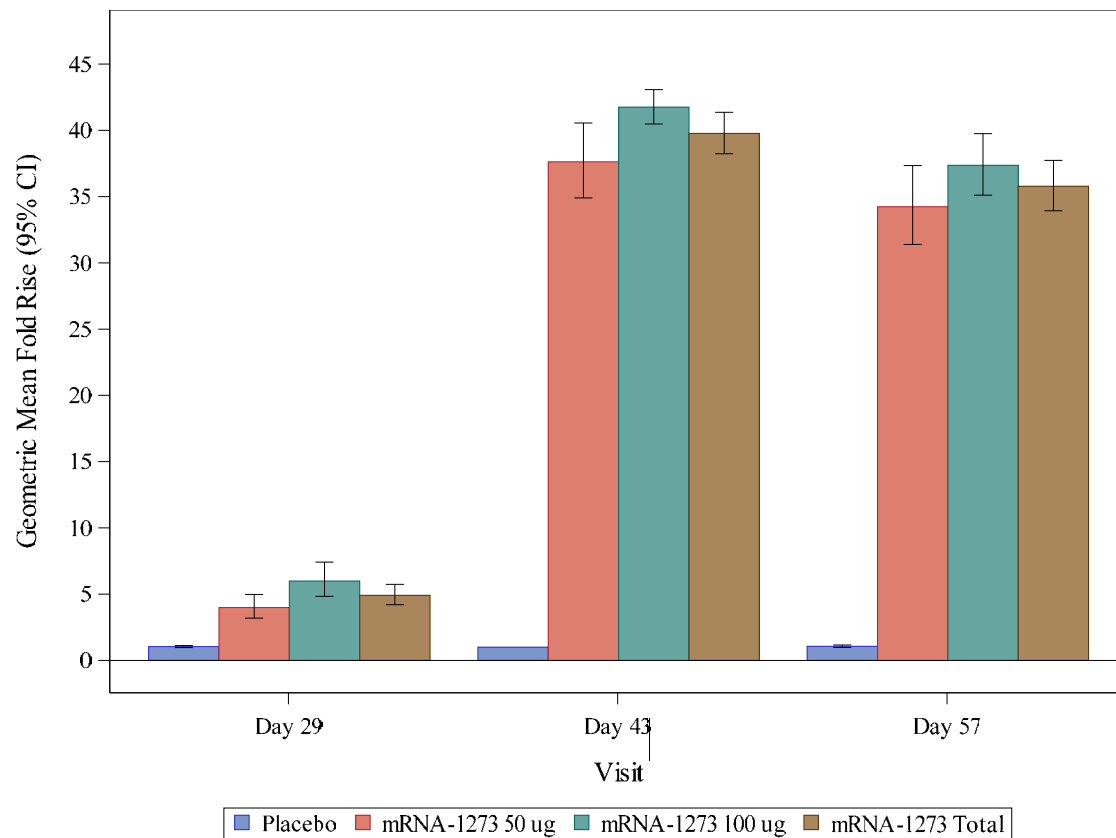
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

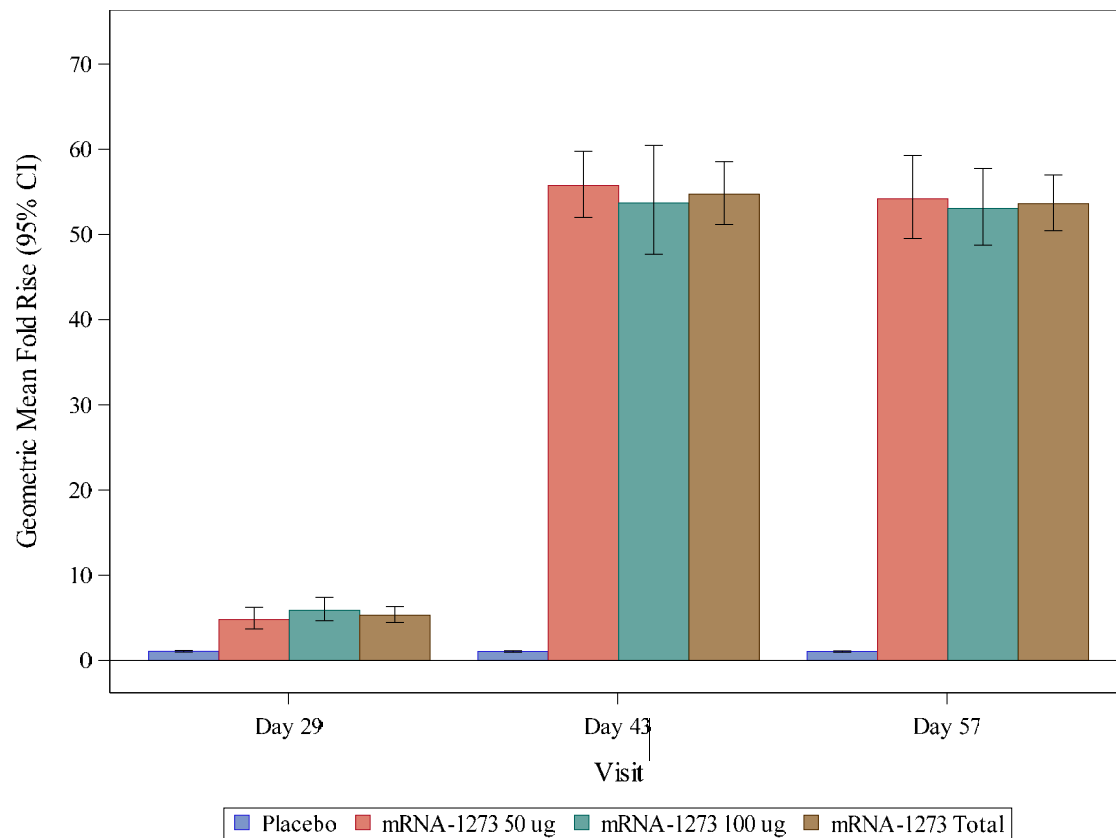
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

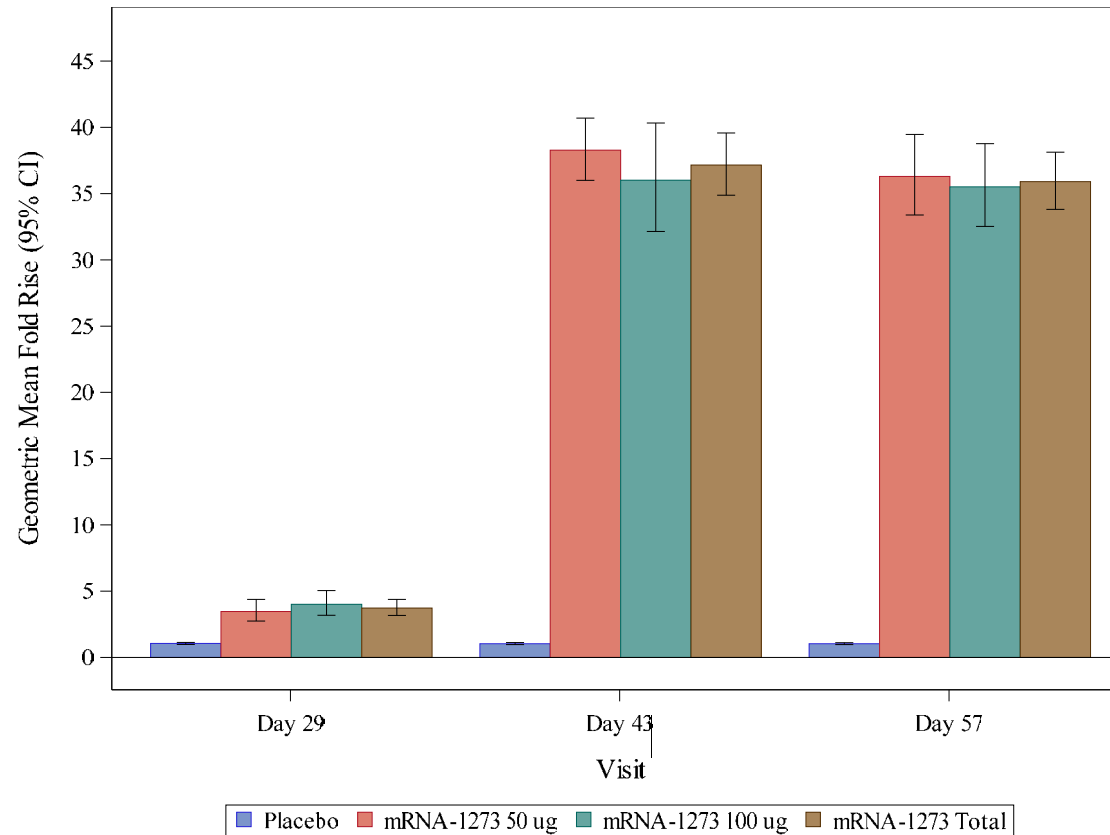
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.1.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (>=55 Years)
Antibody: MN50



Source table: T14.2.2.1.1.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

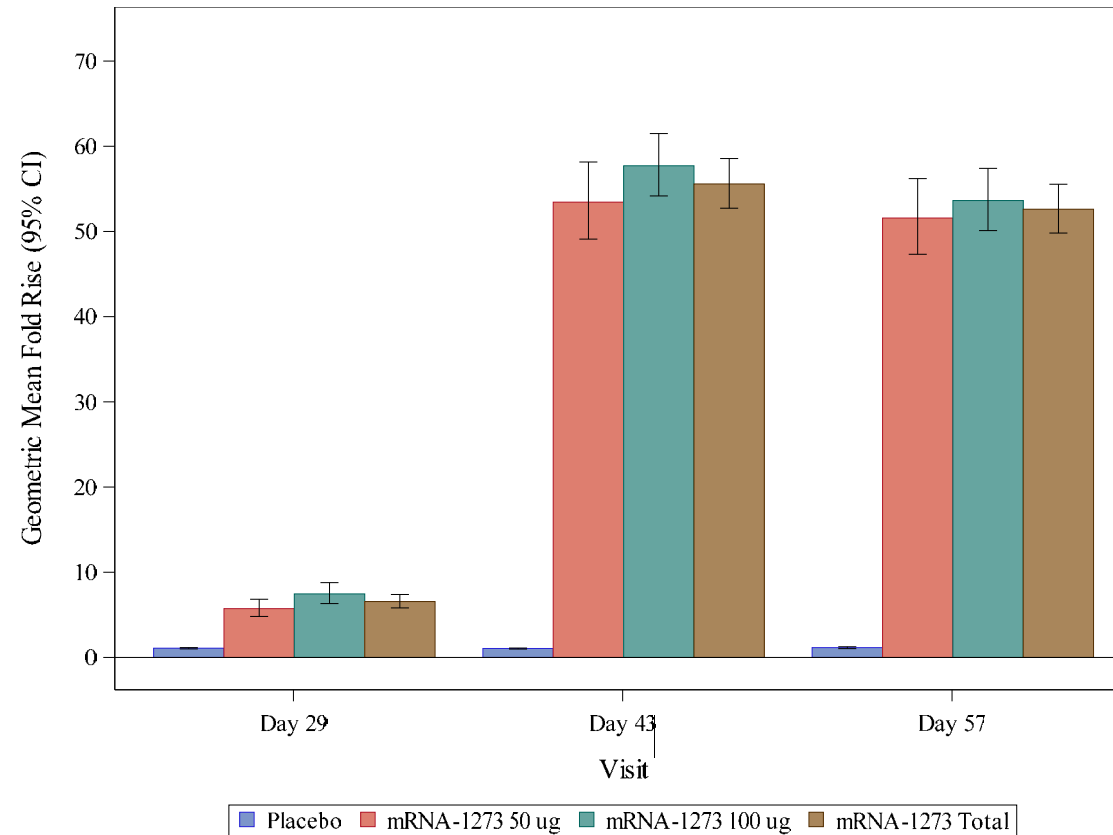
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

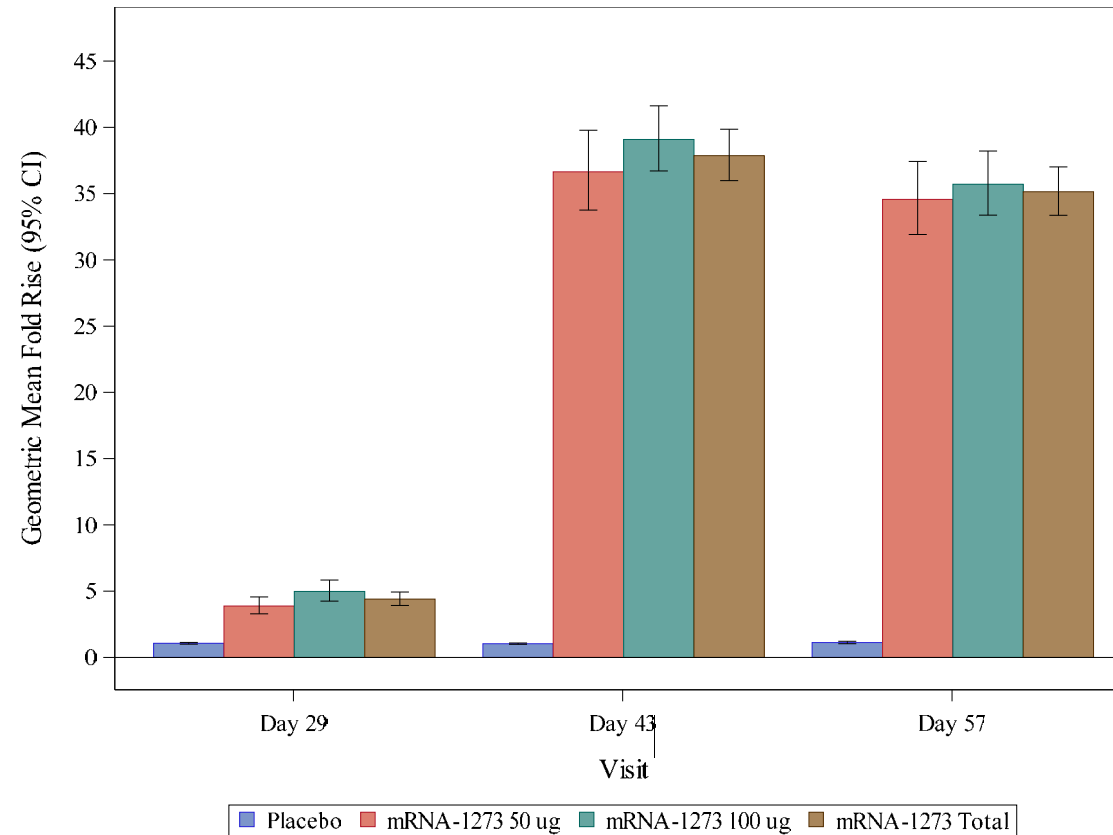
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

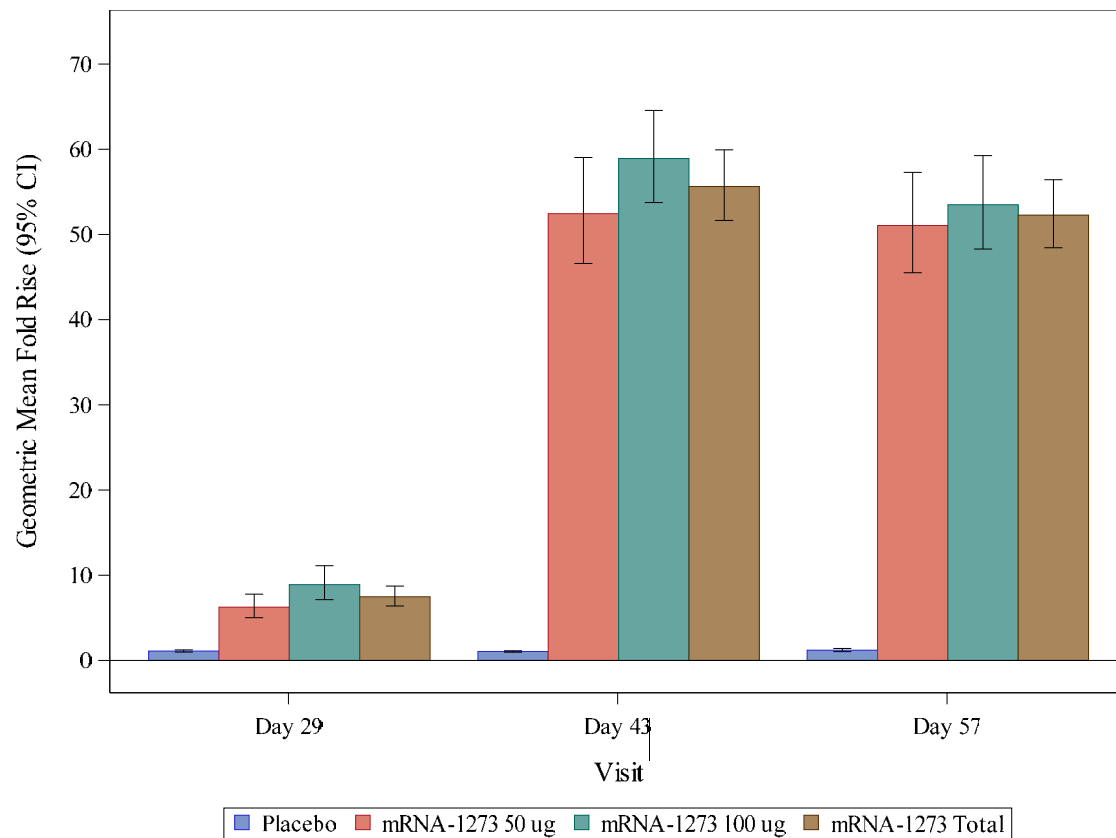
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

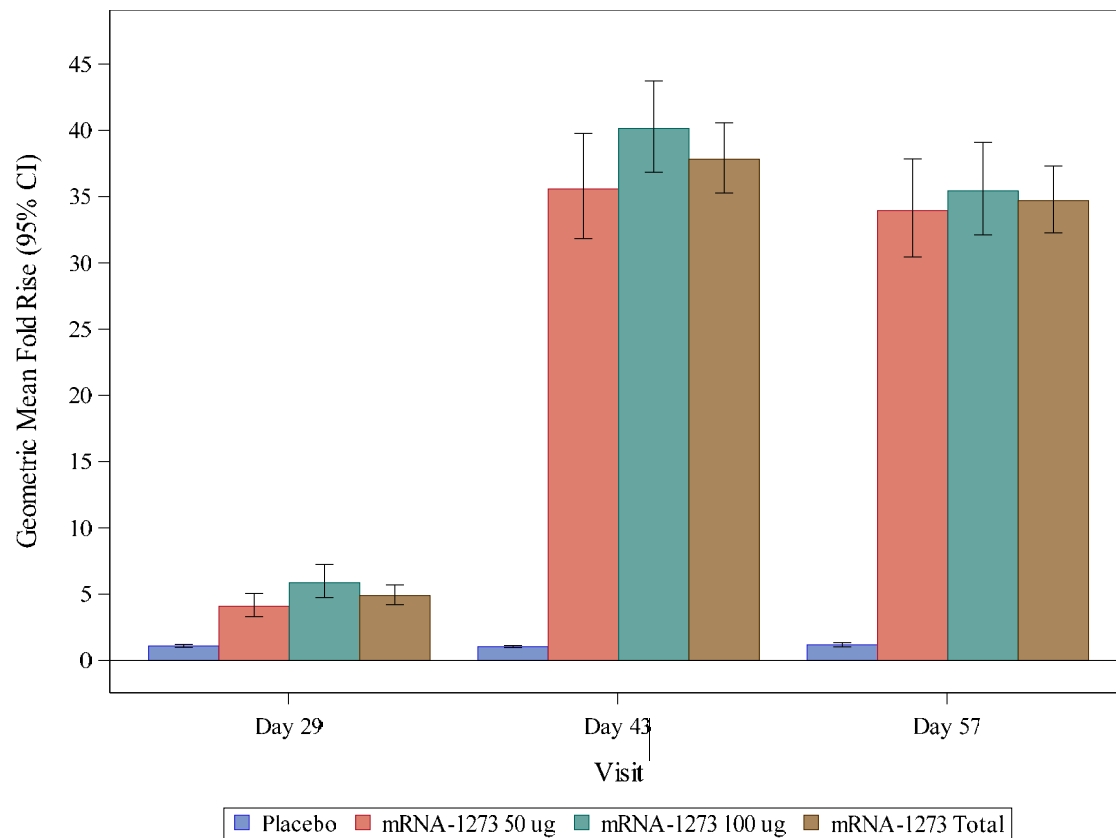
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

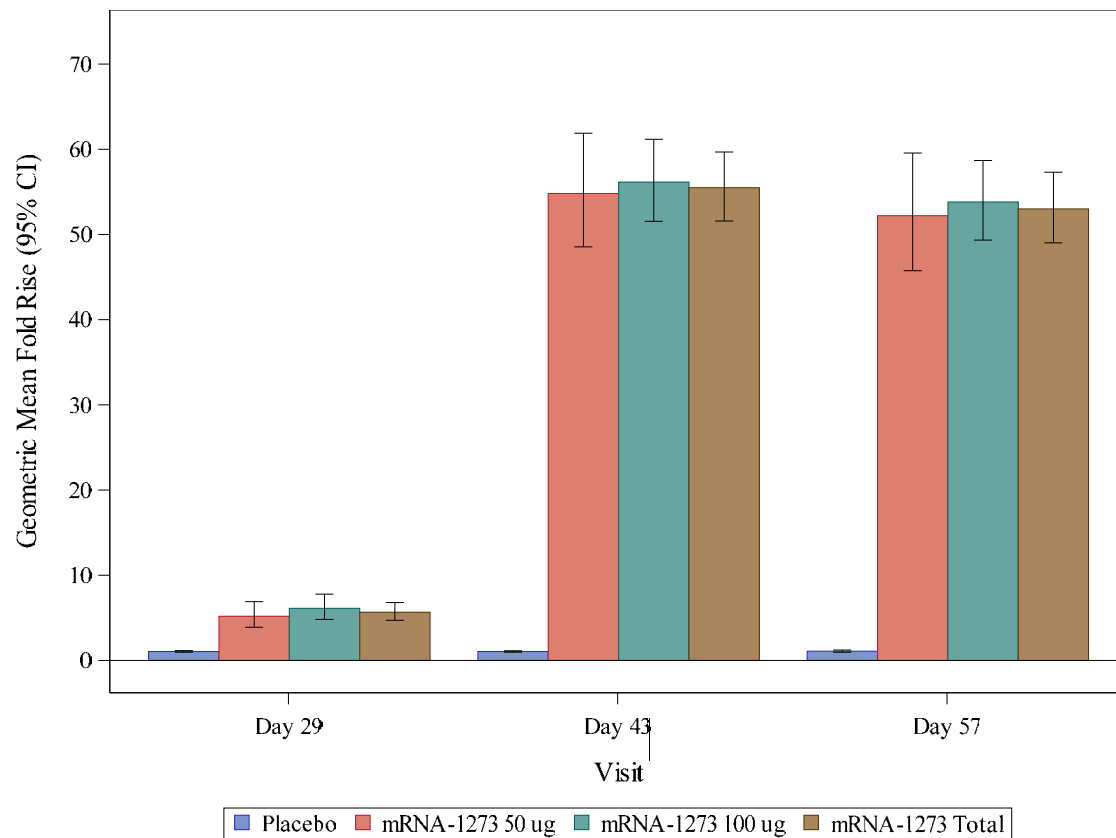
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

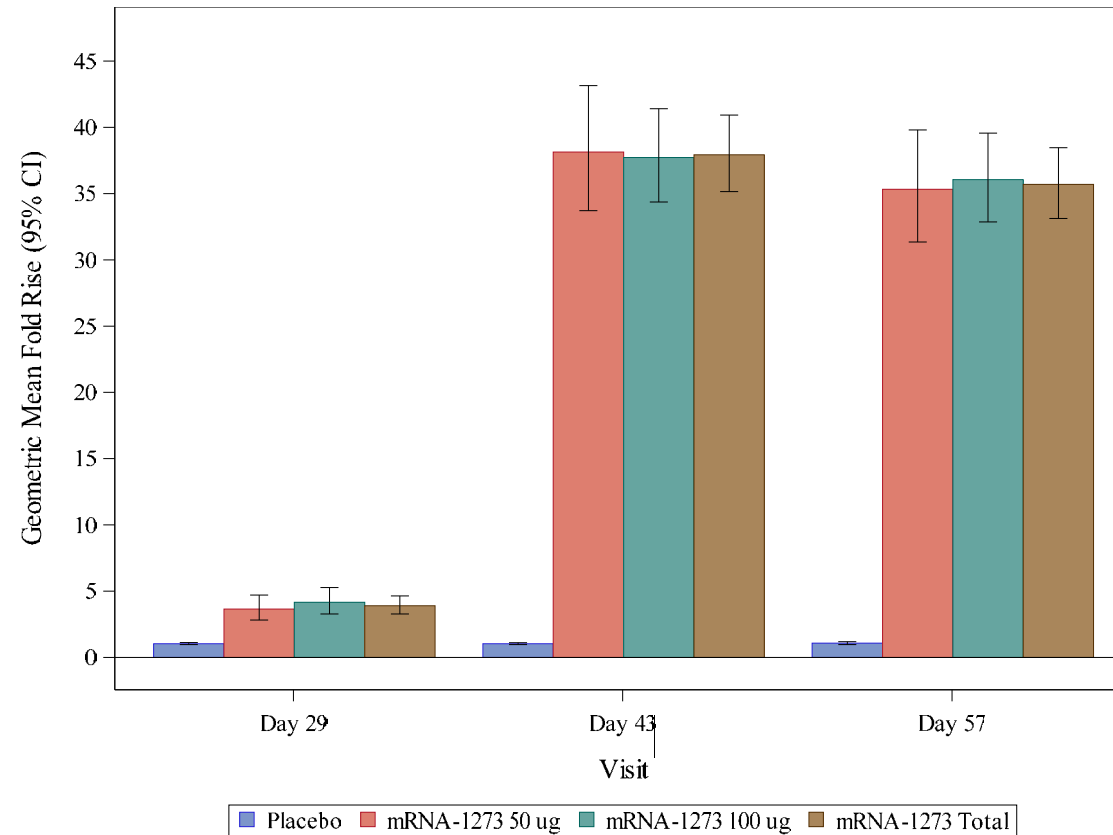
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.1
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (>=55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.1

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

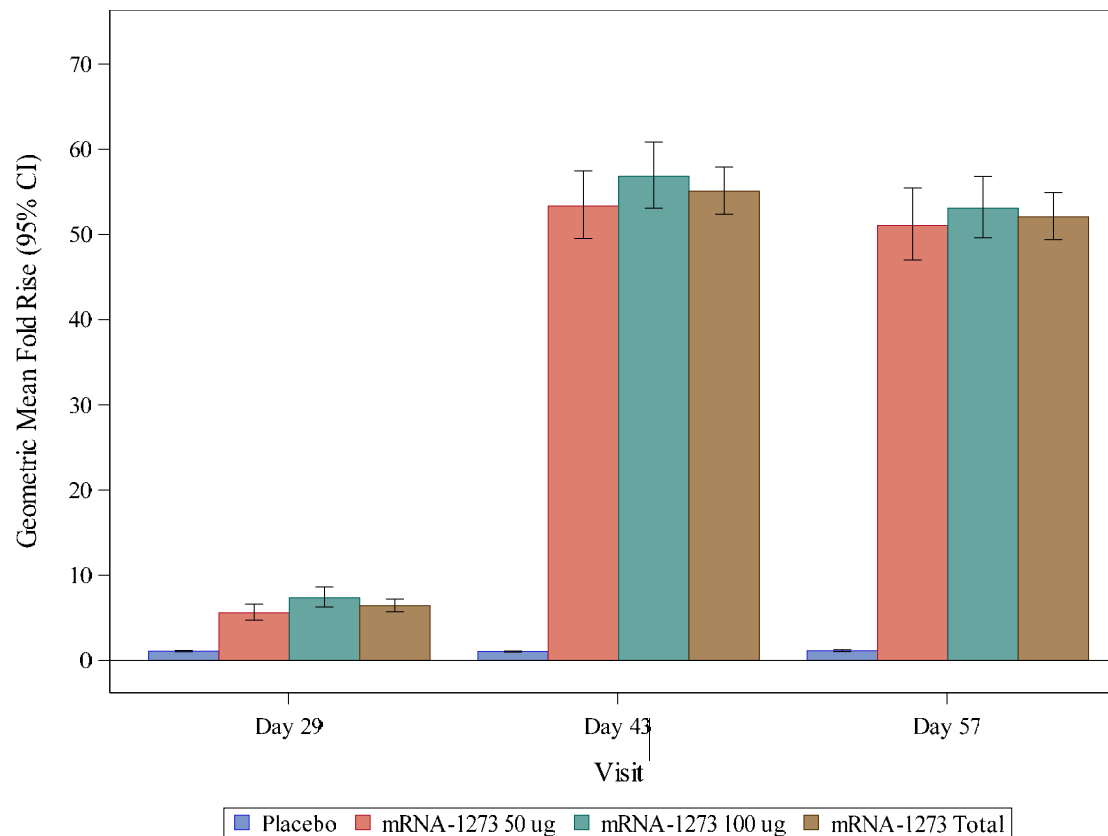
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050201.sas 19NOV2020 05:15 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

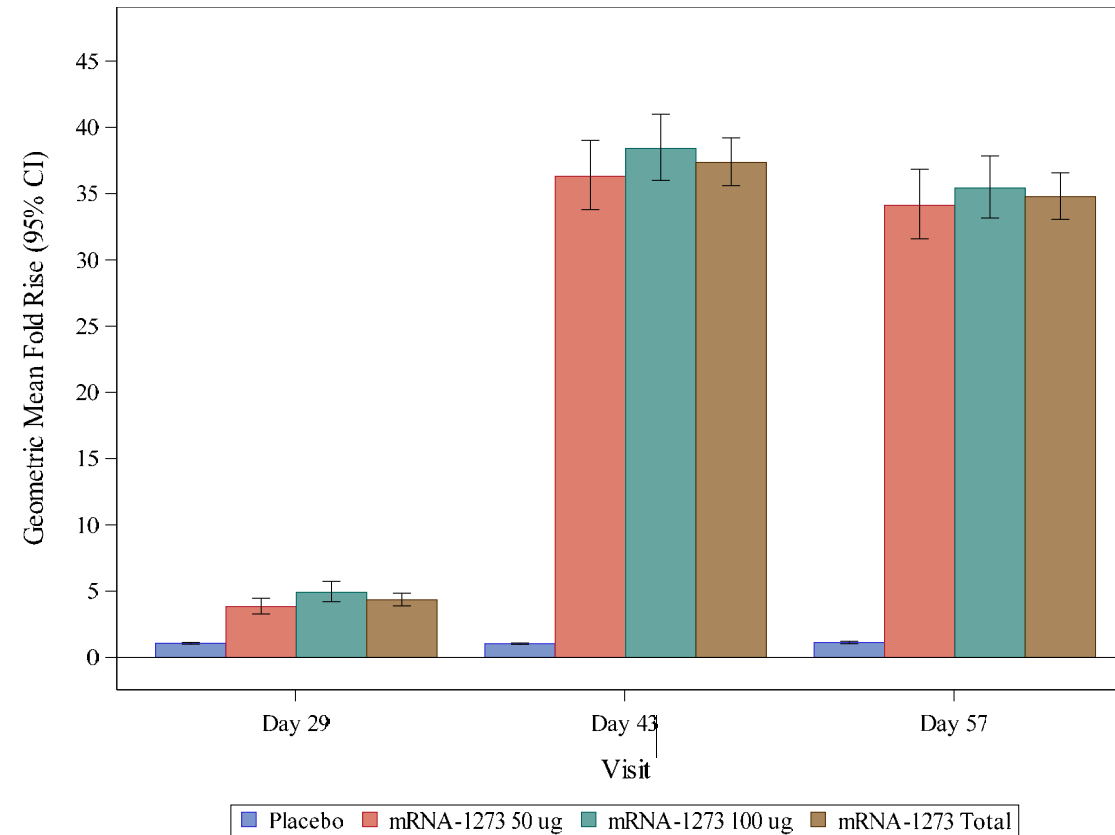
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

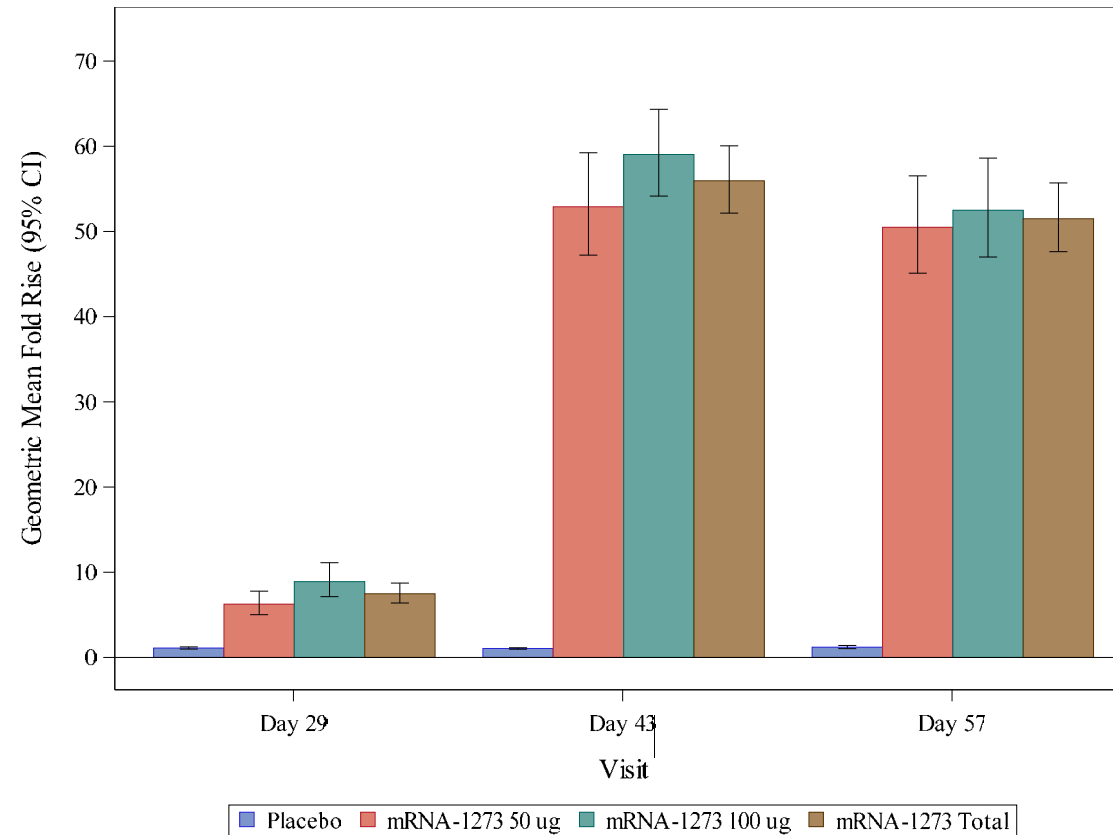
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

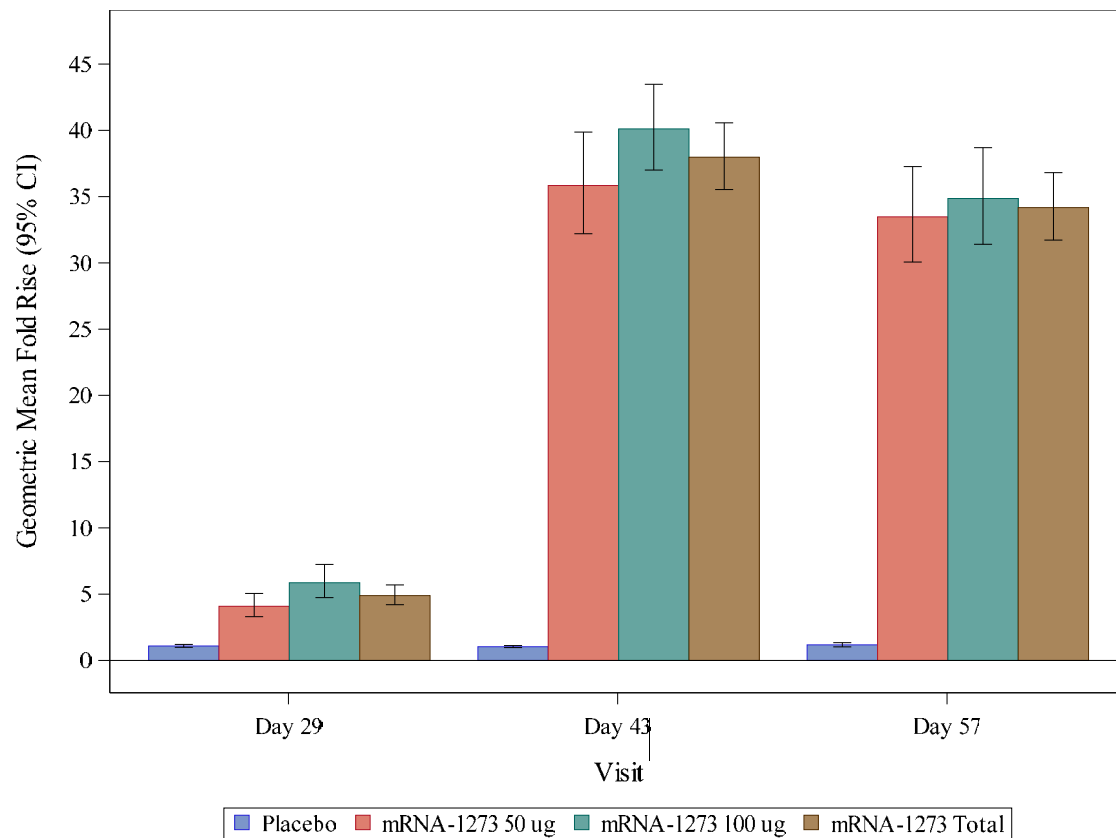
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

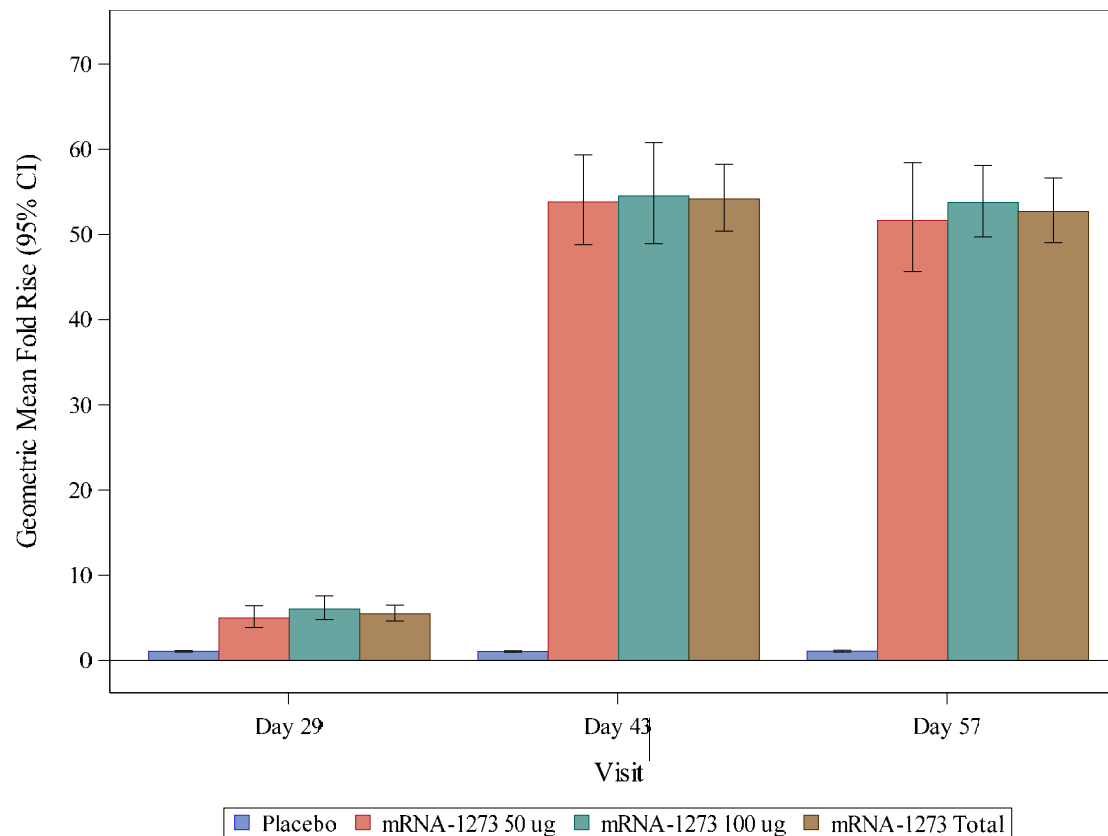
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

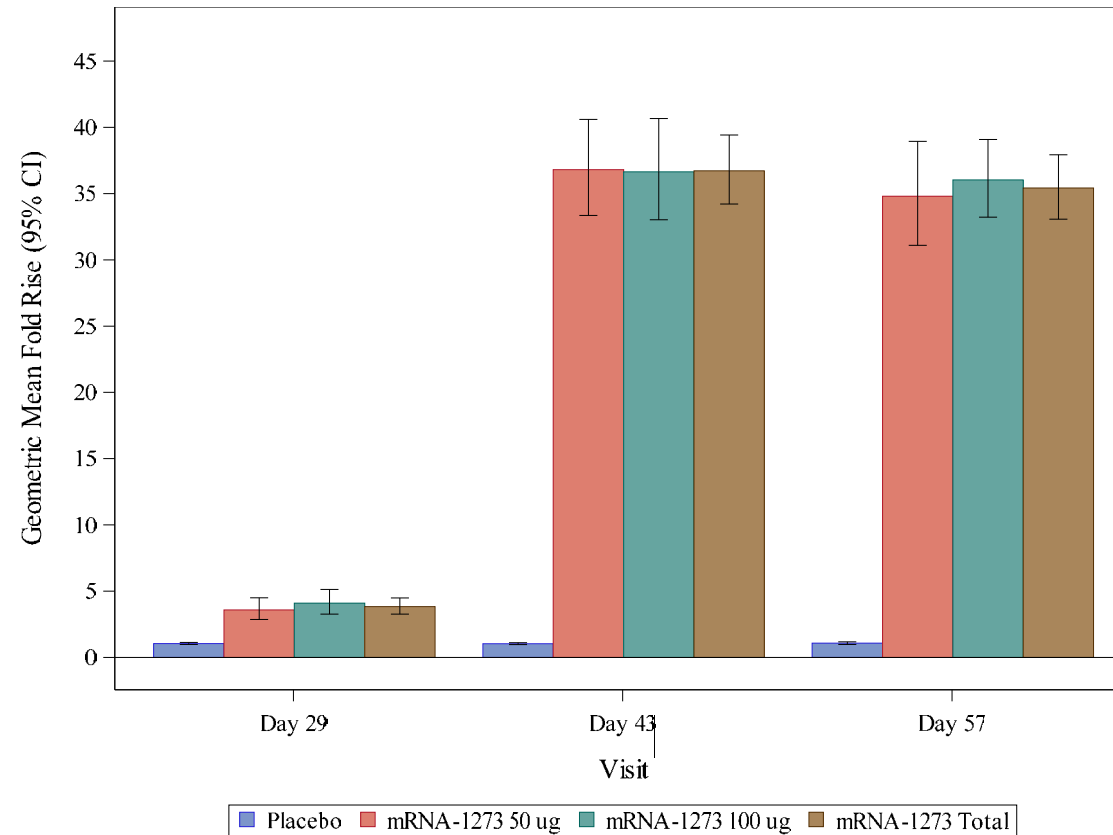
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.5.2.2
Geometric Mean Fold Rise of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (>=55 Years)
Antibody: MN50



Source table: T14.2.2.1.2.2

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

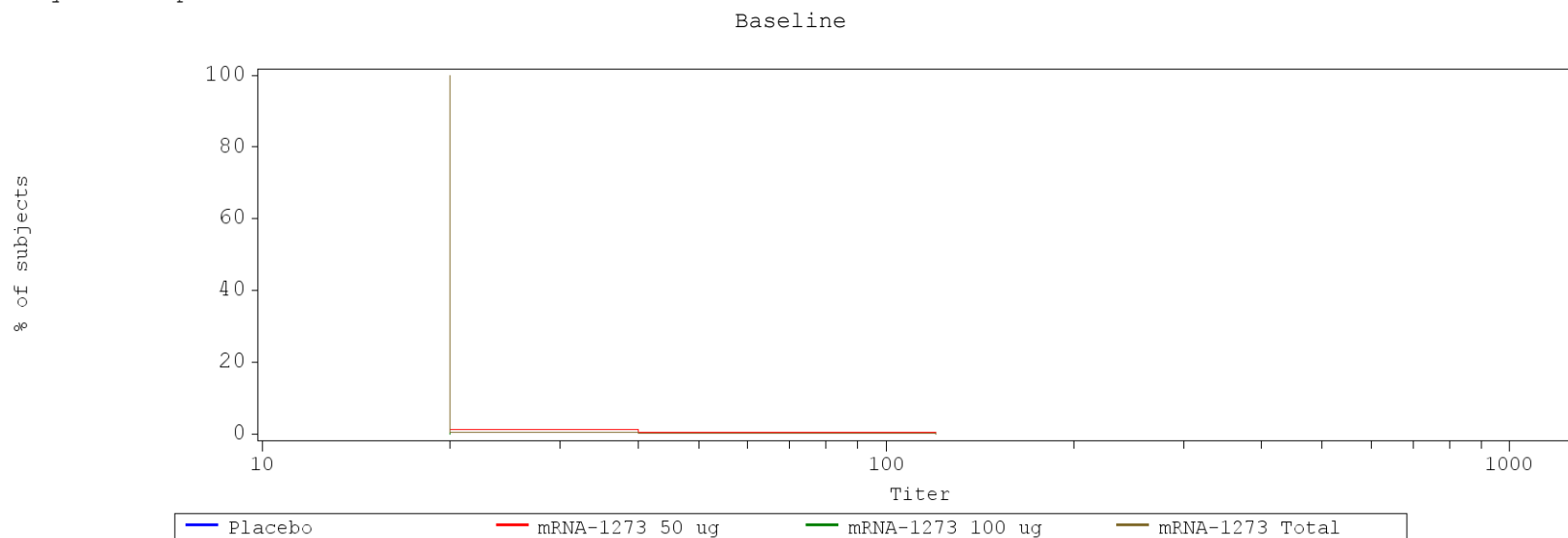
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402050202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

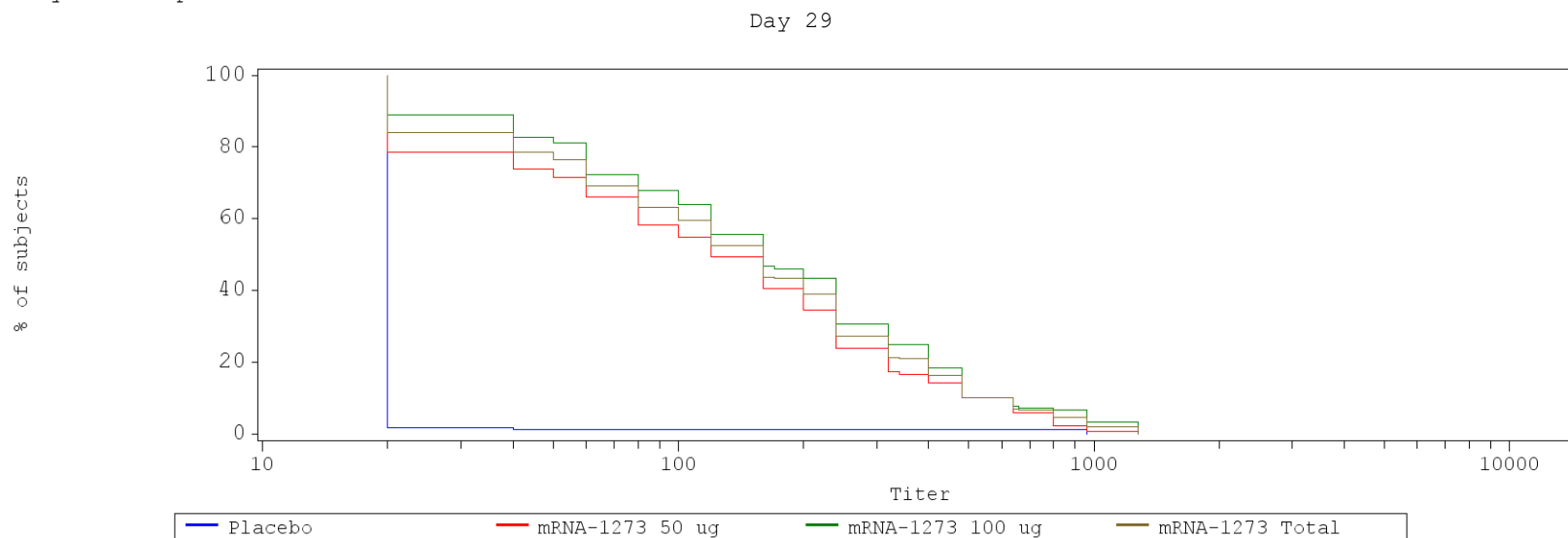
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060101.sas 19NOV2020 00:08 Database Lock Date: 05NOV2020

Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

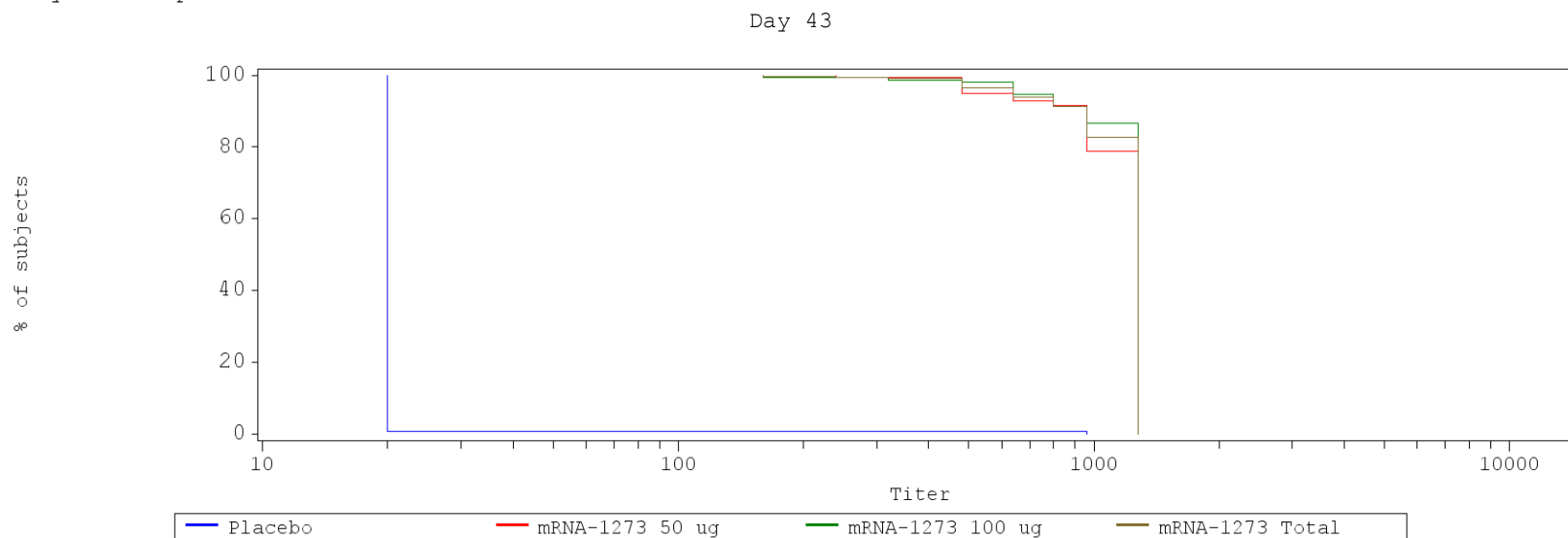
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

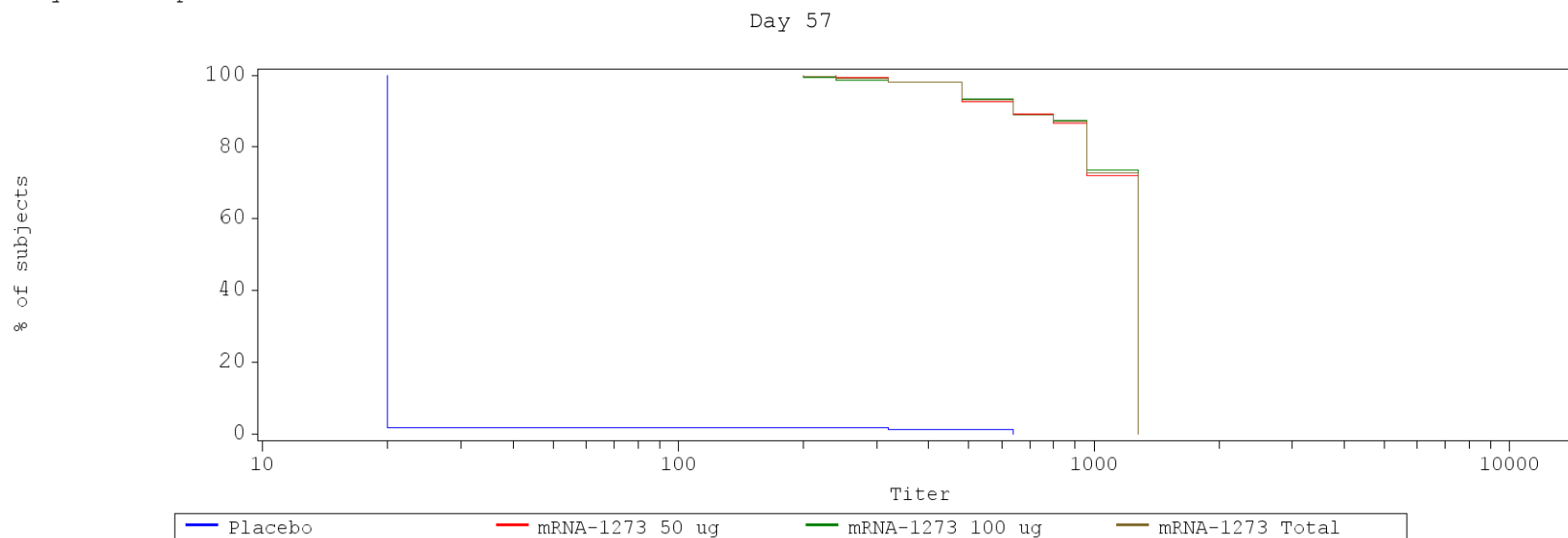
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

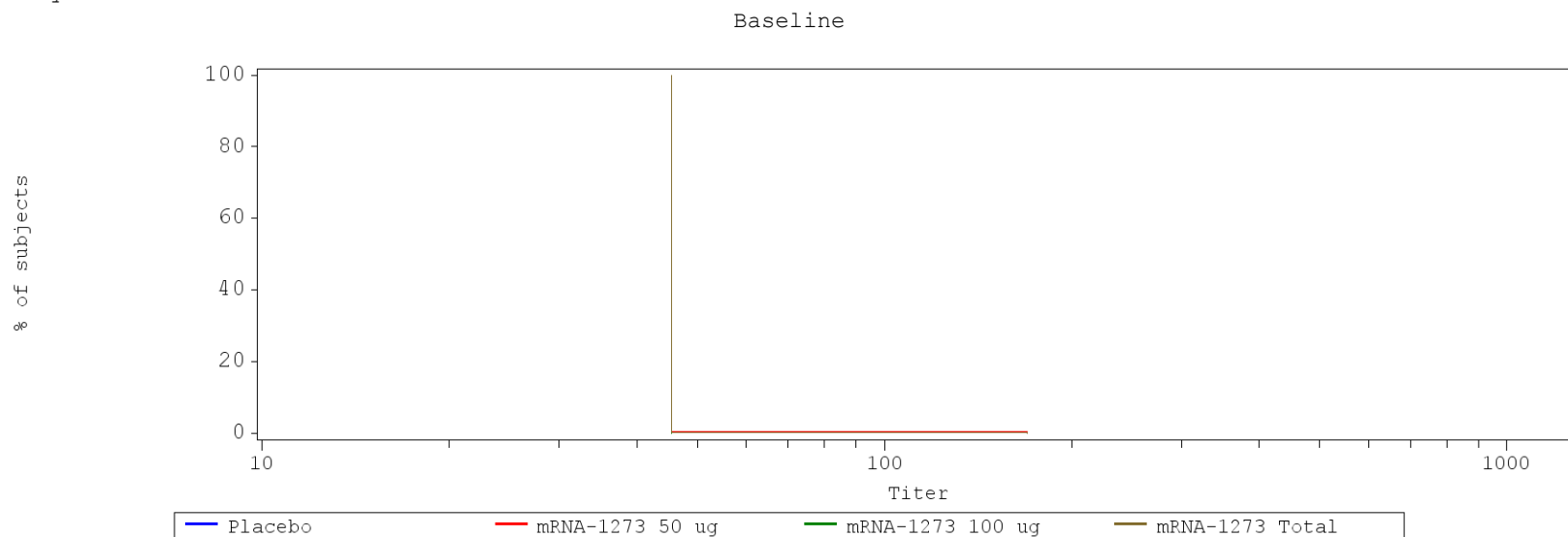
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

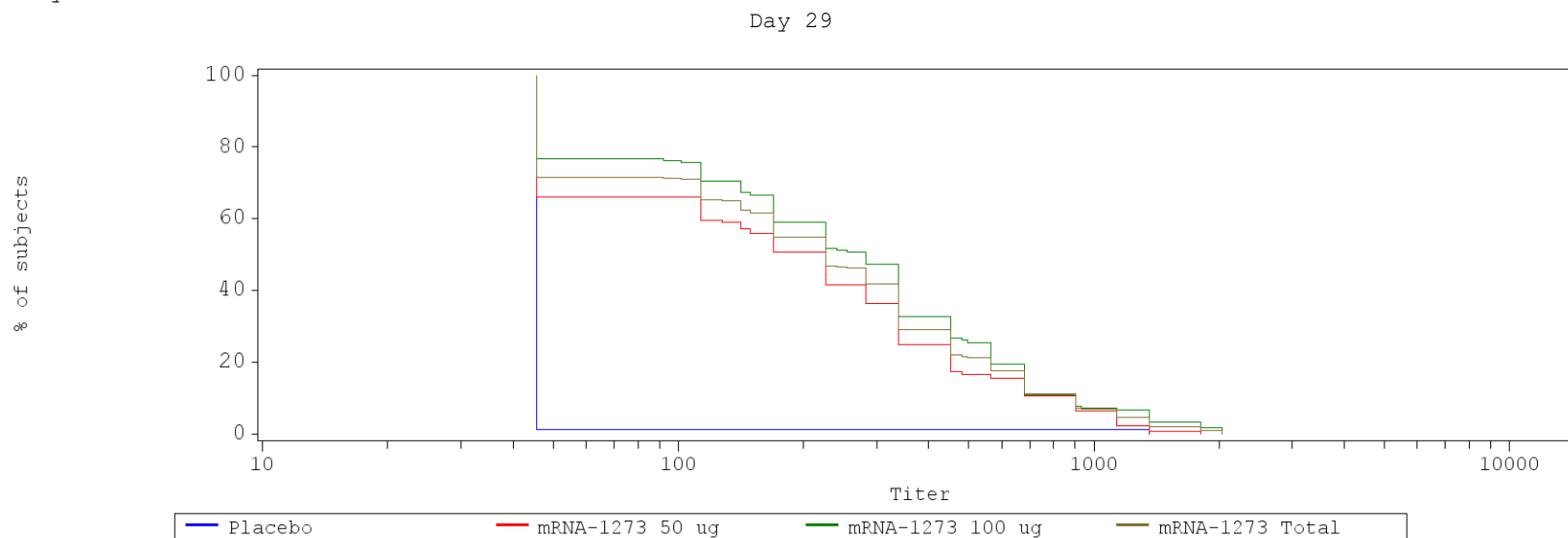
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

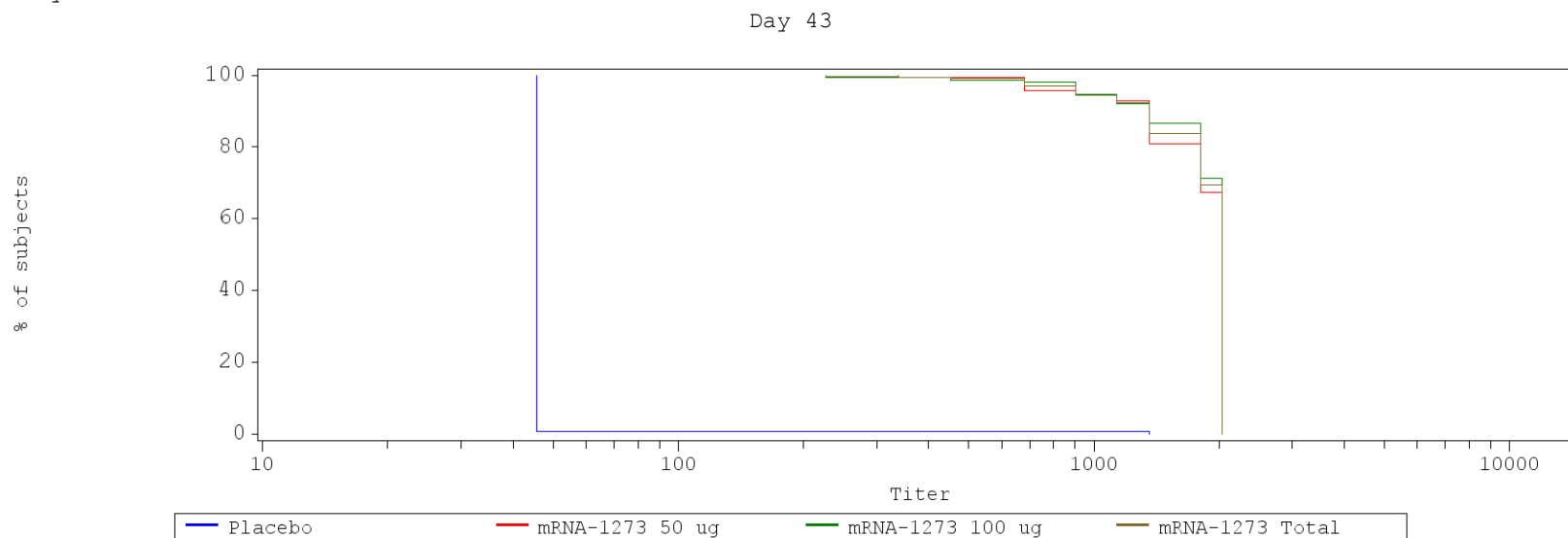
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

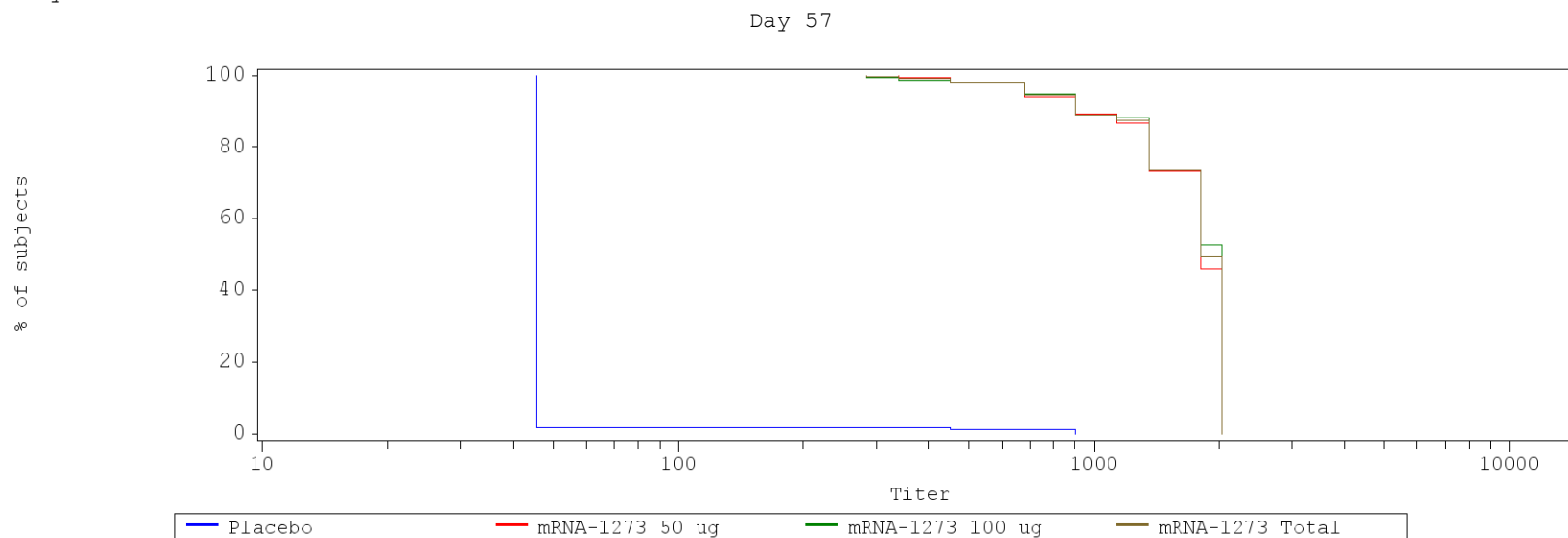
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

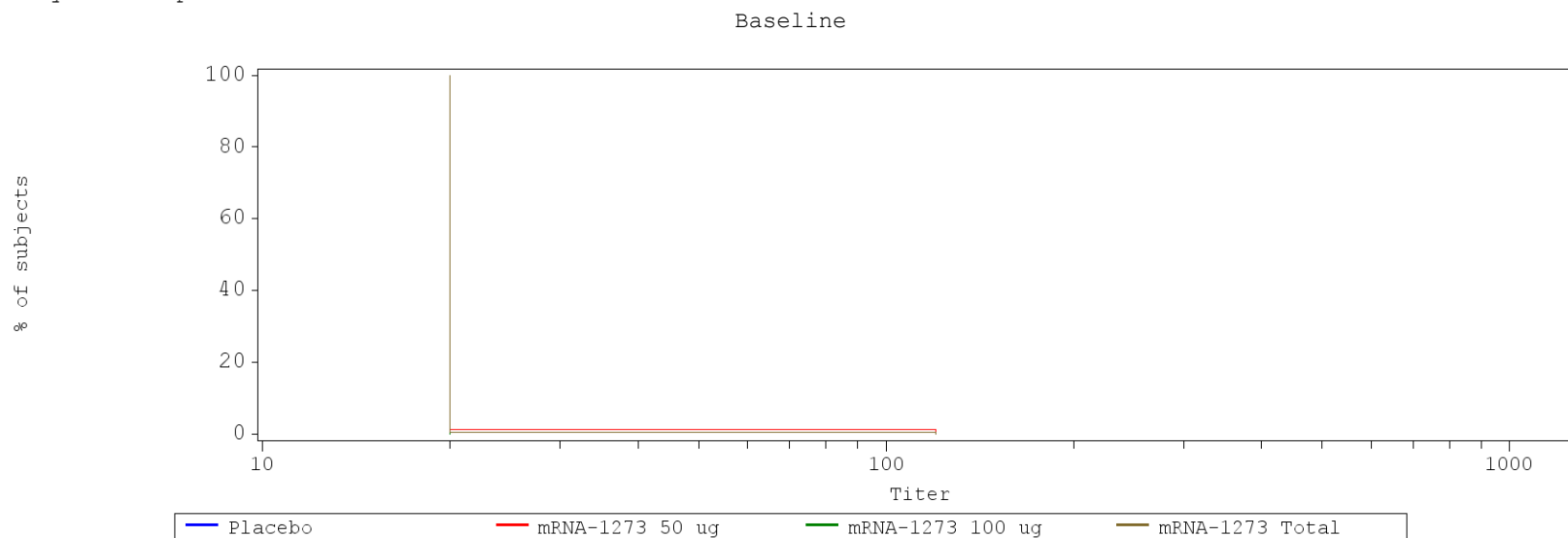
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

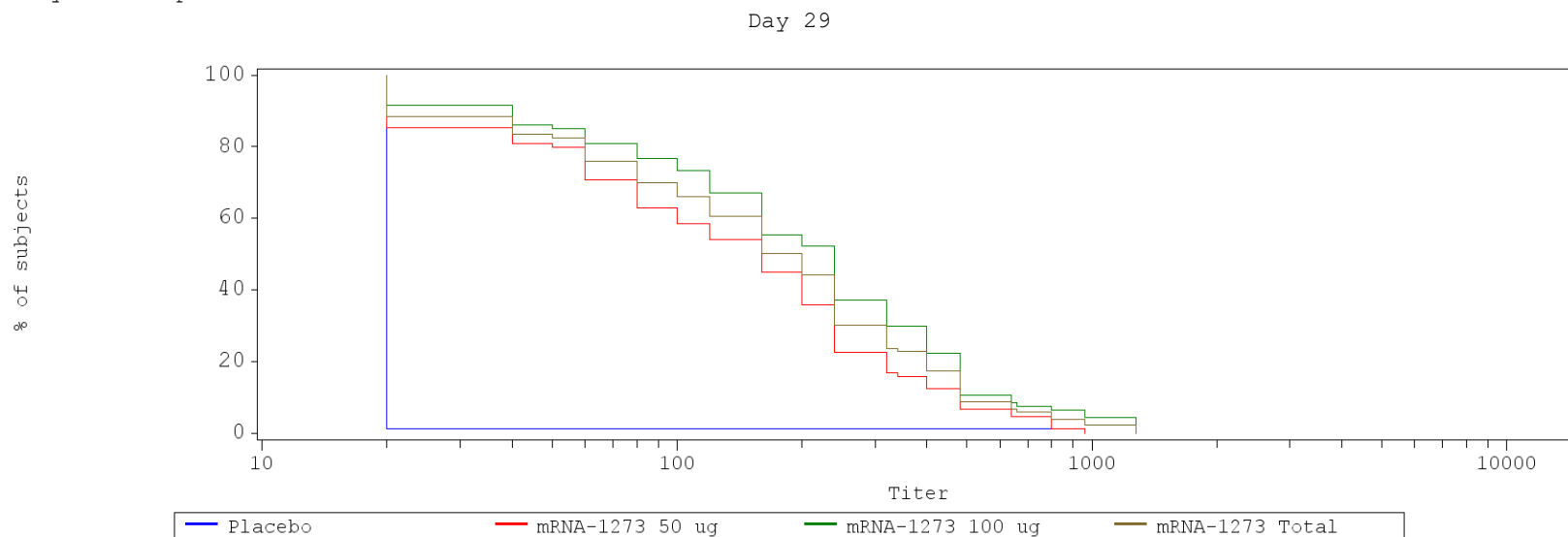
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

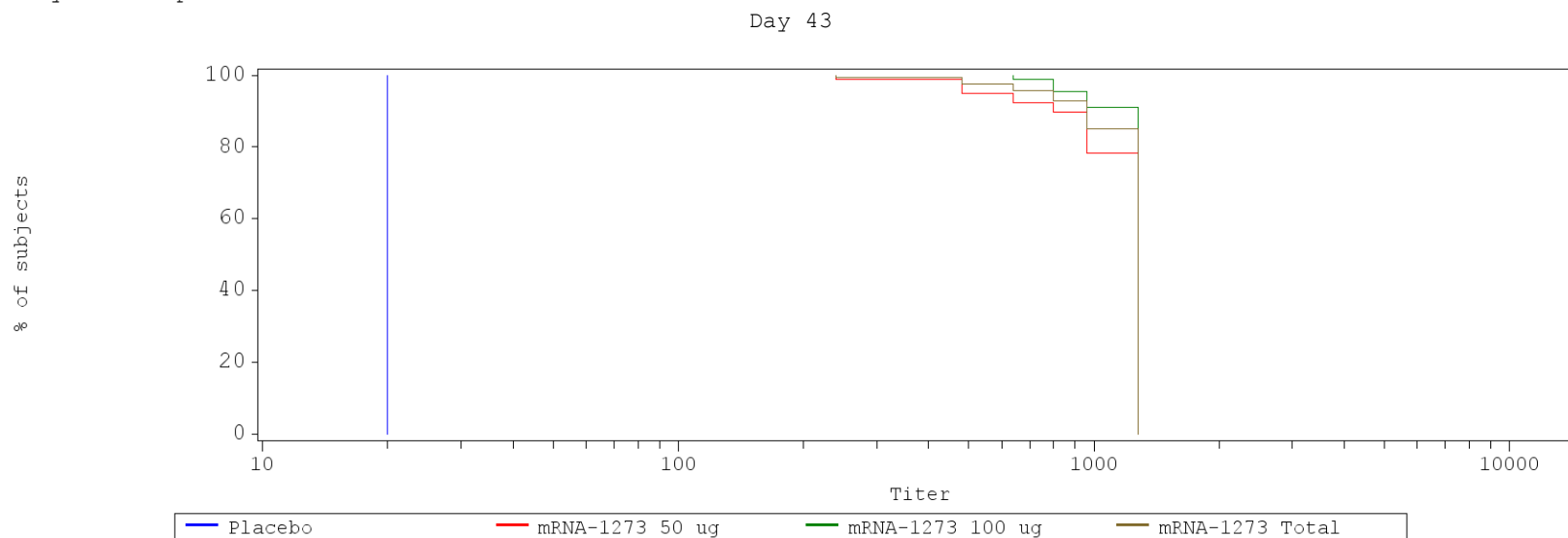
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

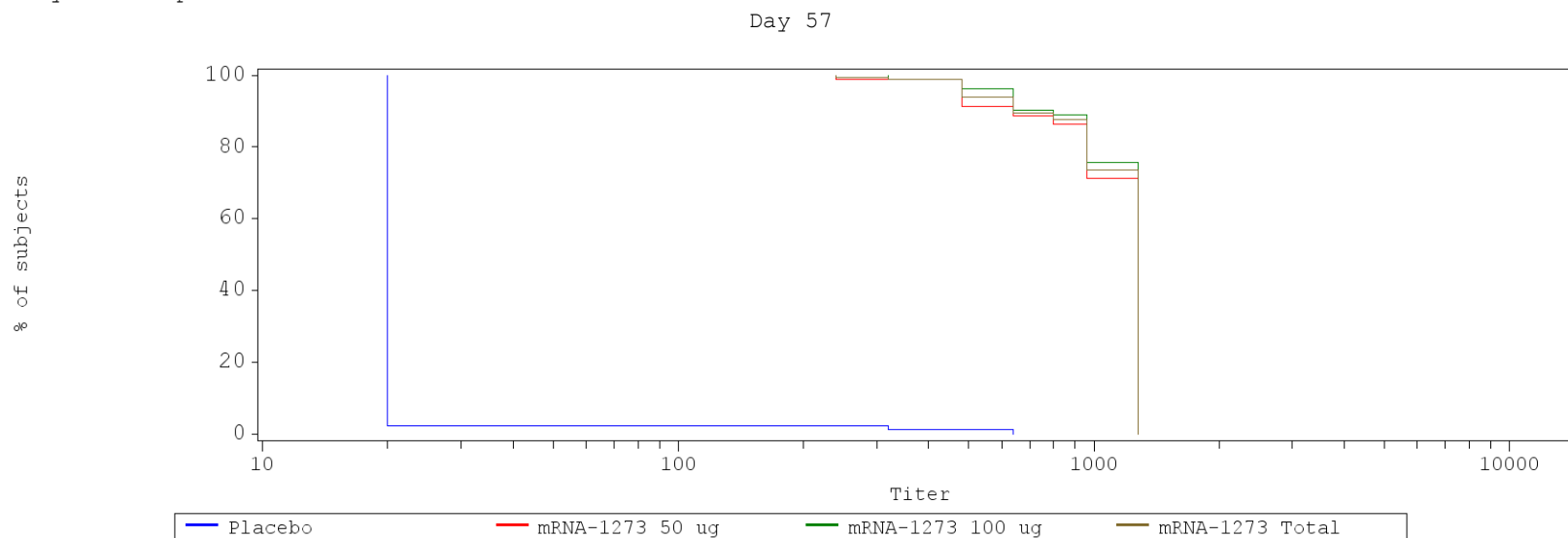
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

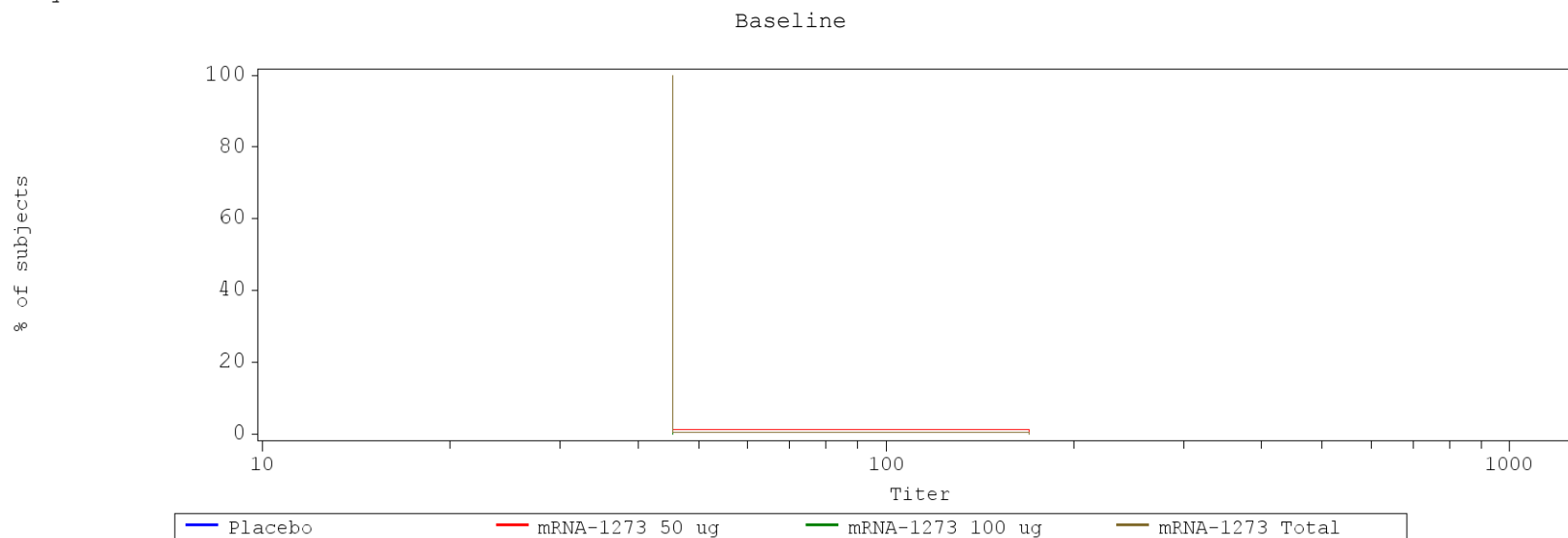
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

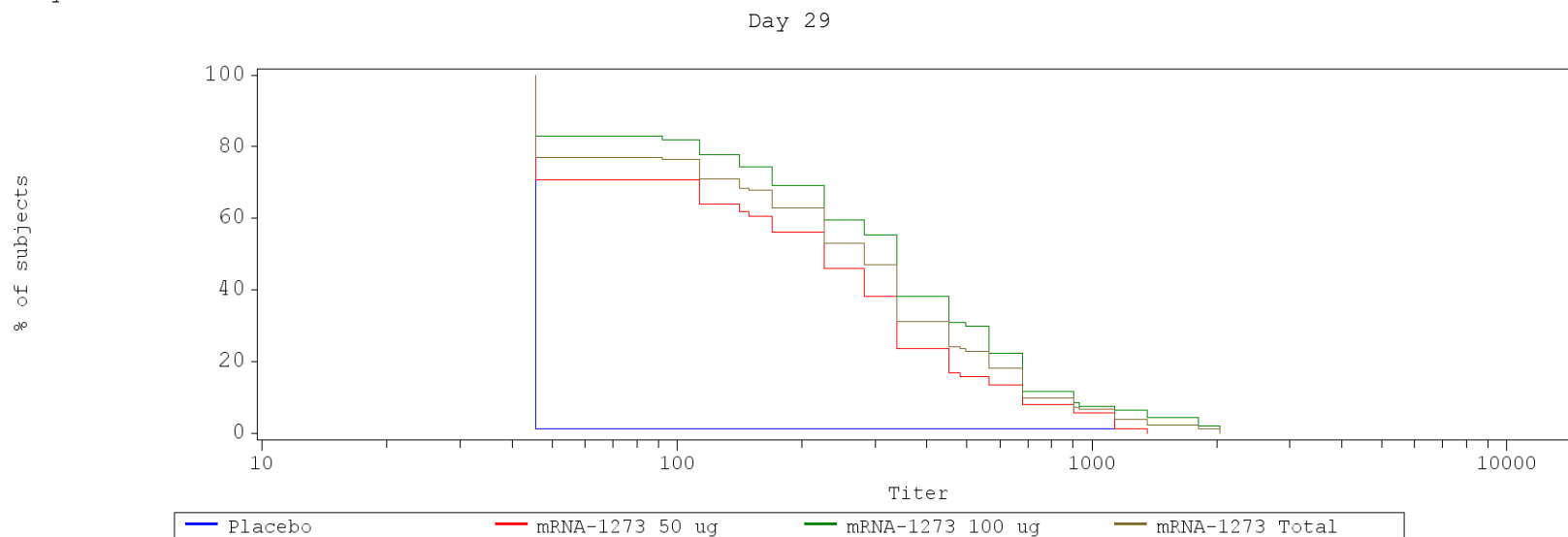
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

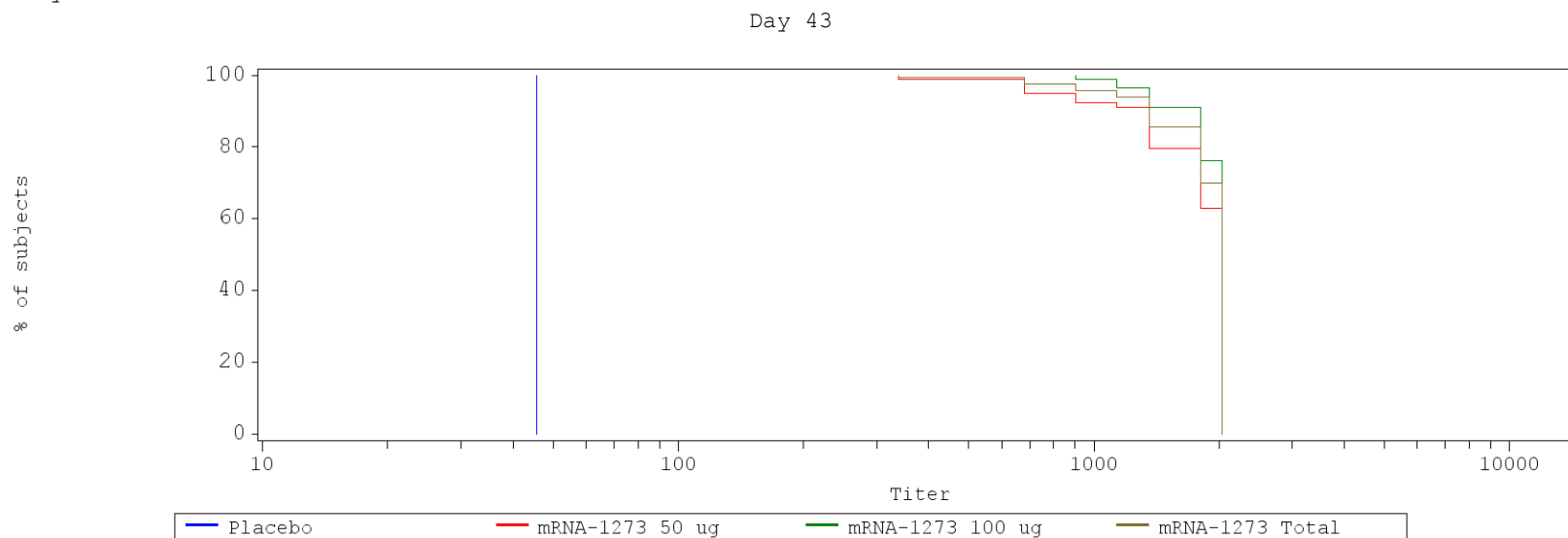
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

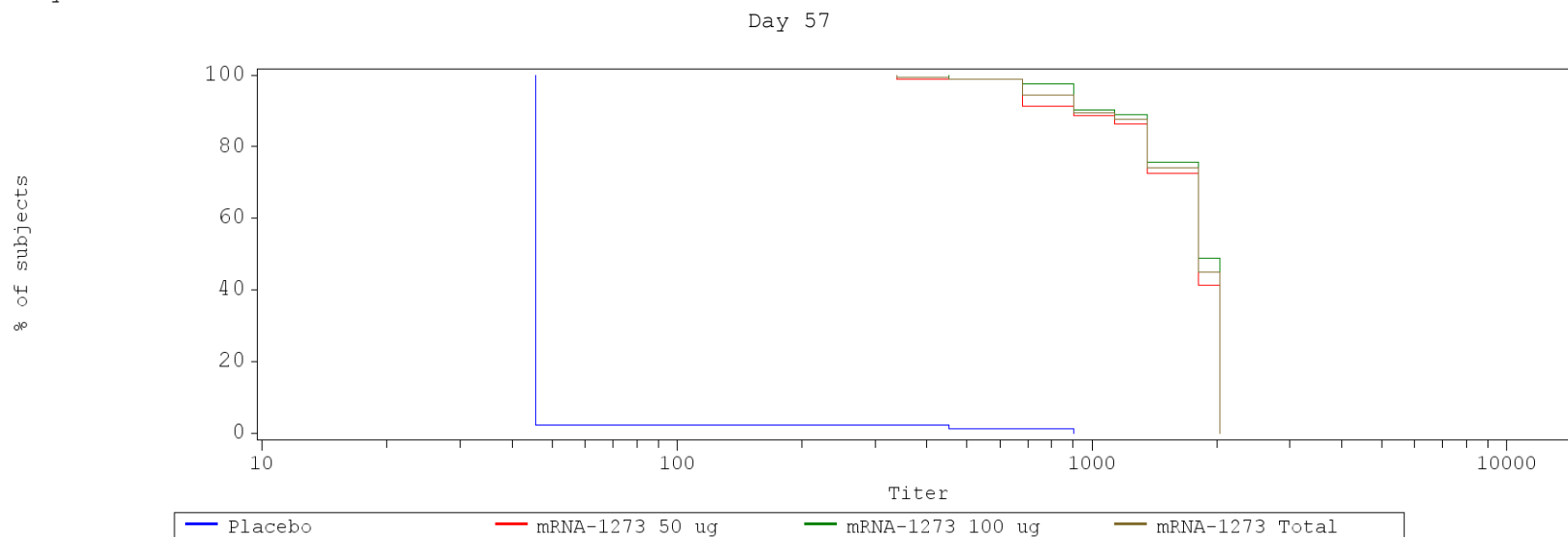
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

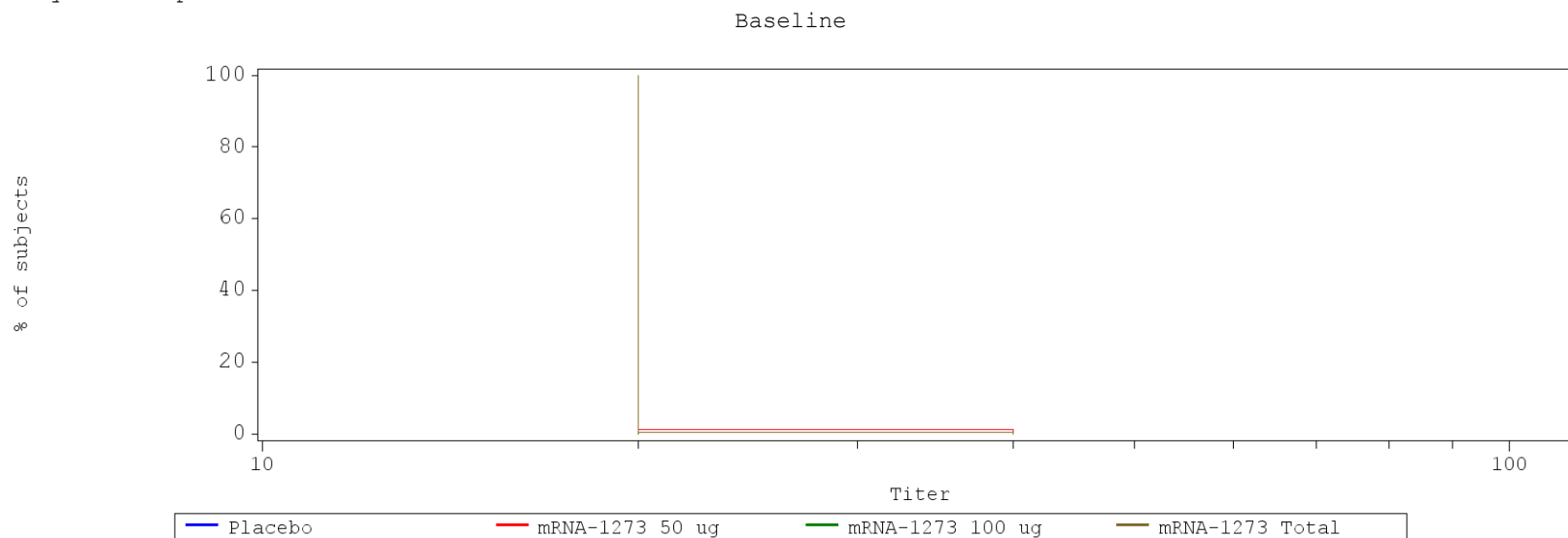
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

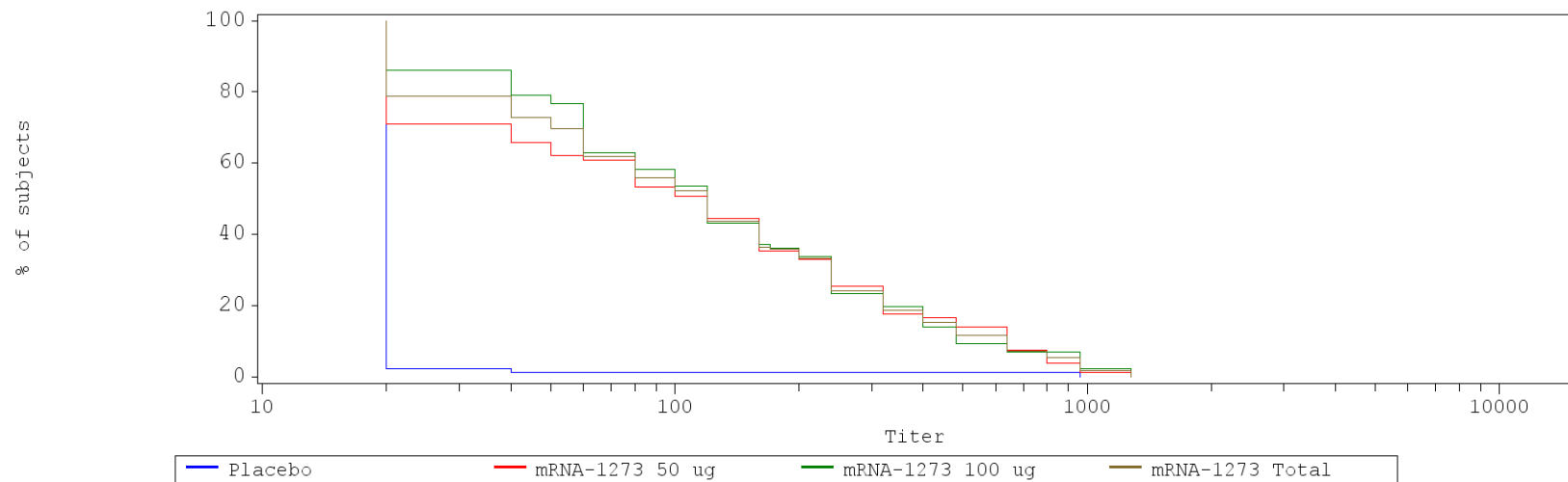
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer

Day 29



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

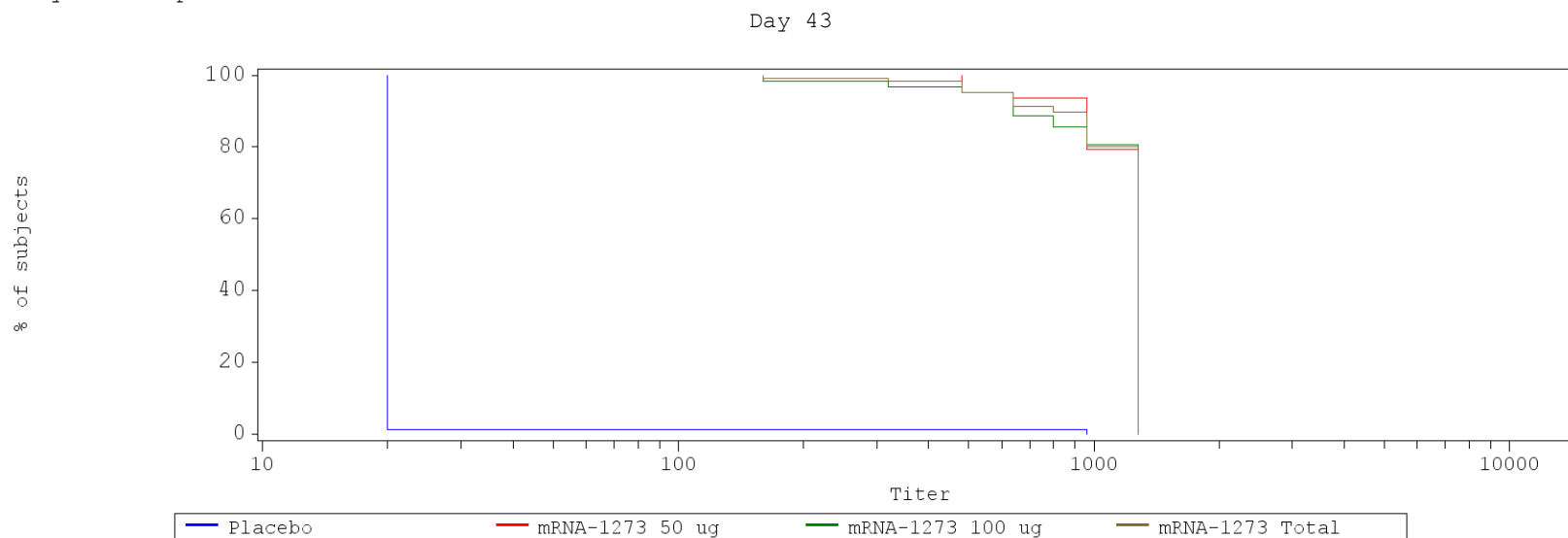
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

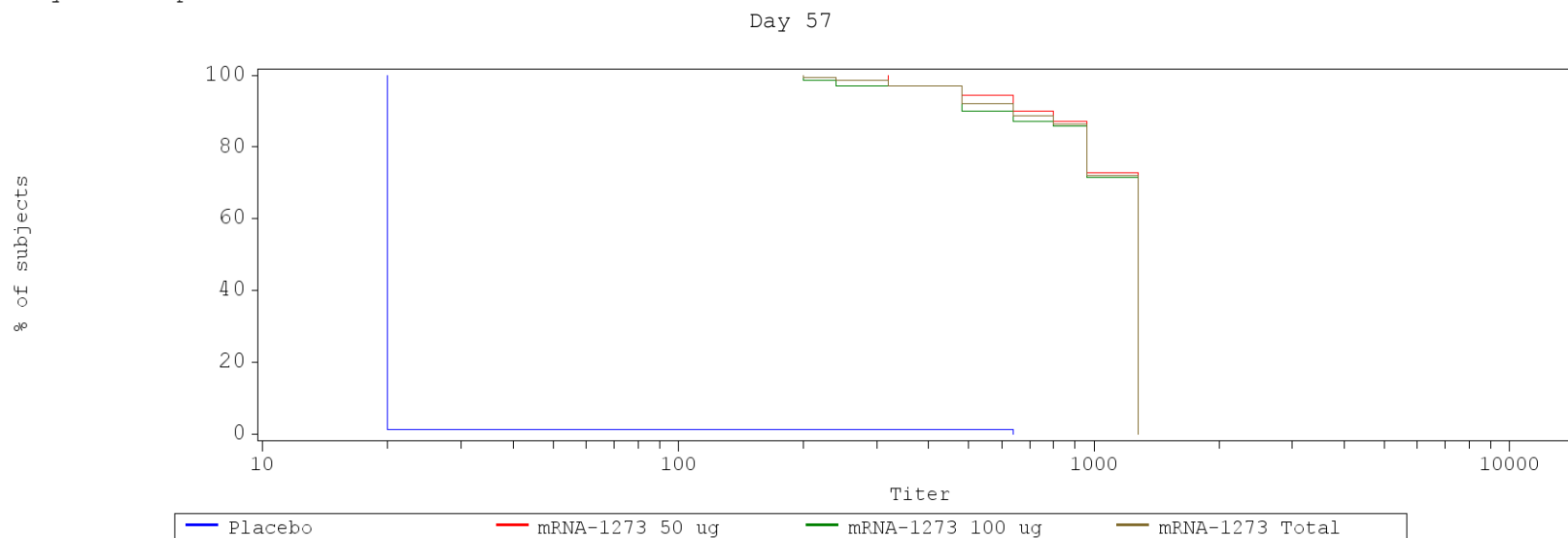
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

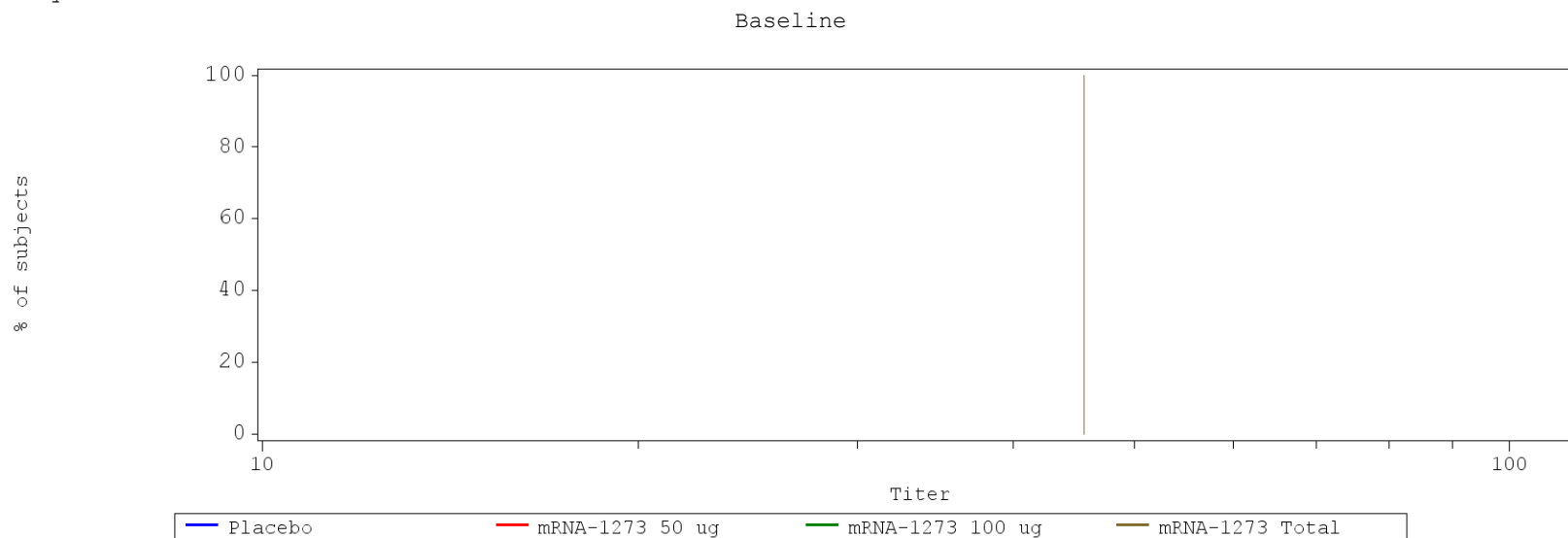
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

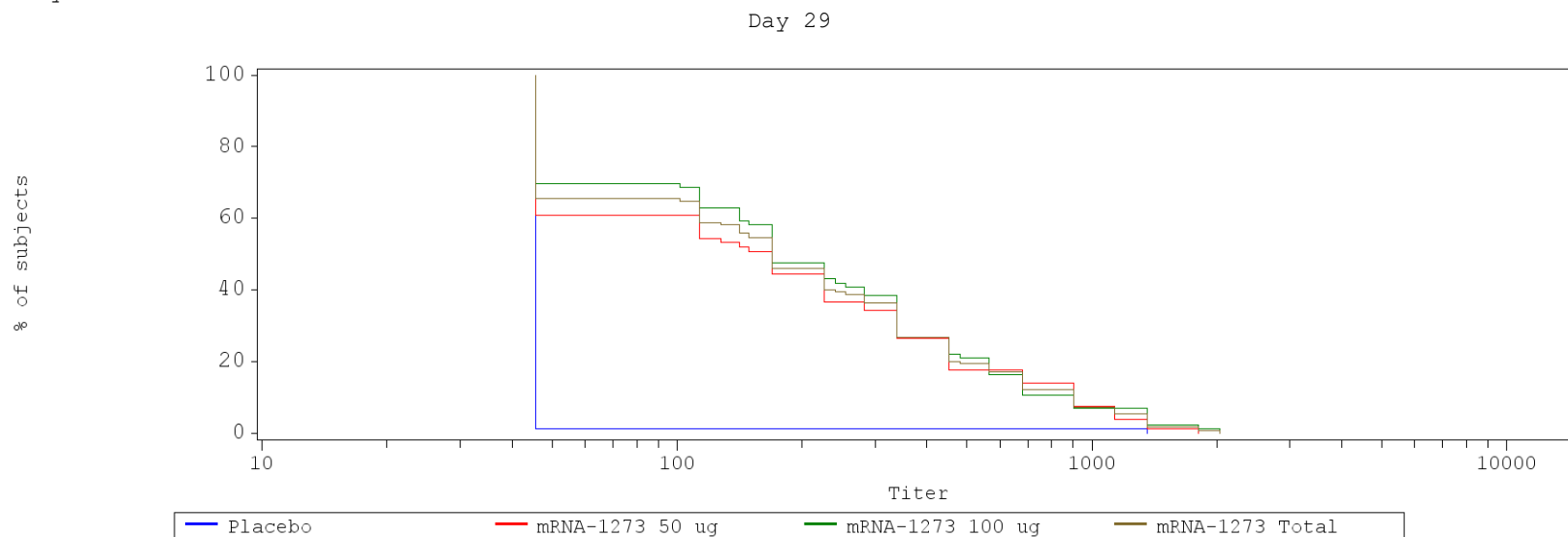
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

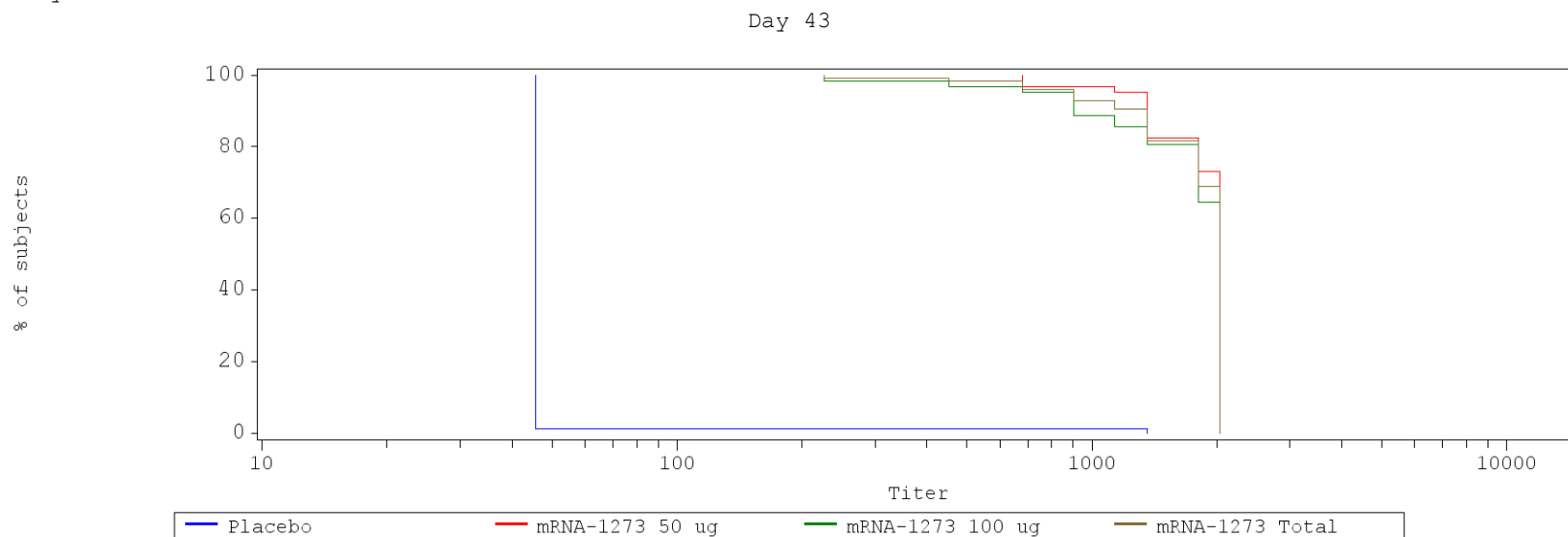
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

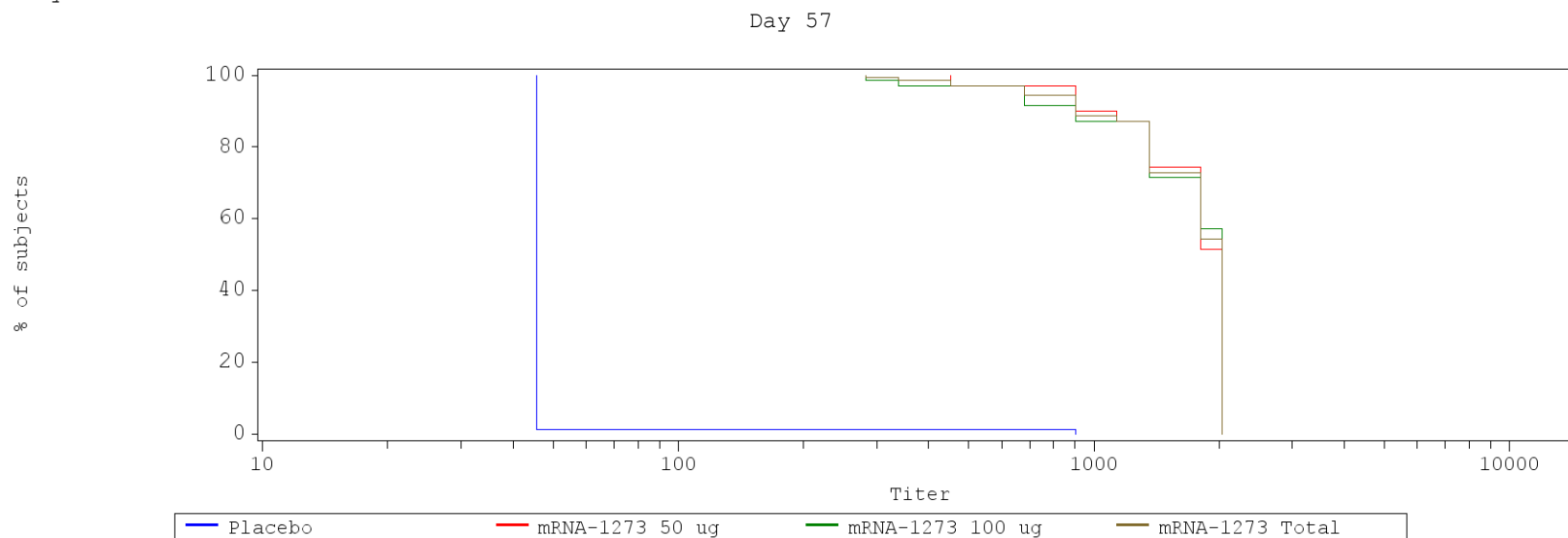
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

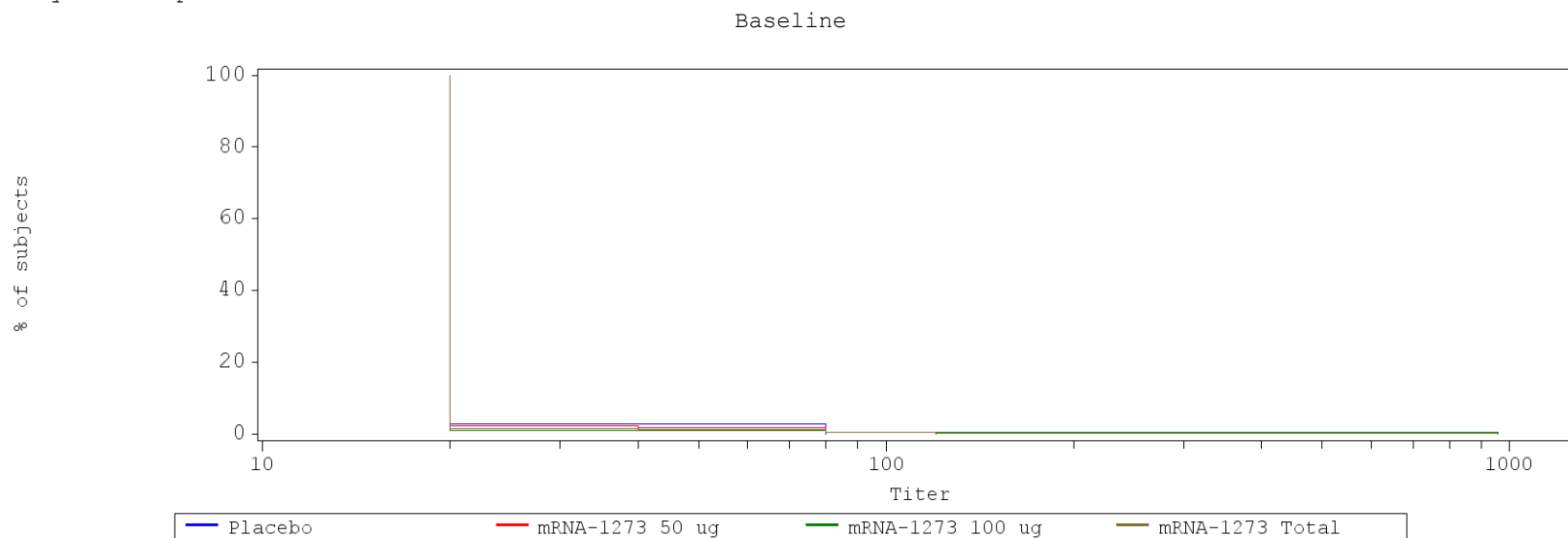
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

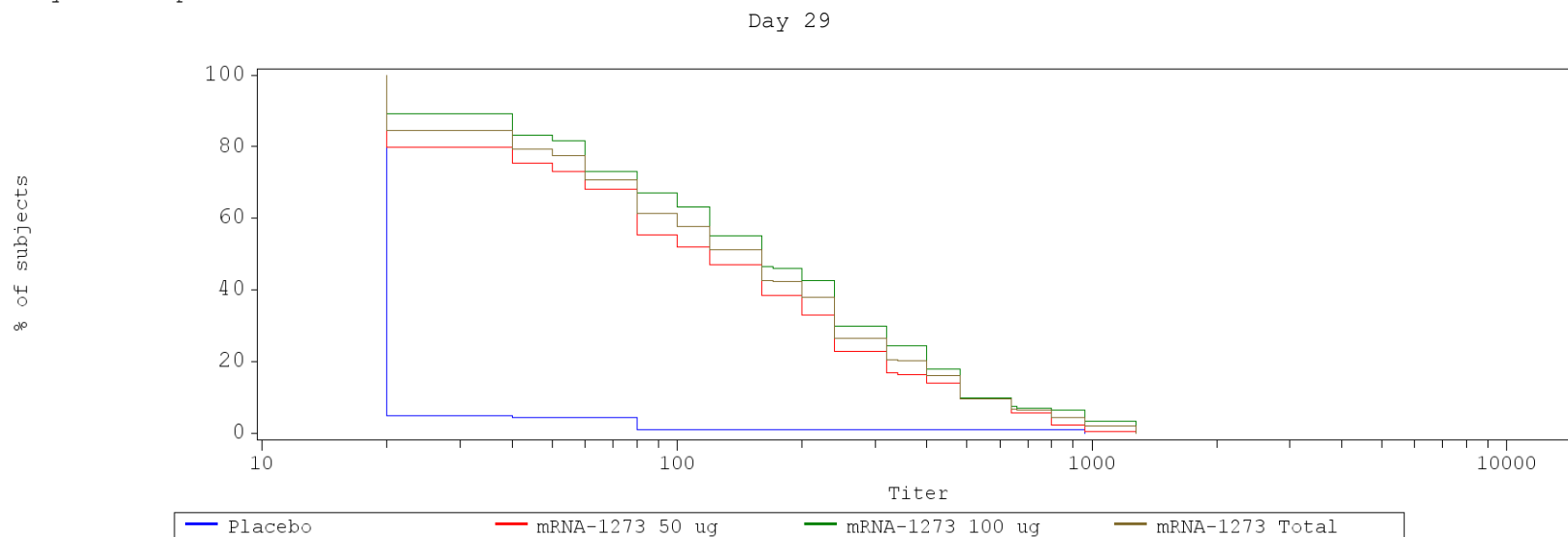
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

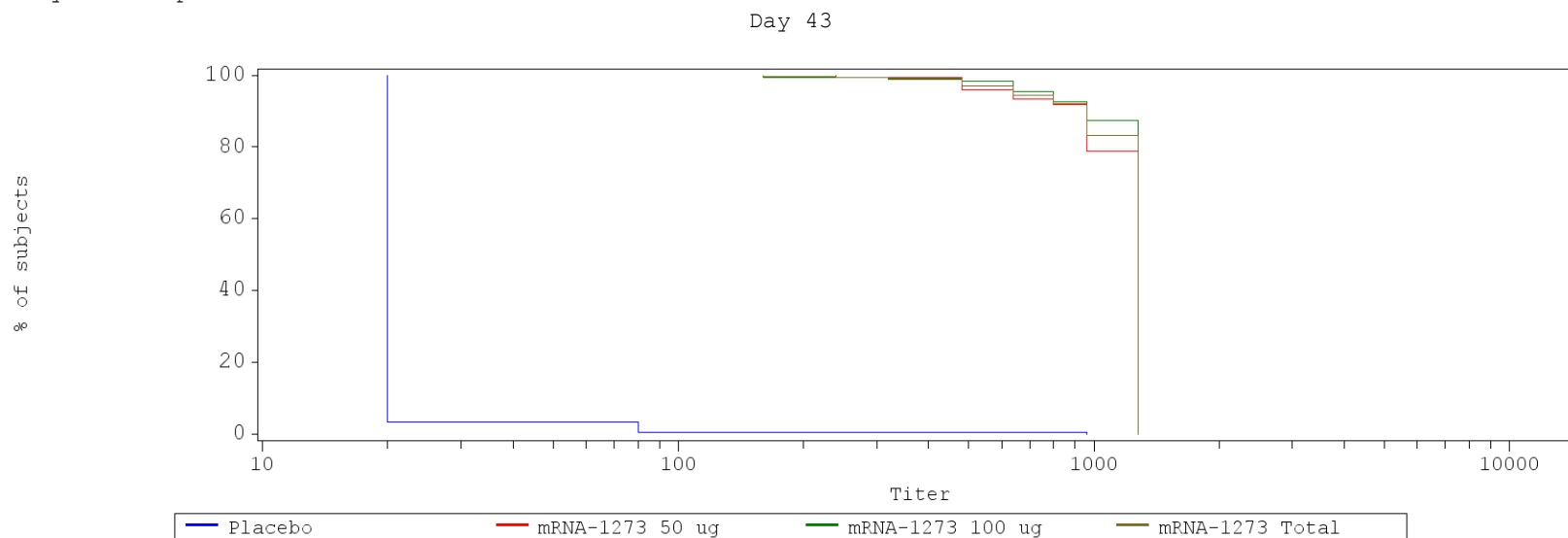
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

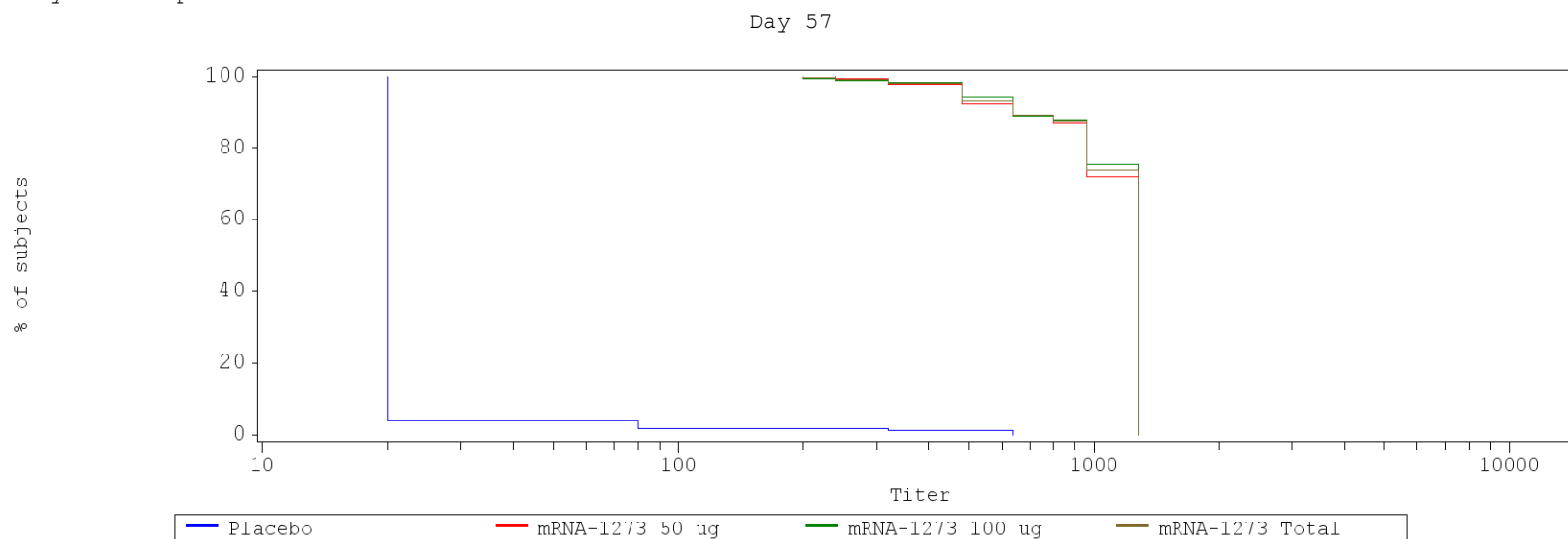
Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060102.sas 19NOV2020 04:20 Database Lock Date: 05NOV2020

Figure 14.2.6.1.2

Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall

Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

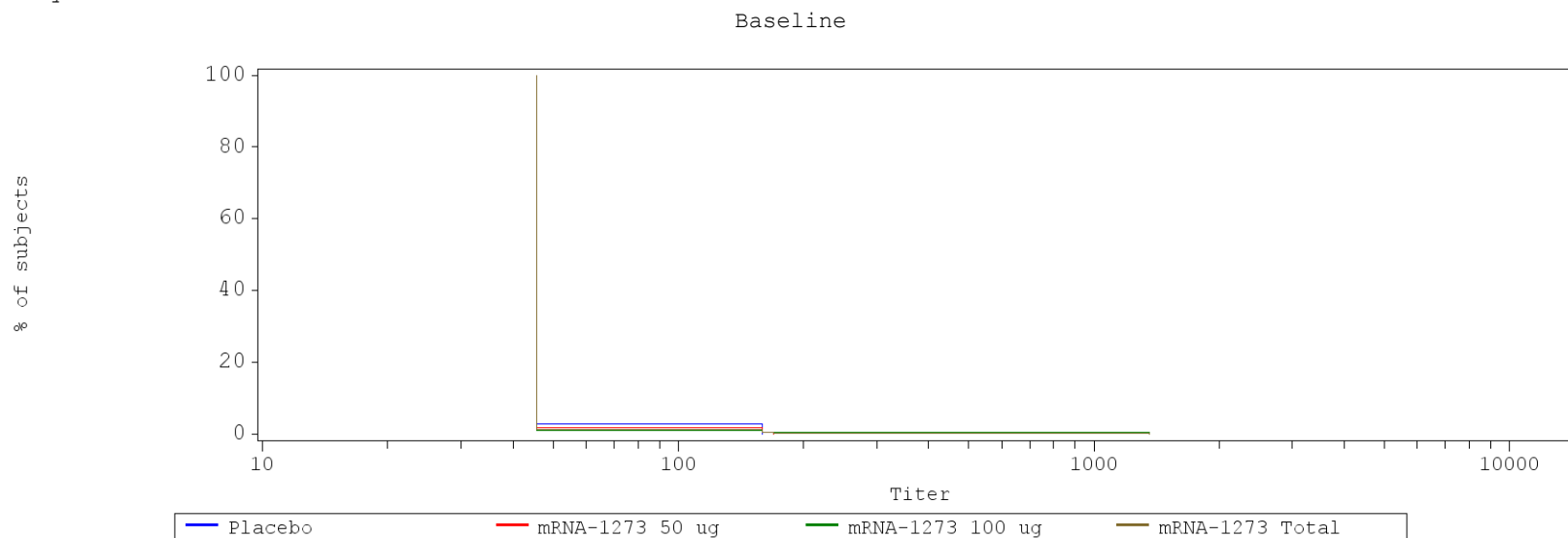
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

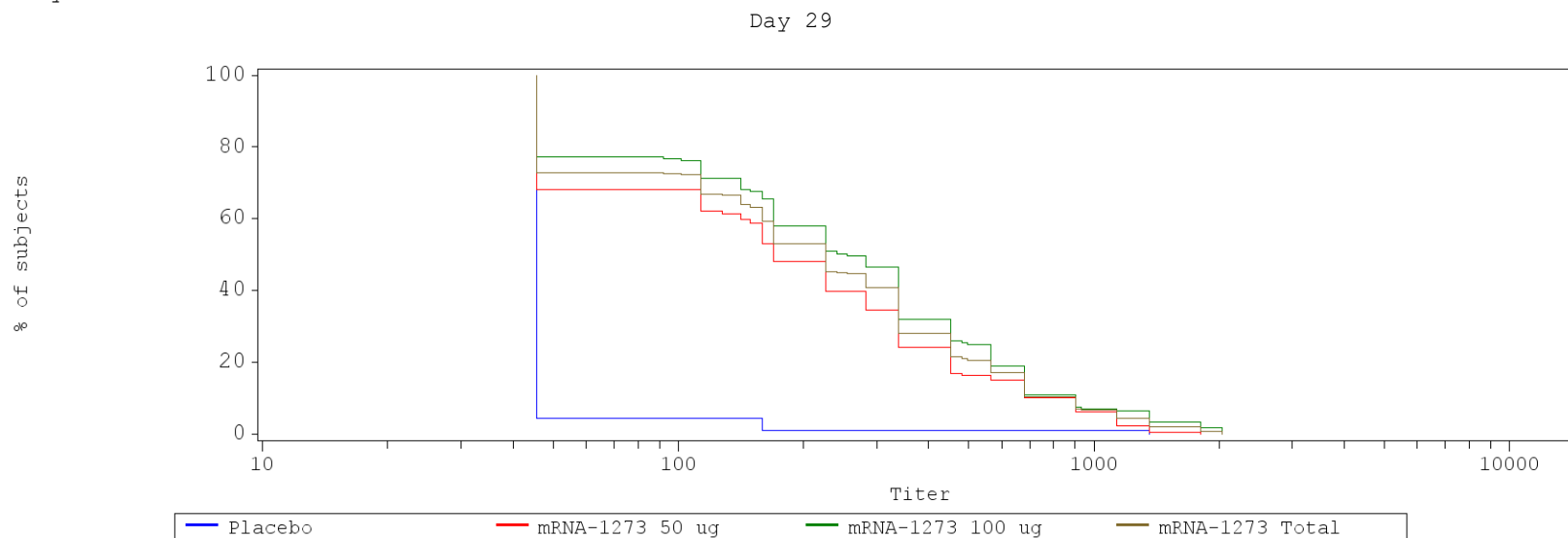
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

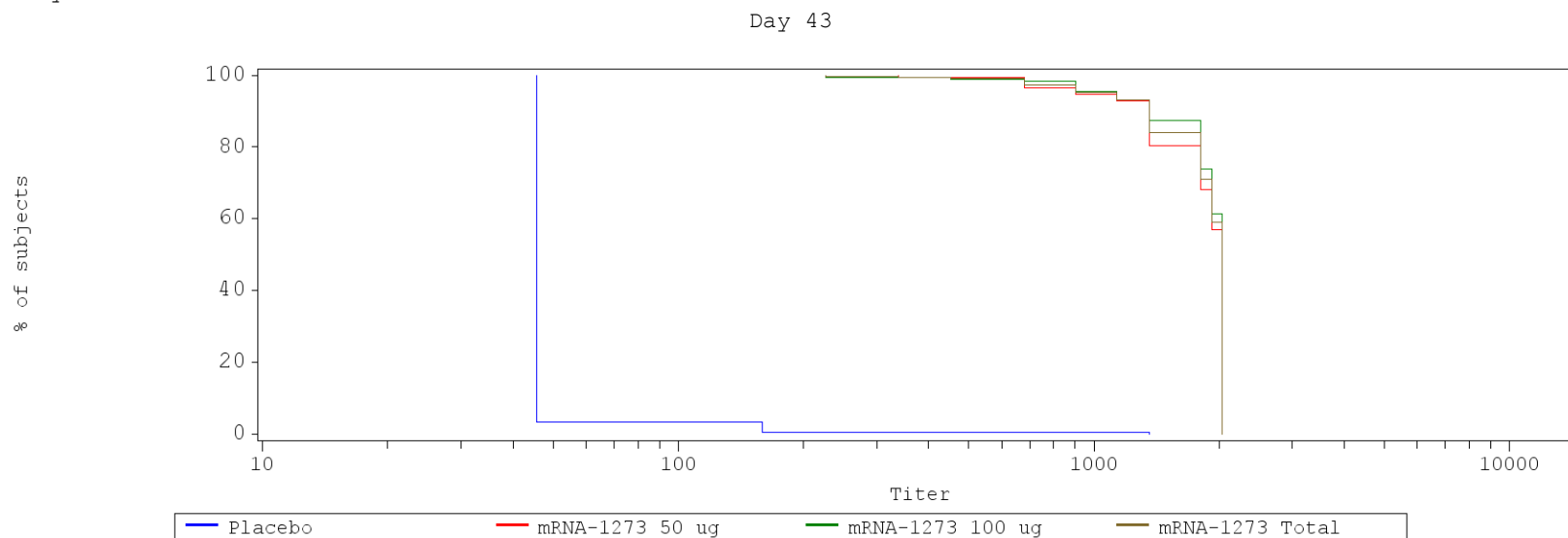
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

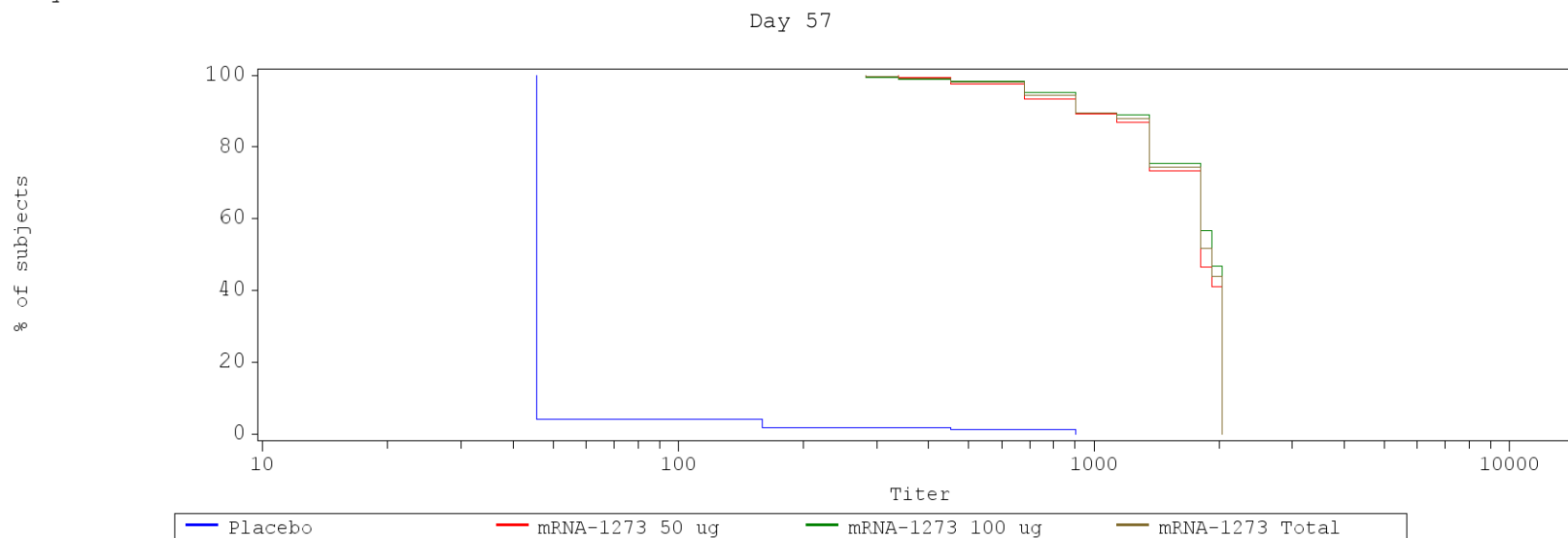
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

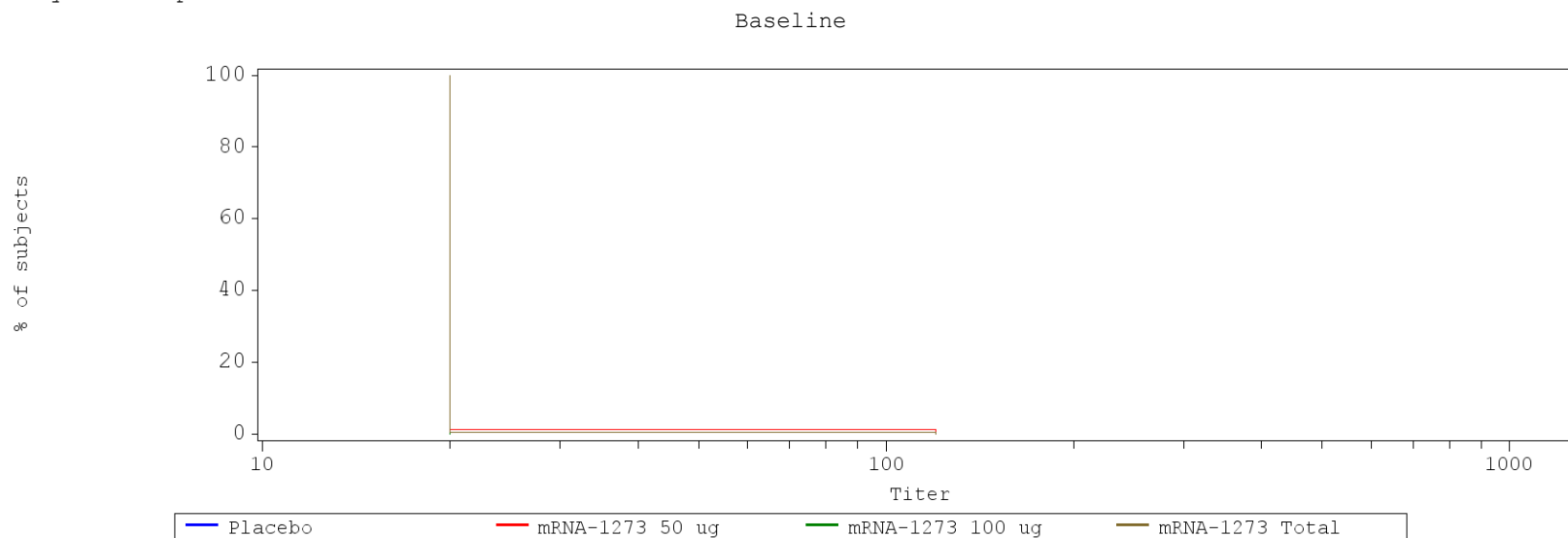
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

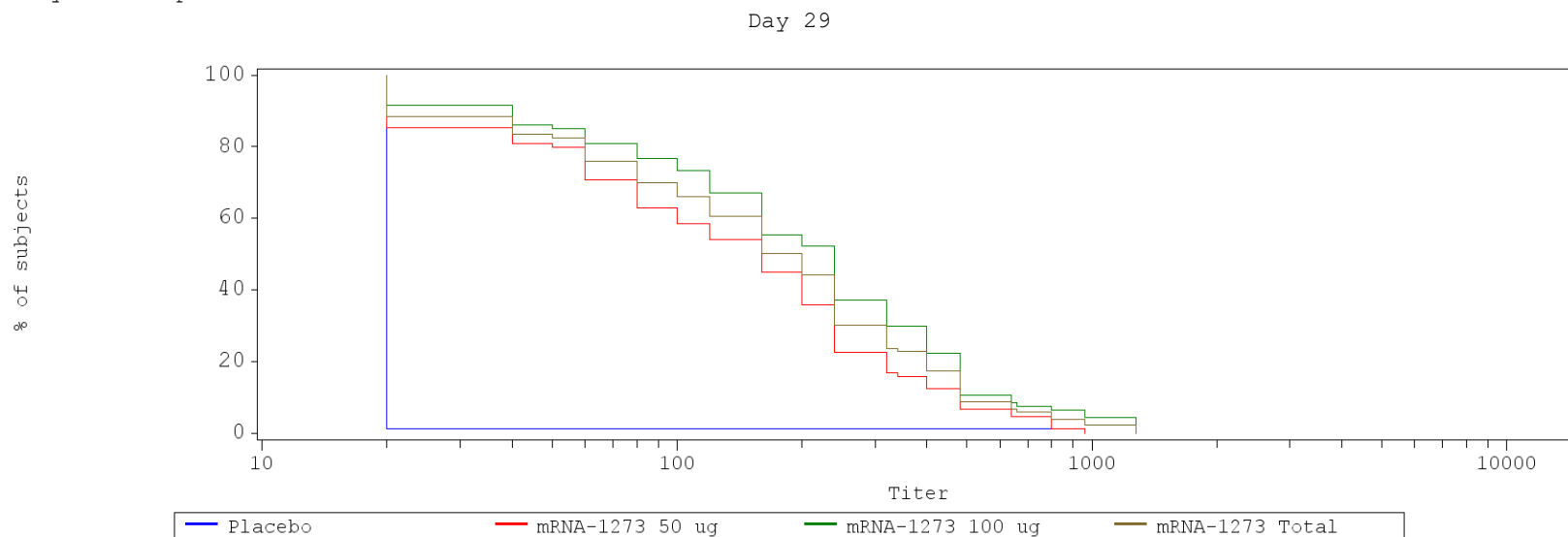
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

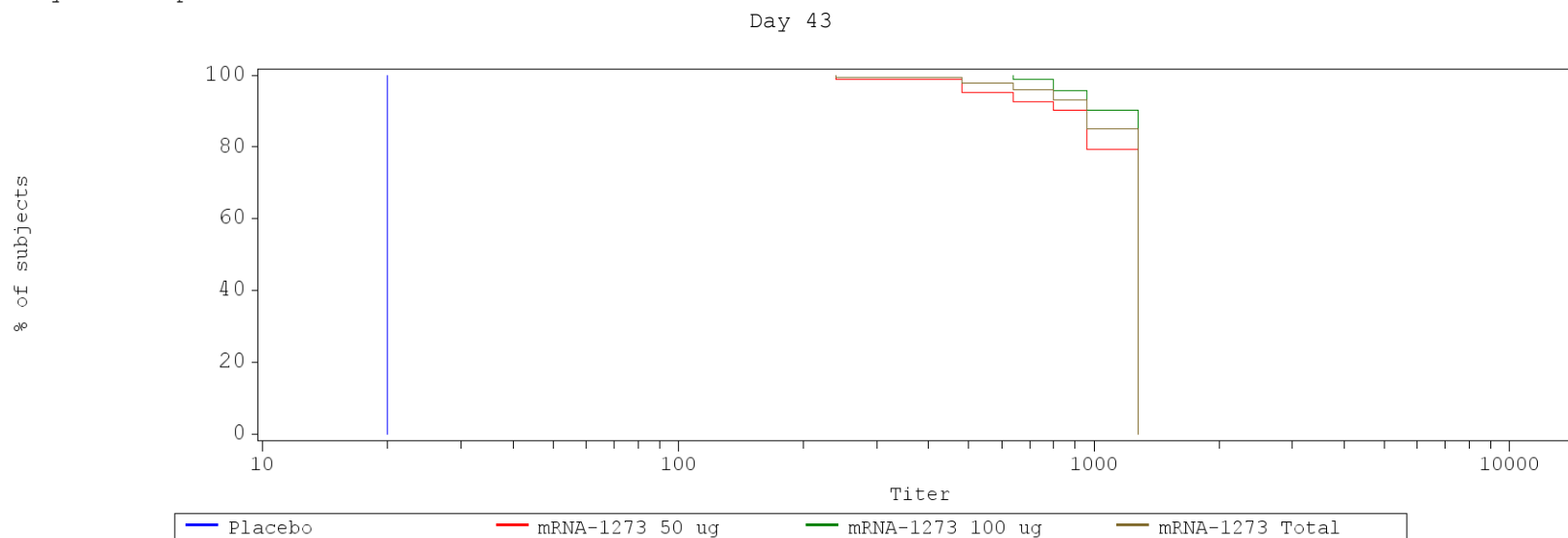
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

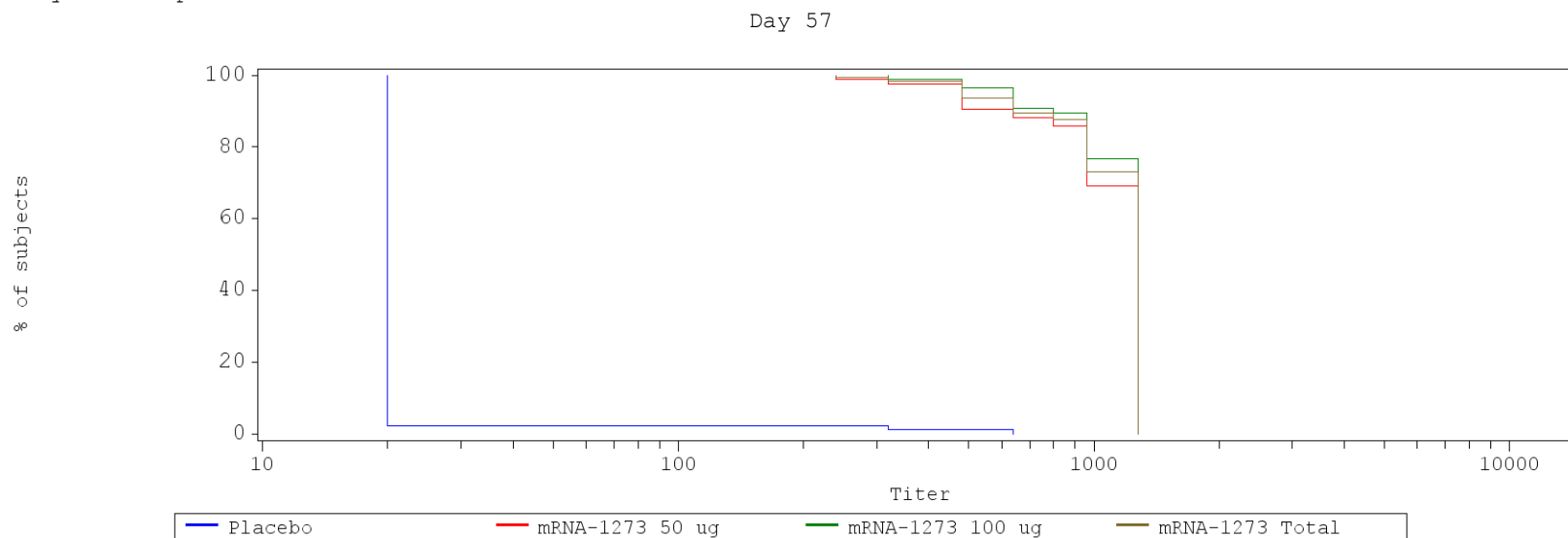
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

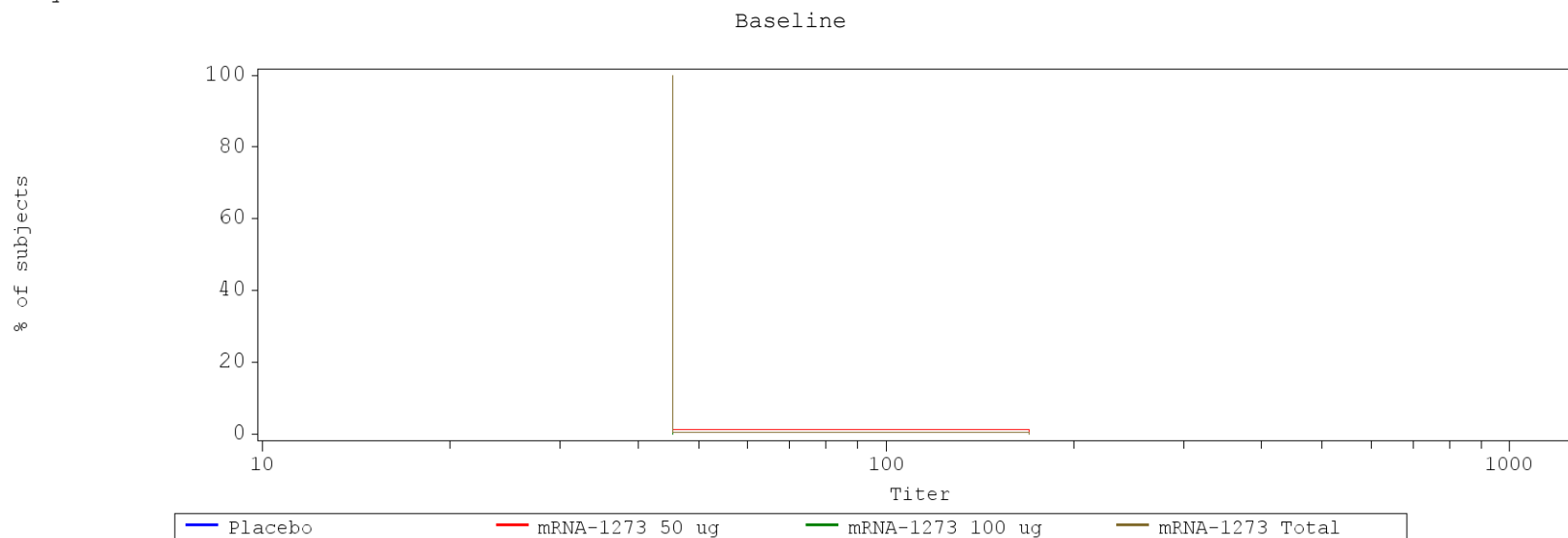
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

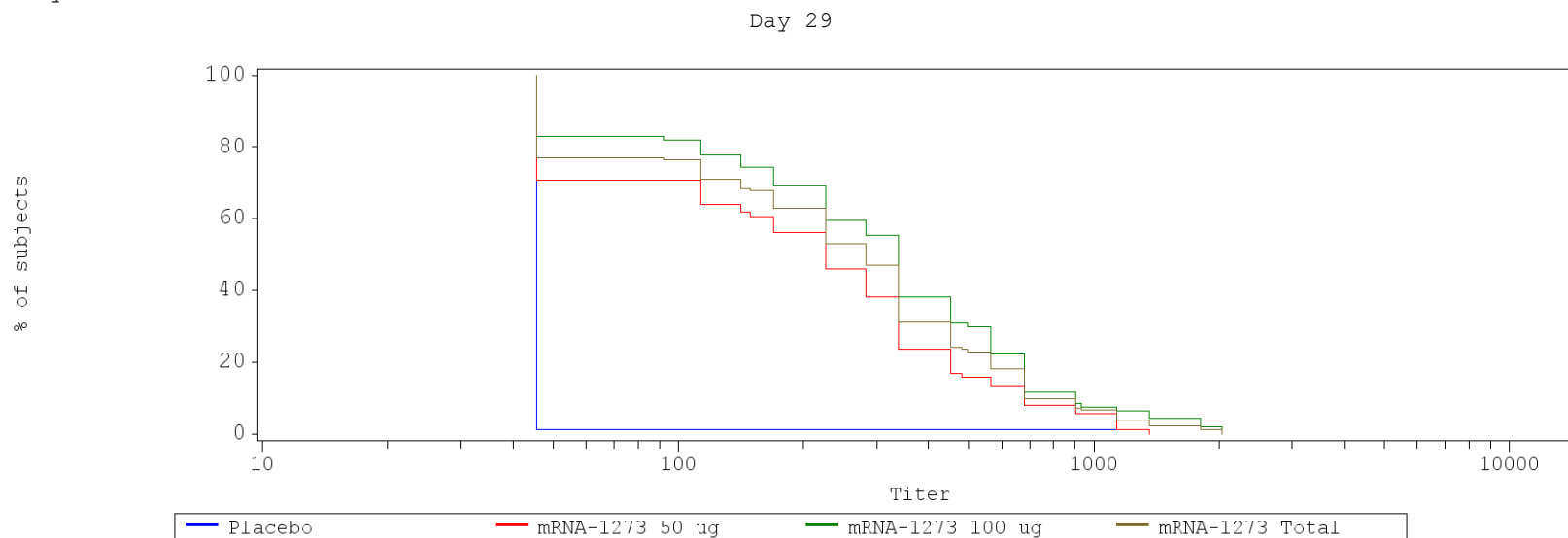
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

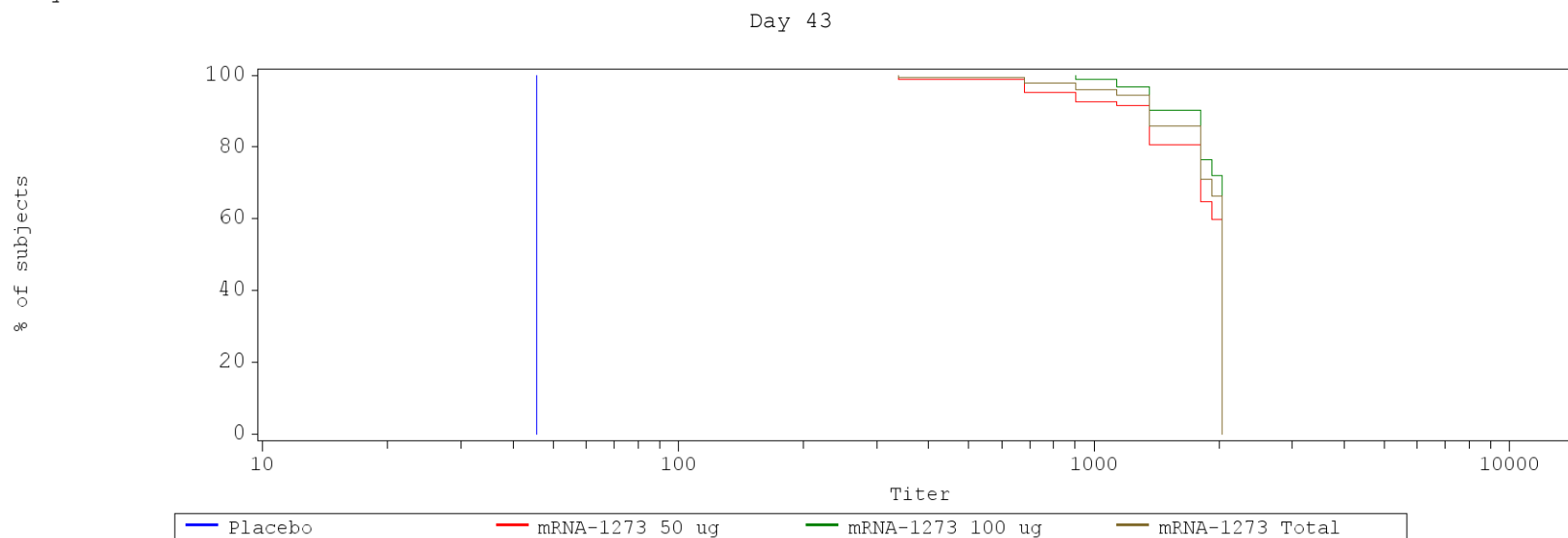
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

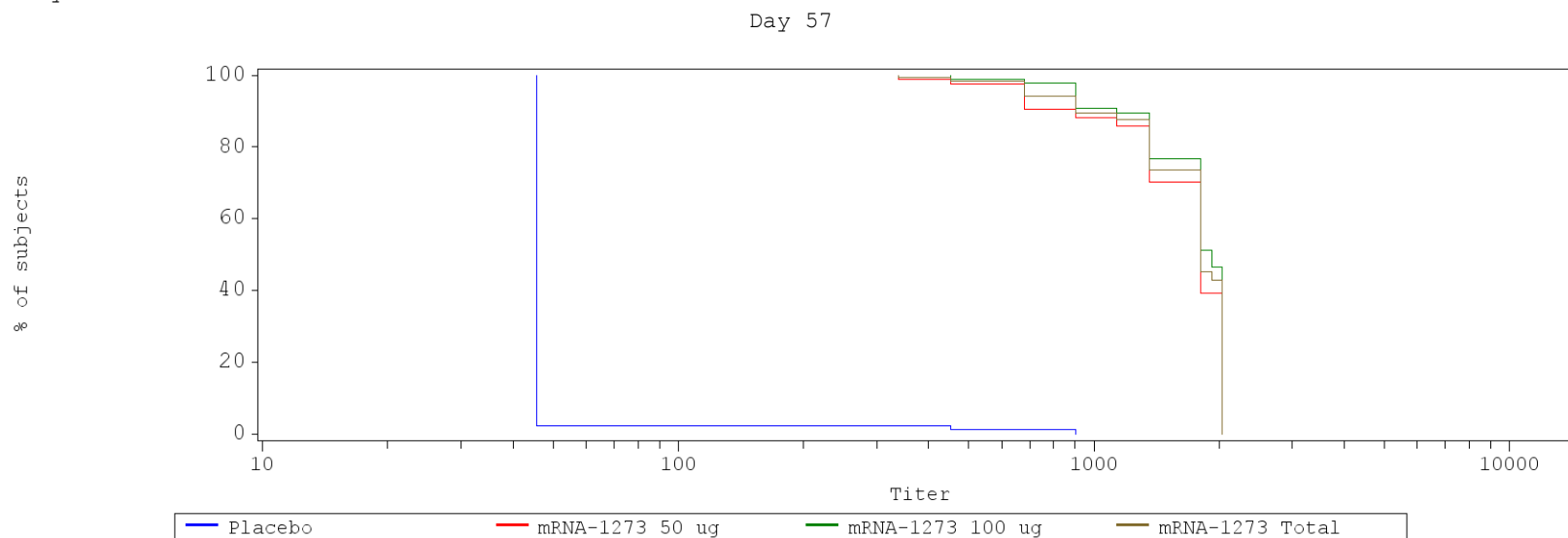
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

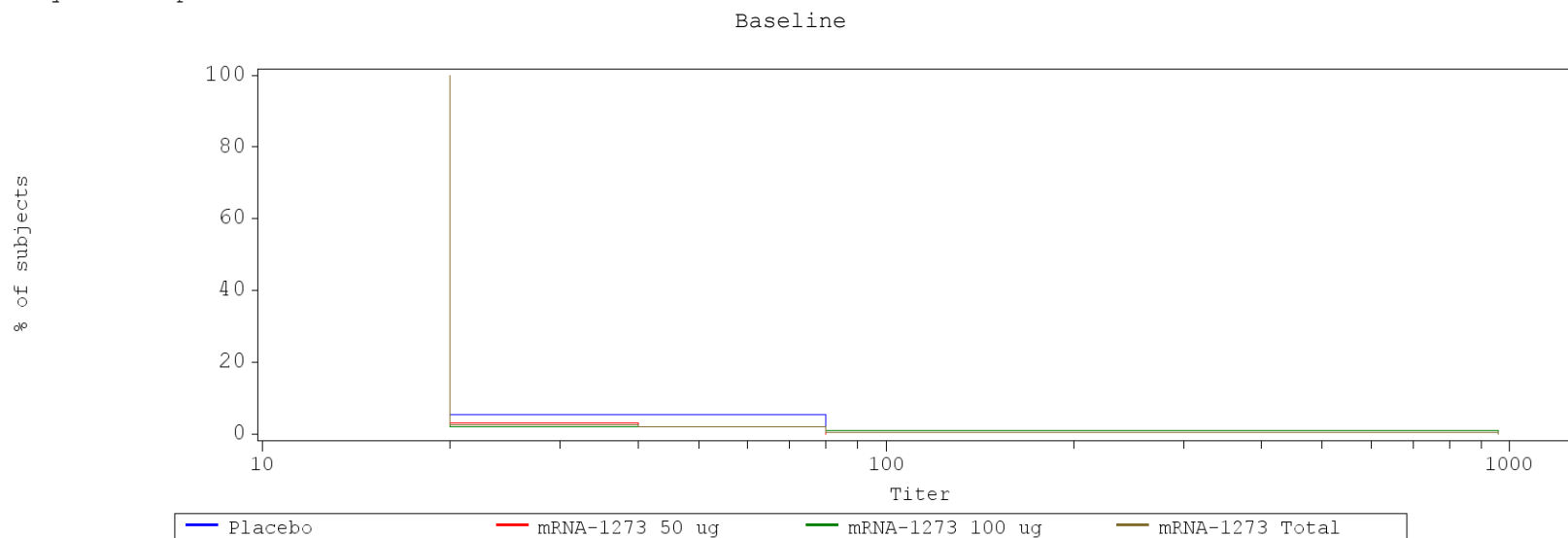
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

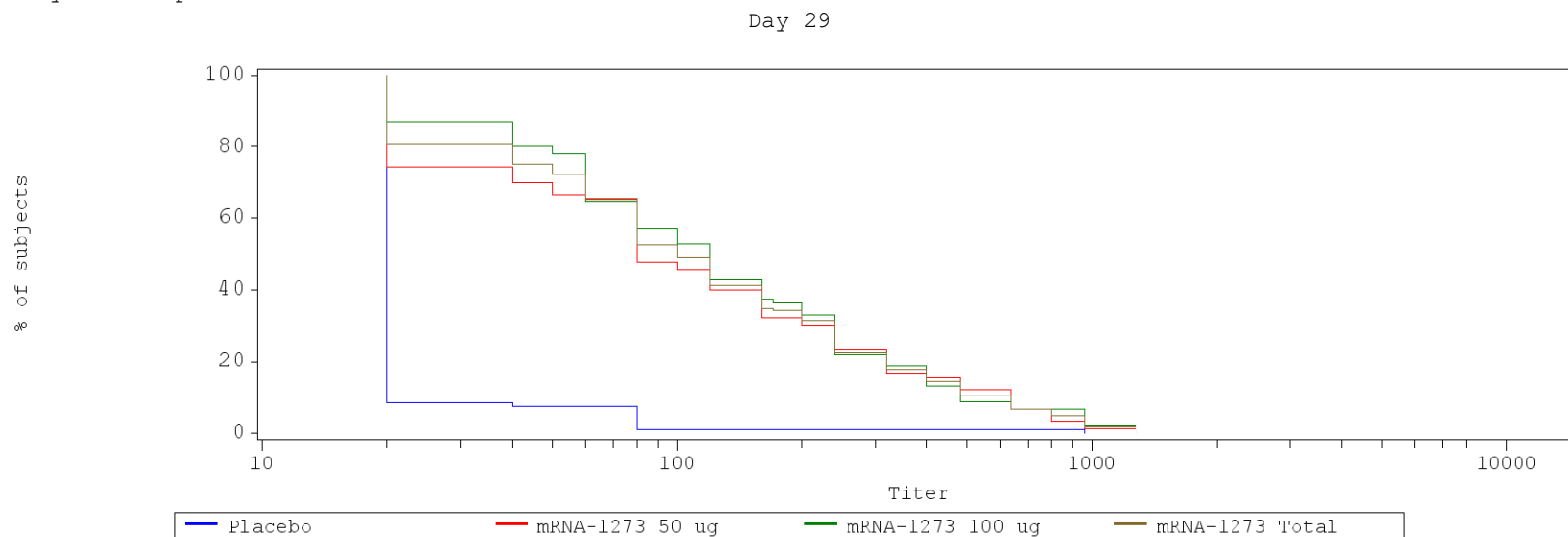
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

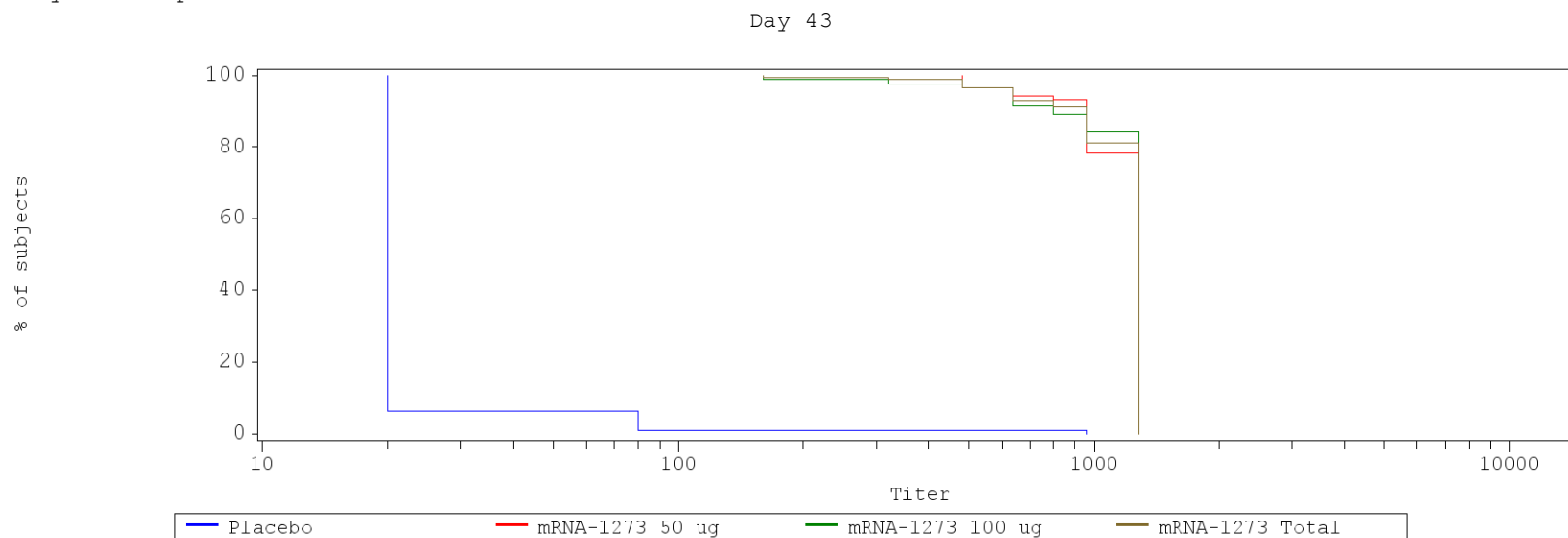
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

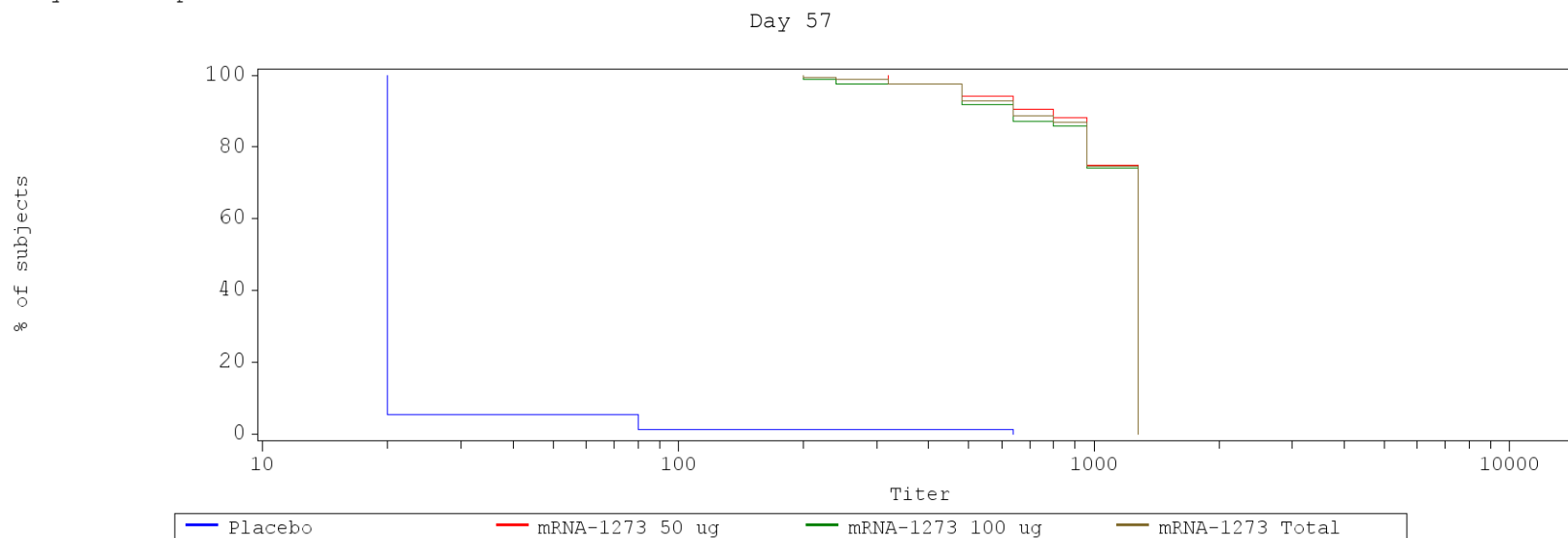
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

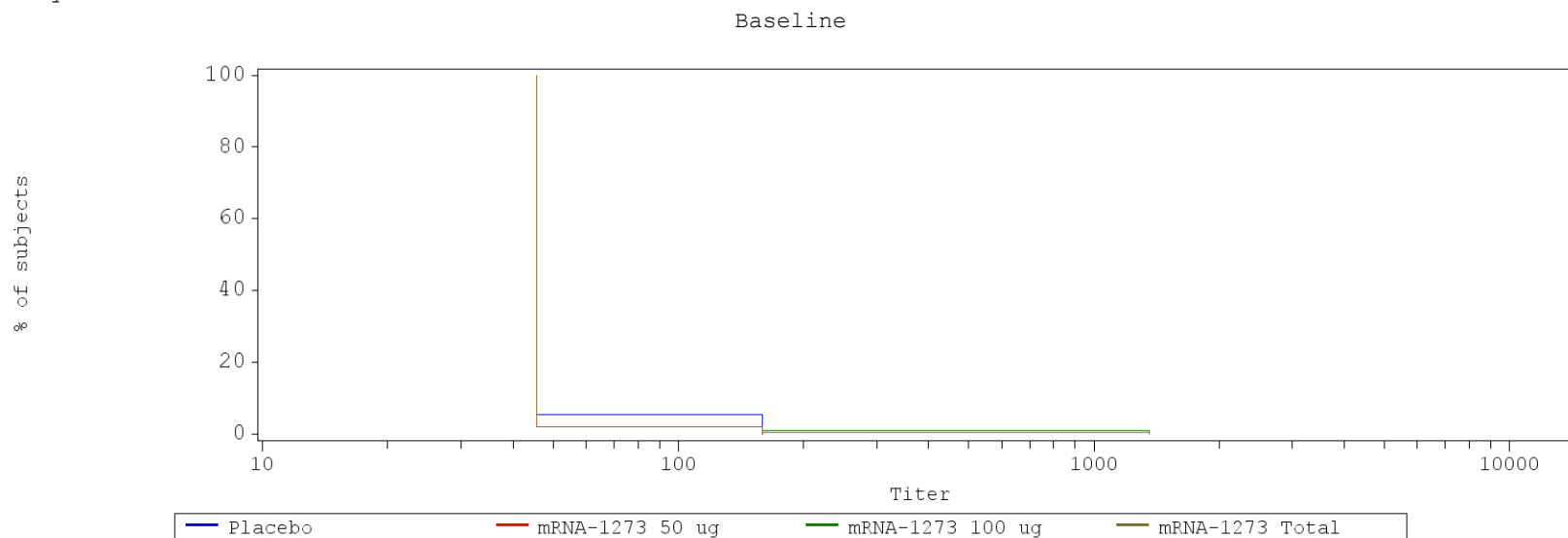
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

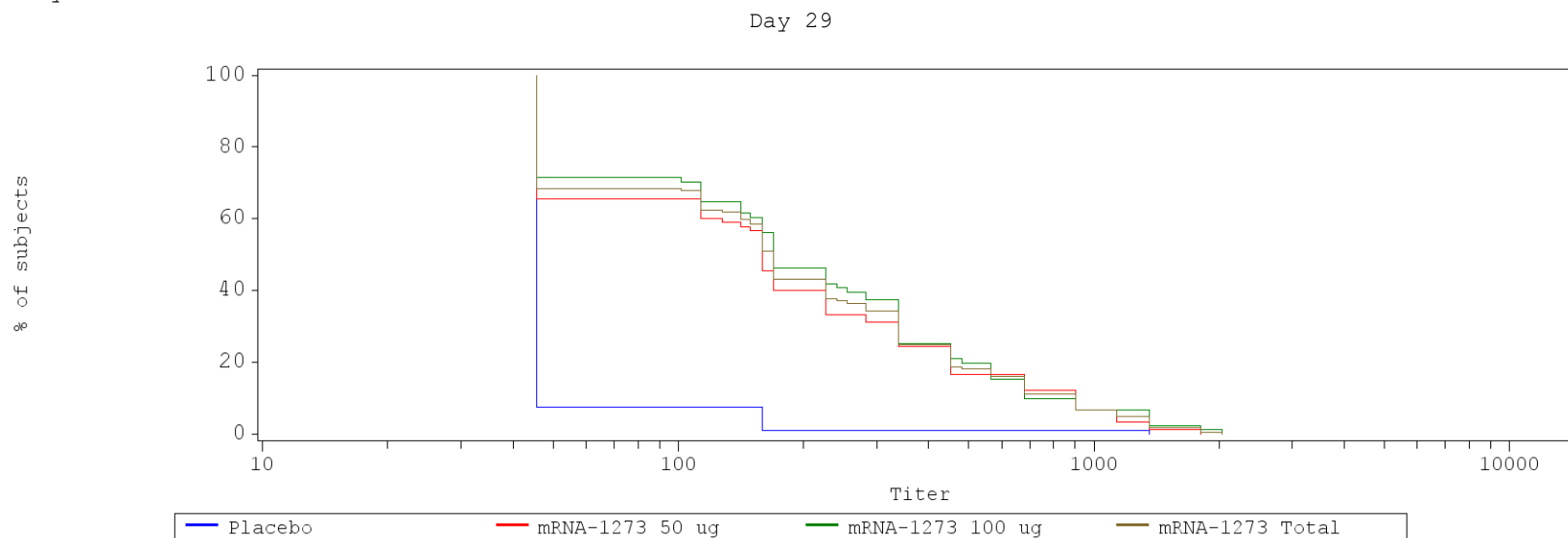
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

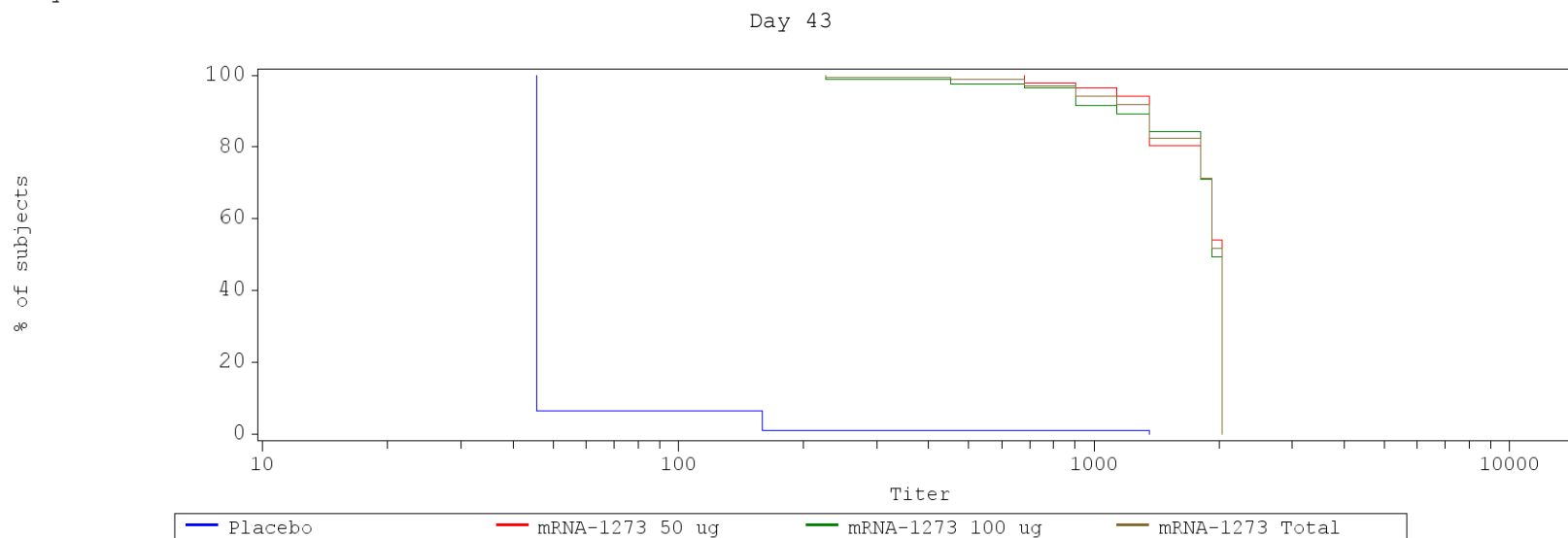
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

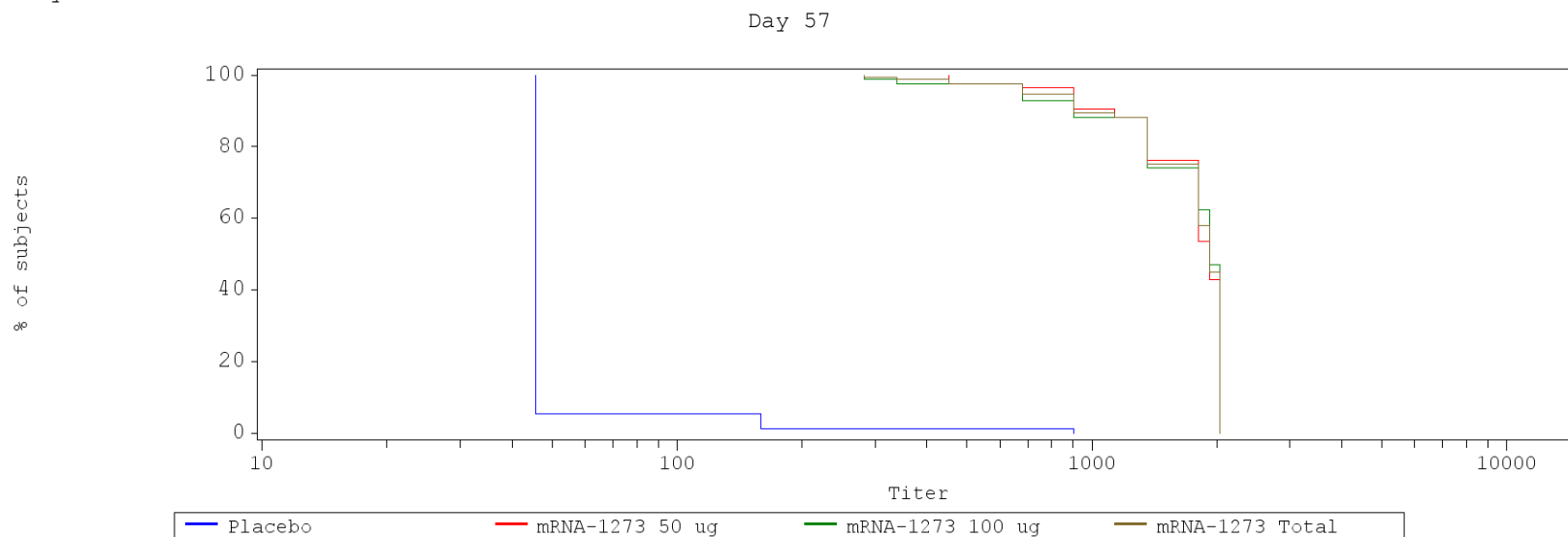
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

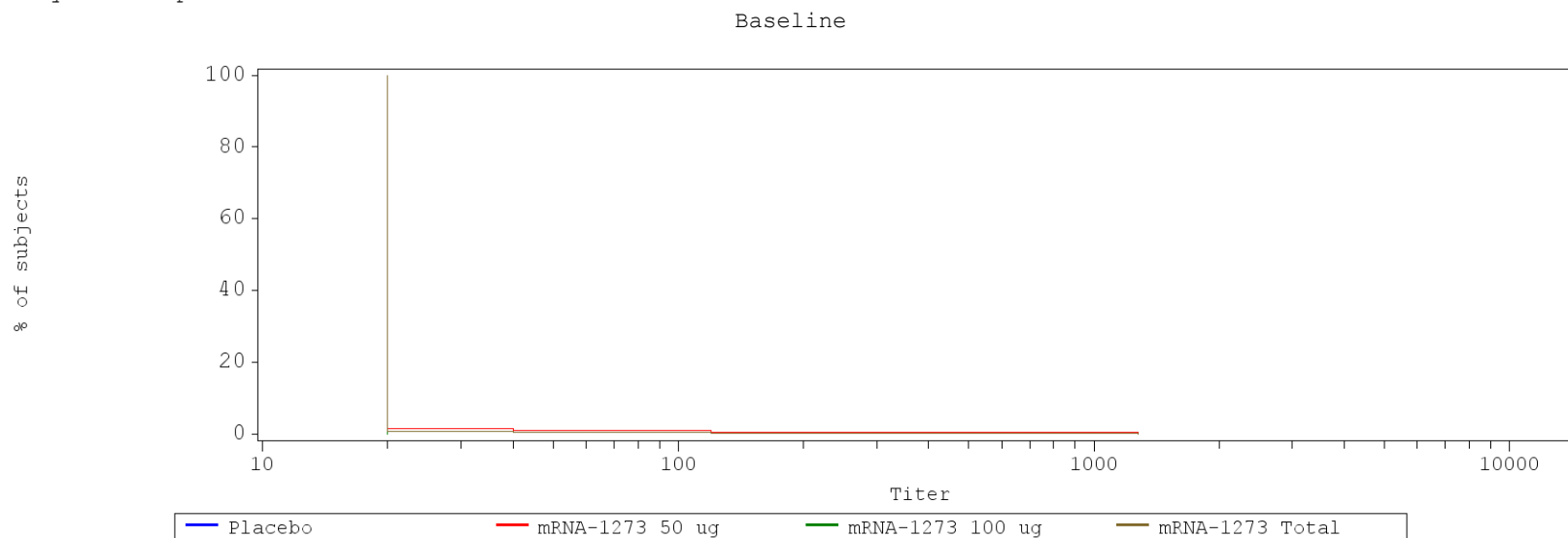
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

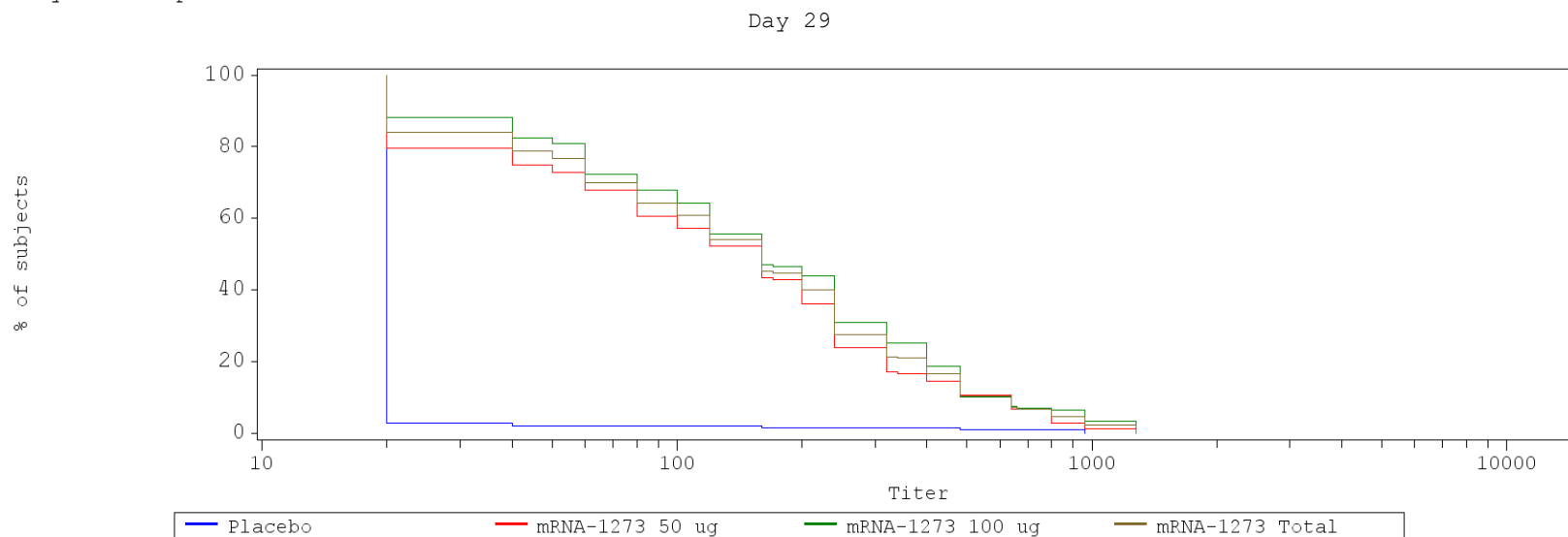
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

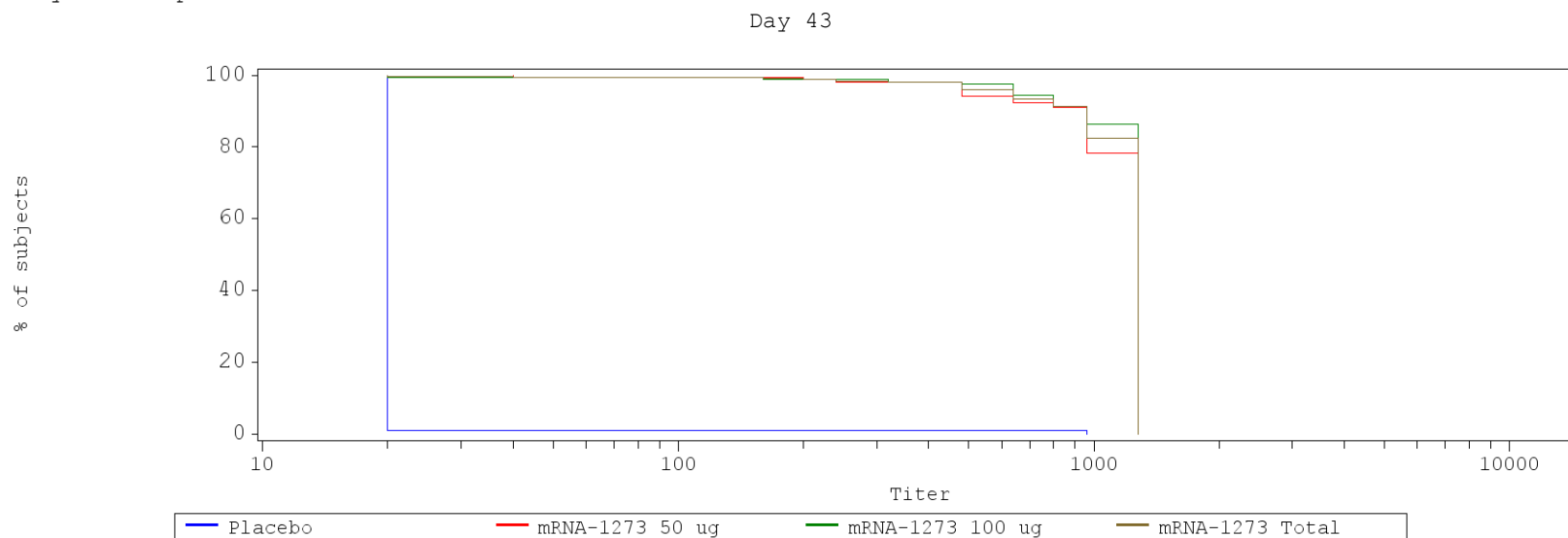
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

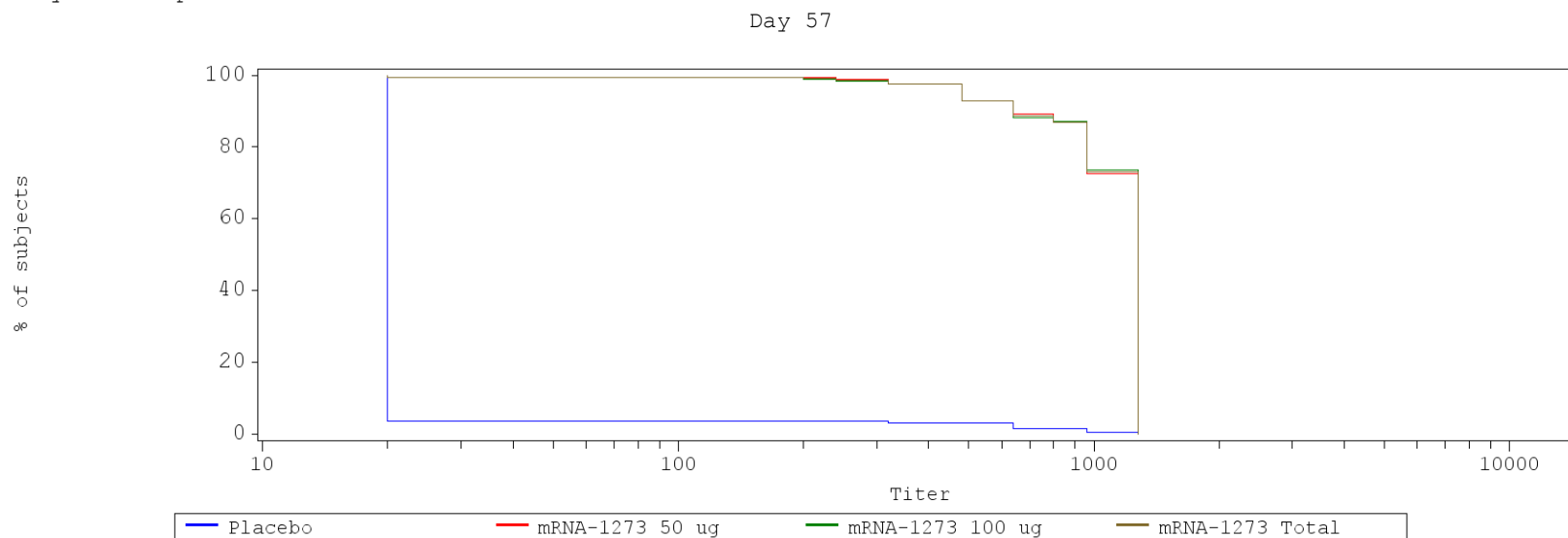
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

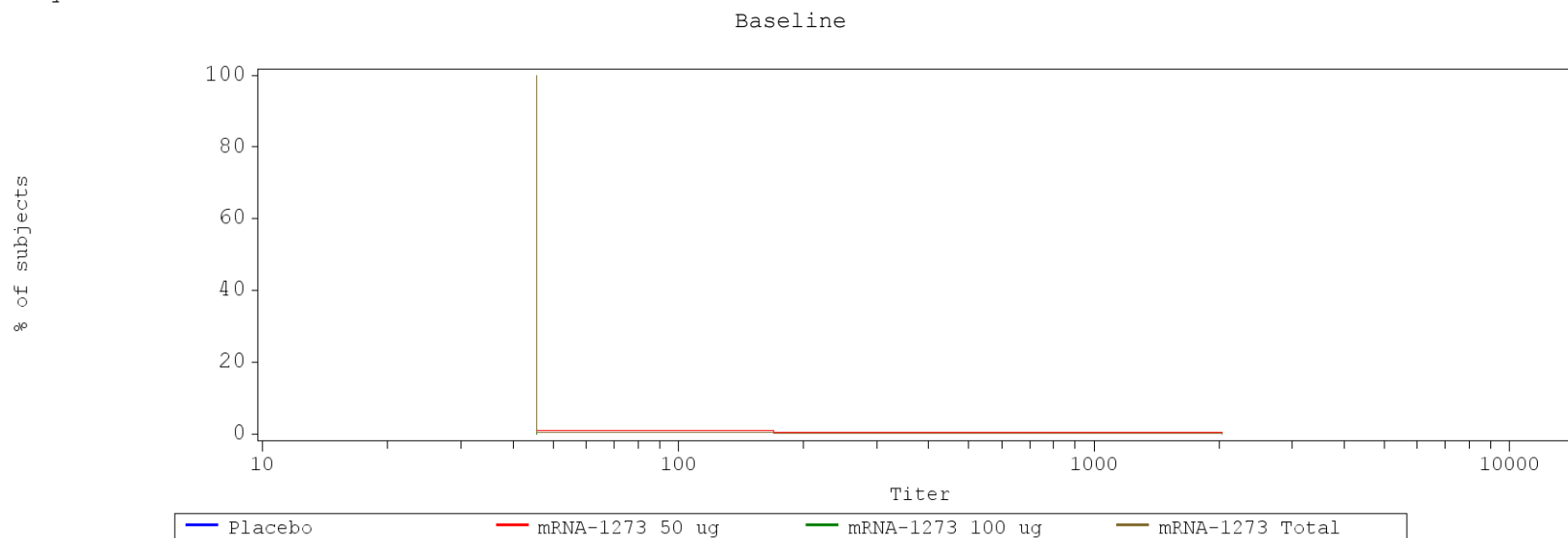
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

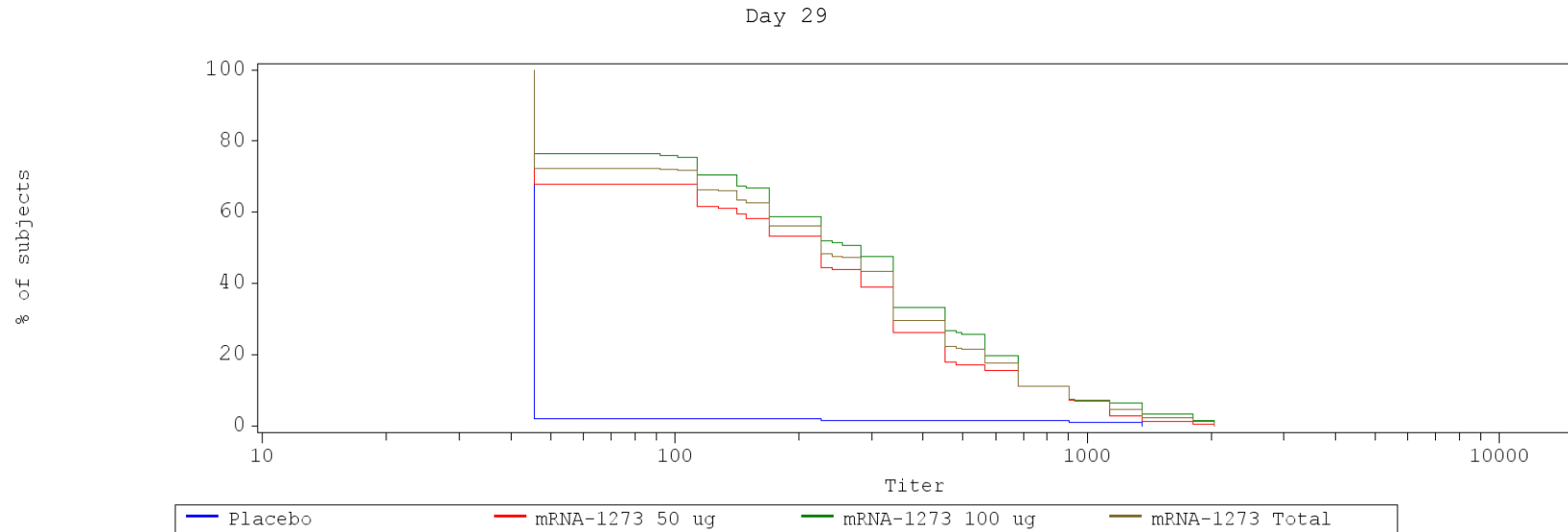
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

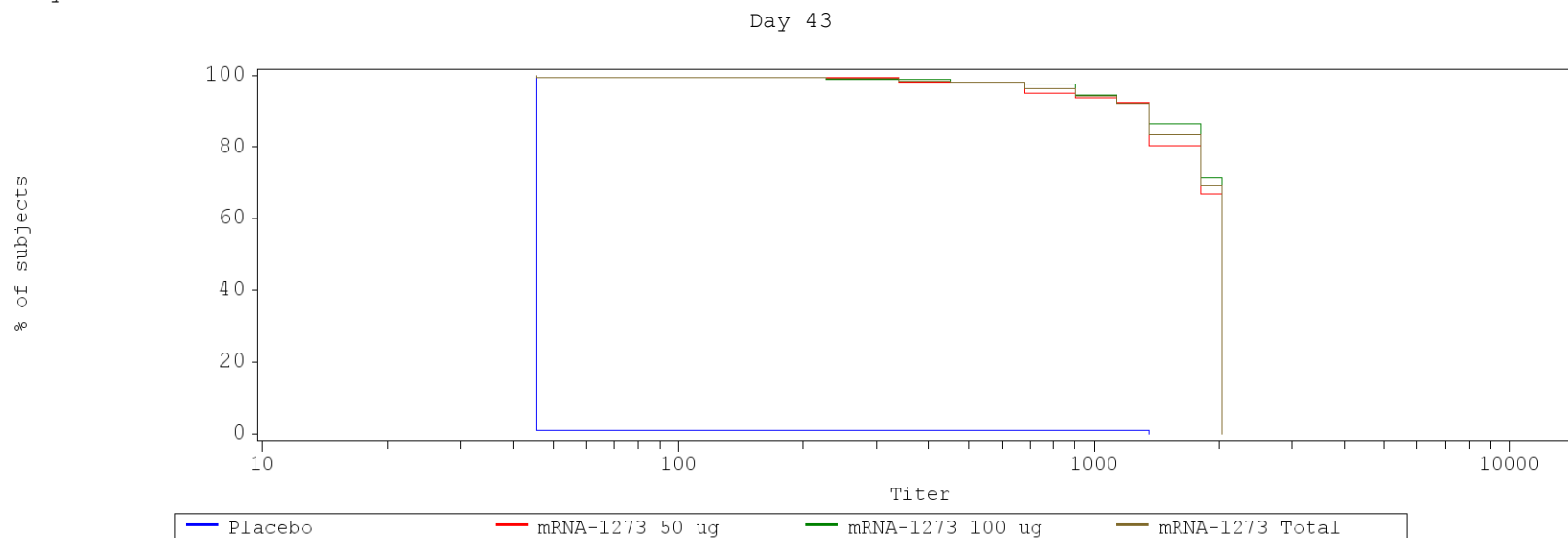
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

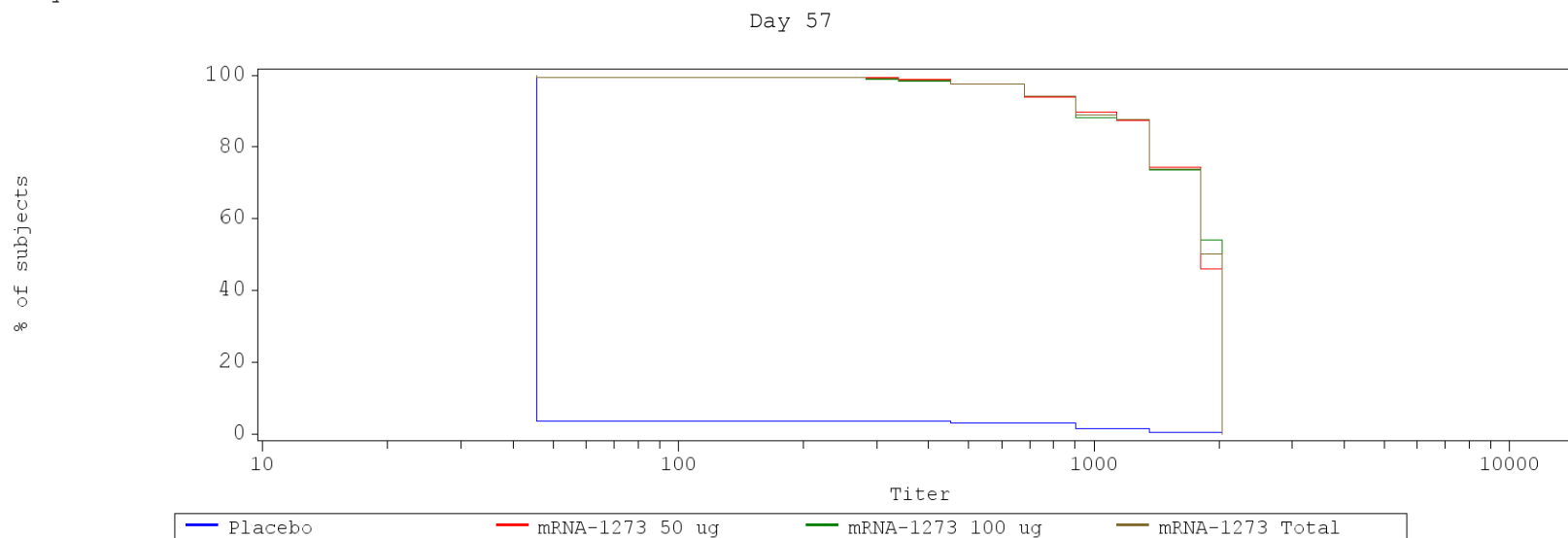
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

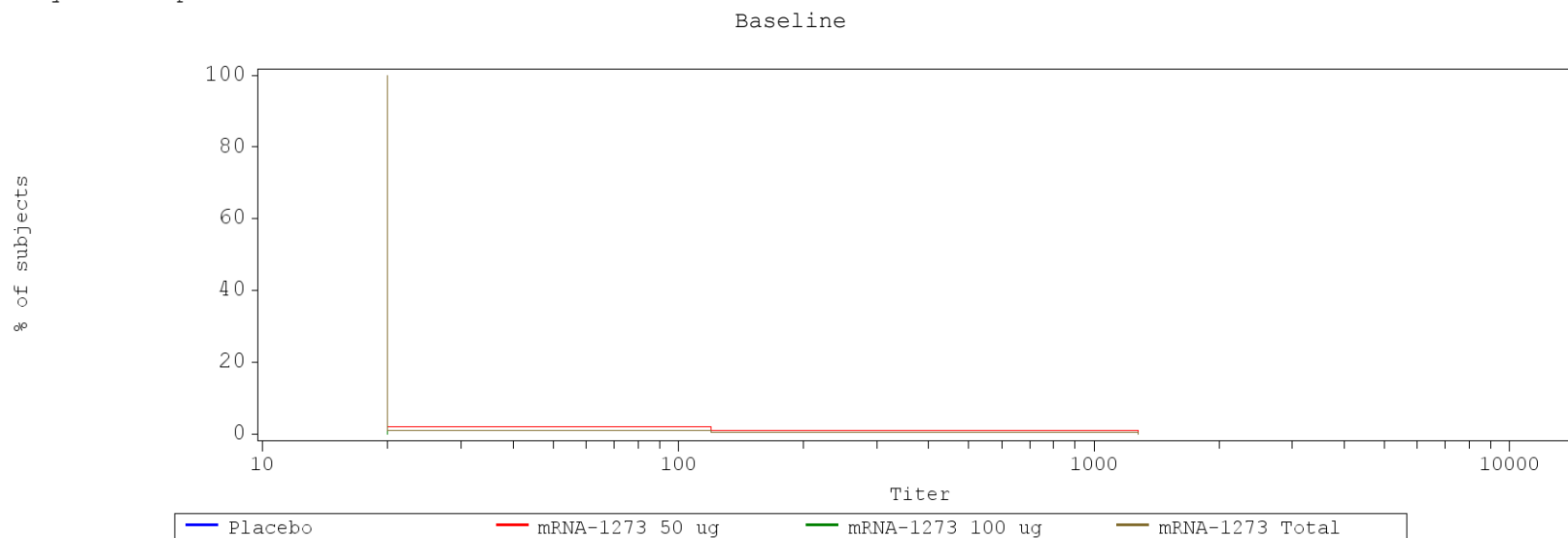
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

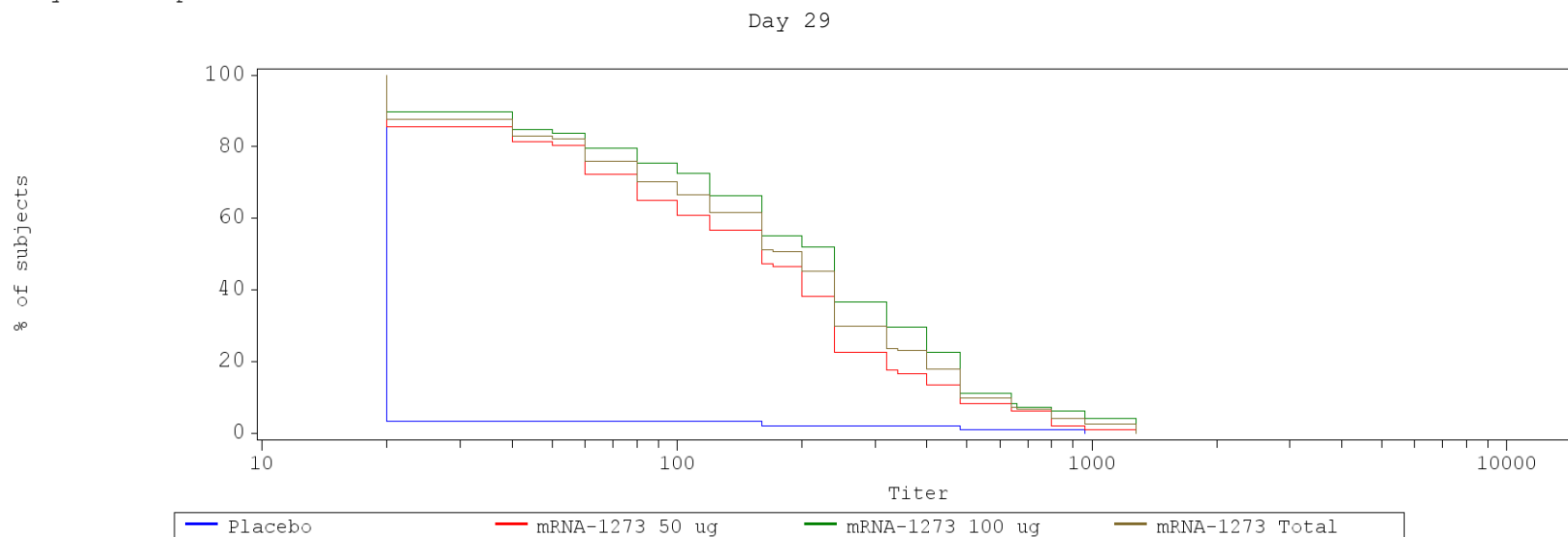
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

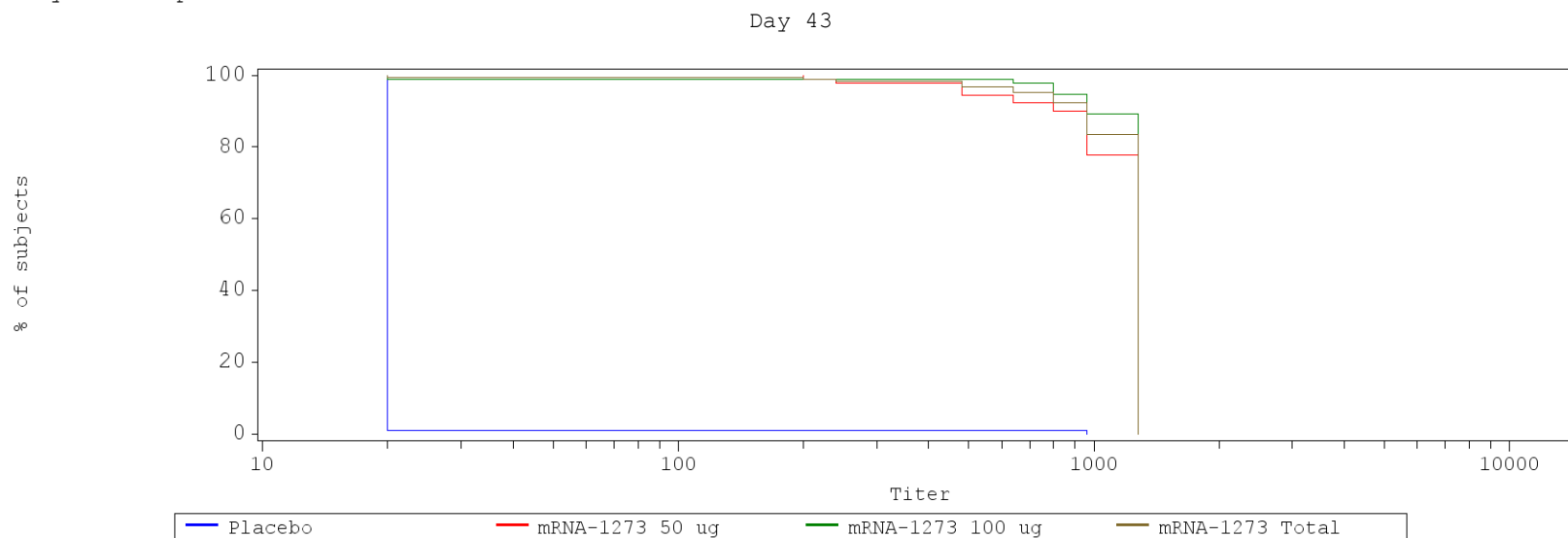
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

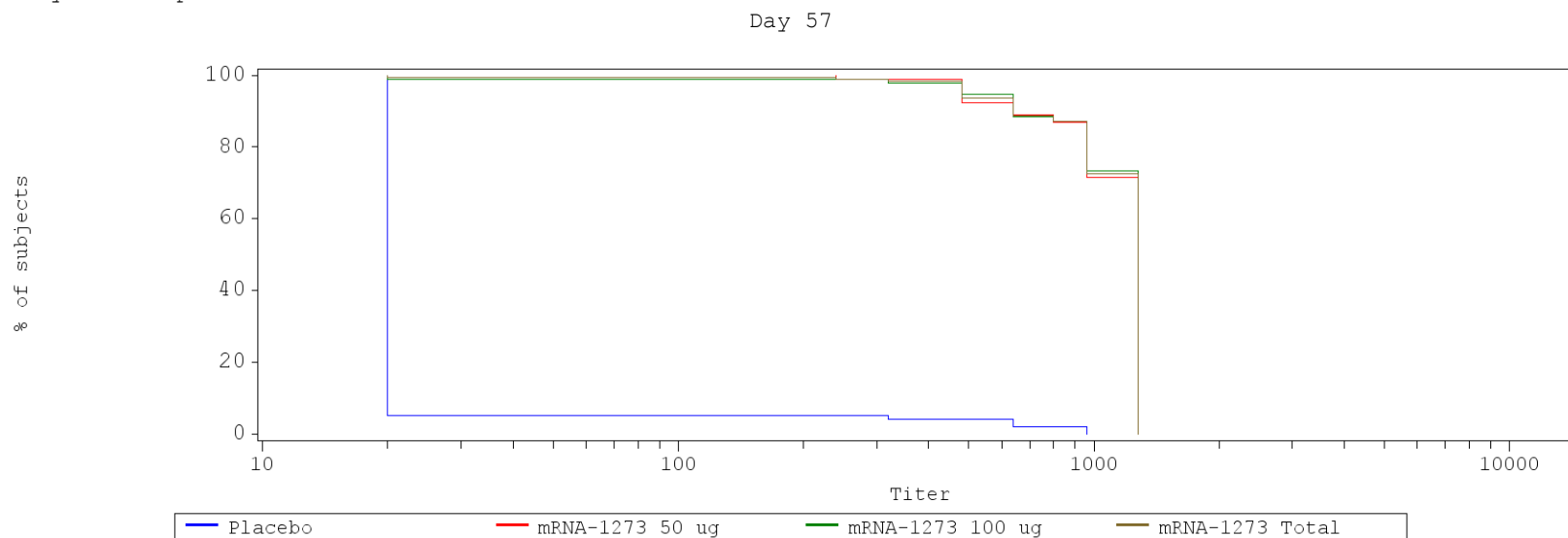
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

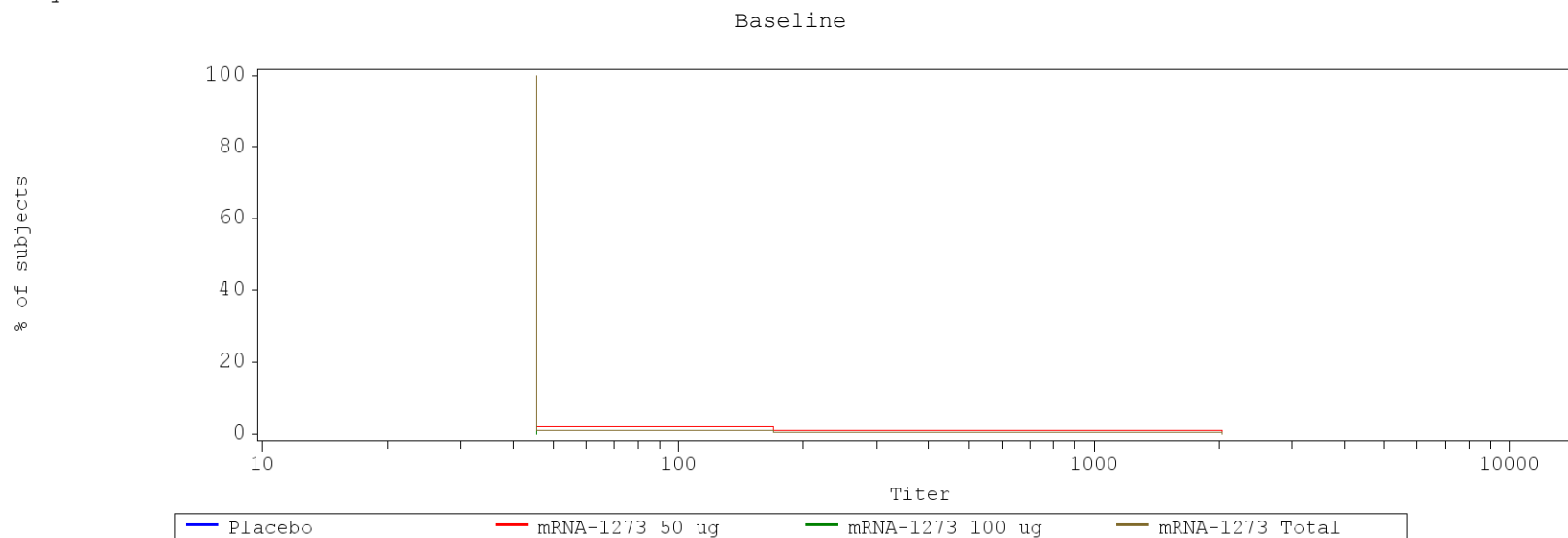
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

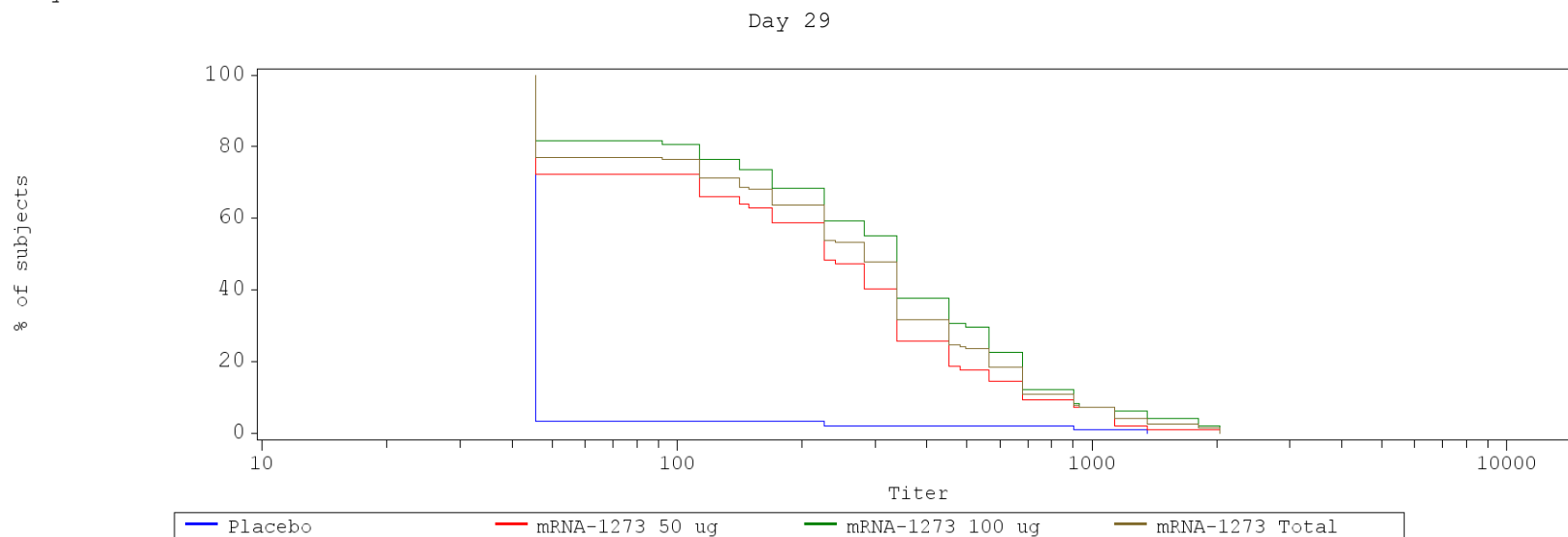
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

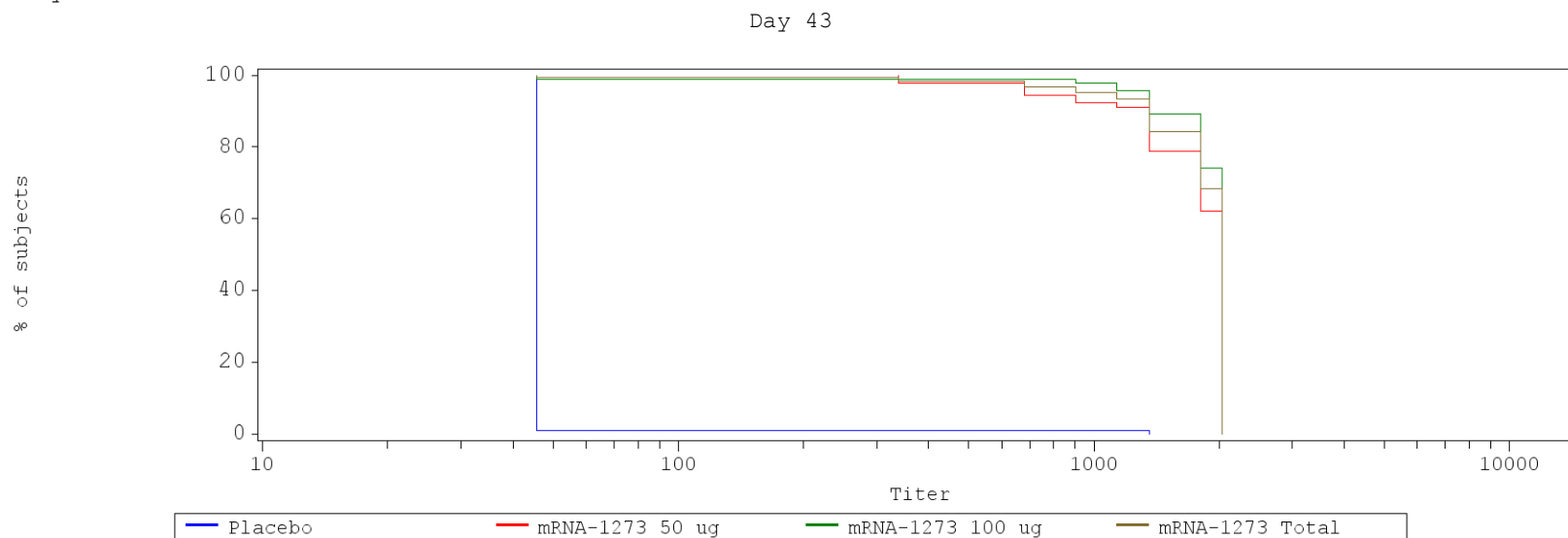
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

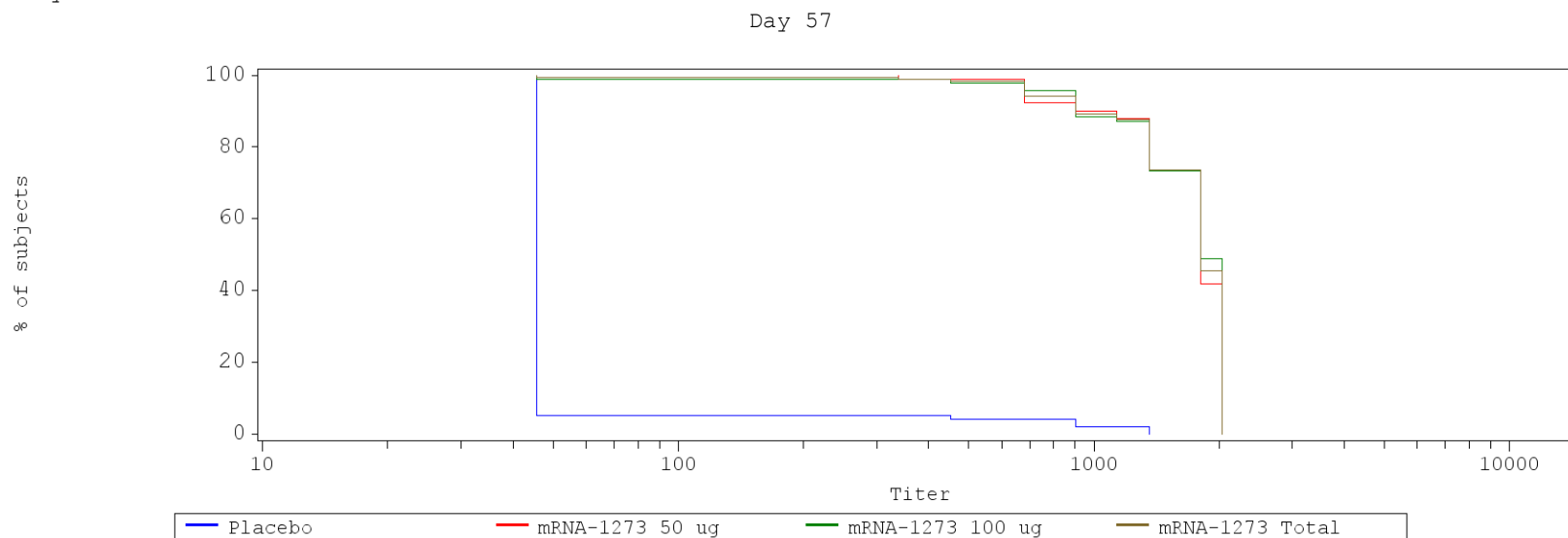
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

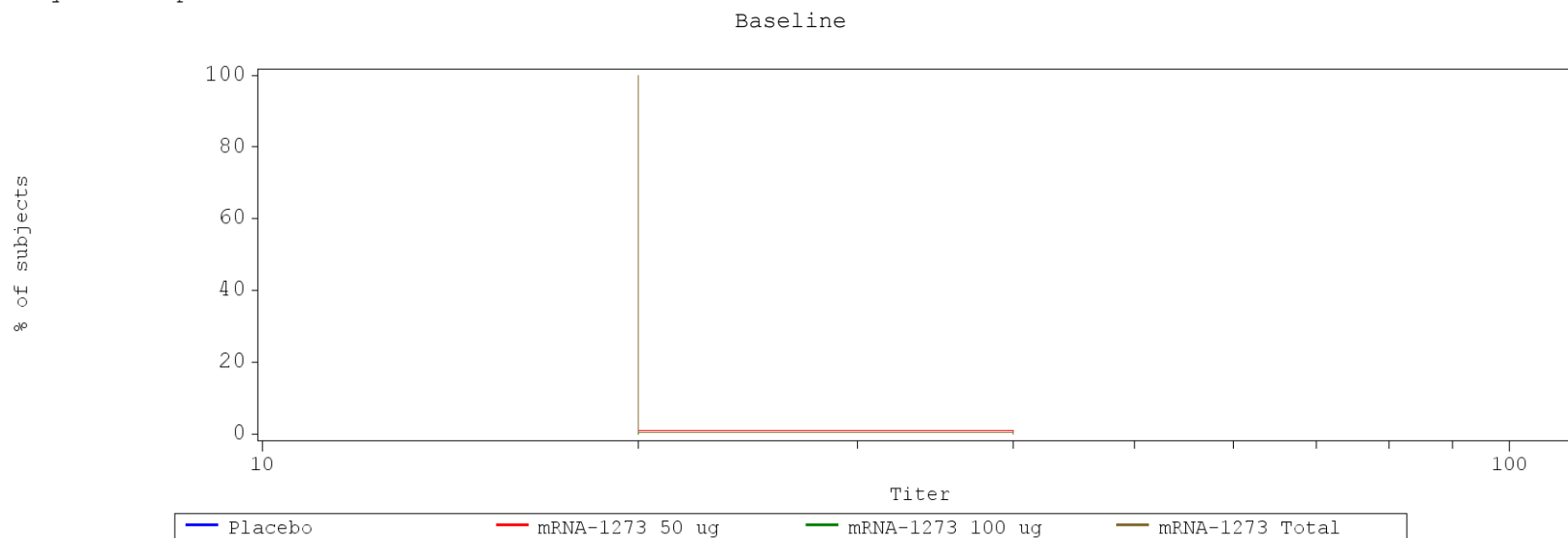
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

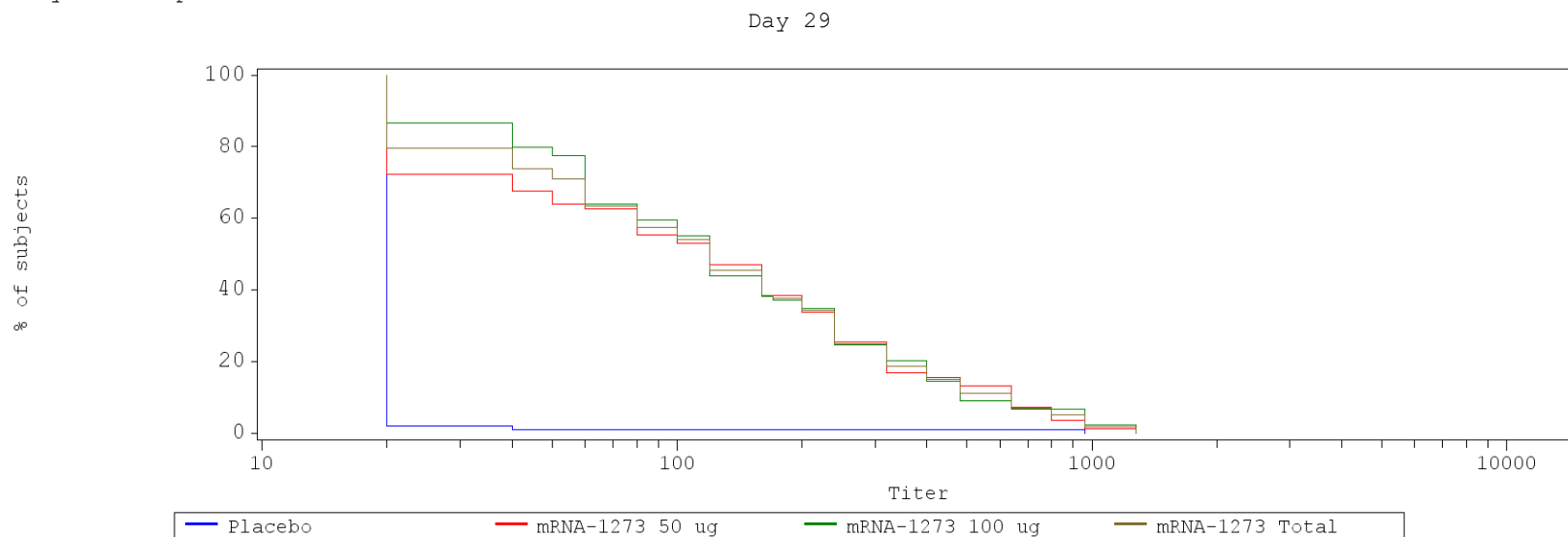
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

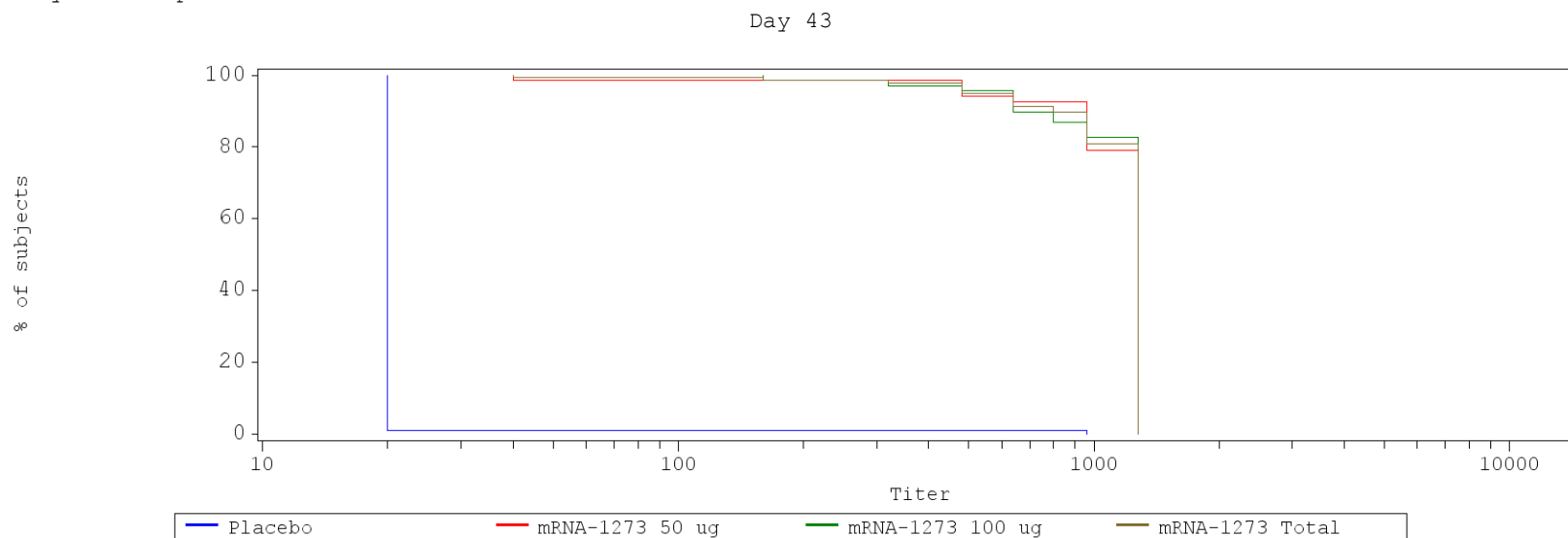
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

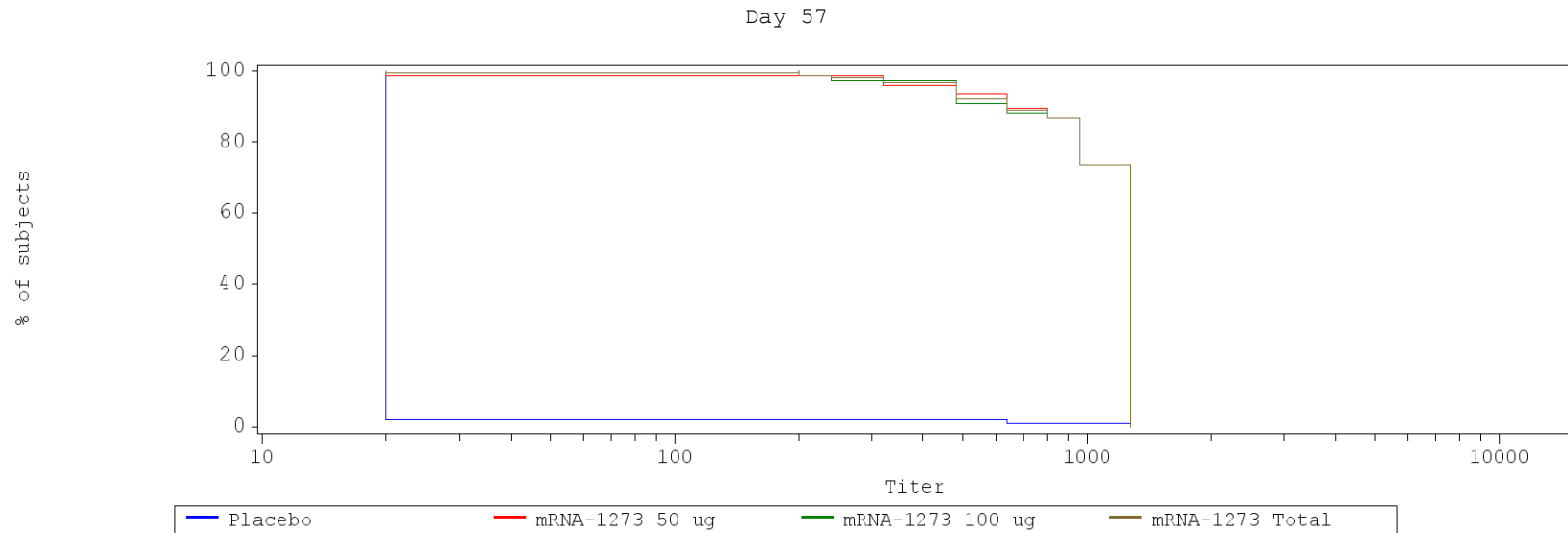
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

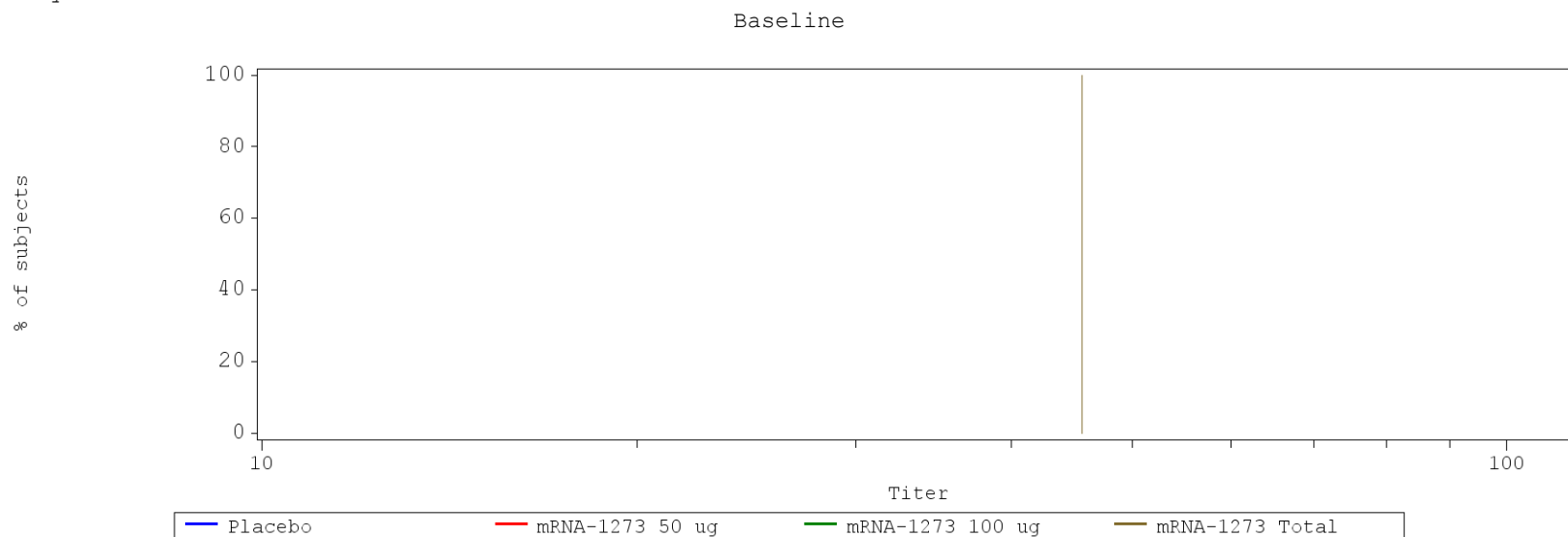
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

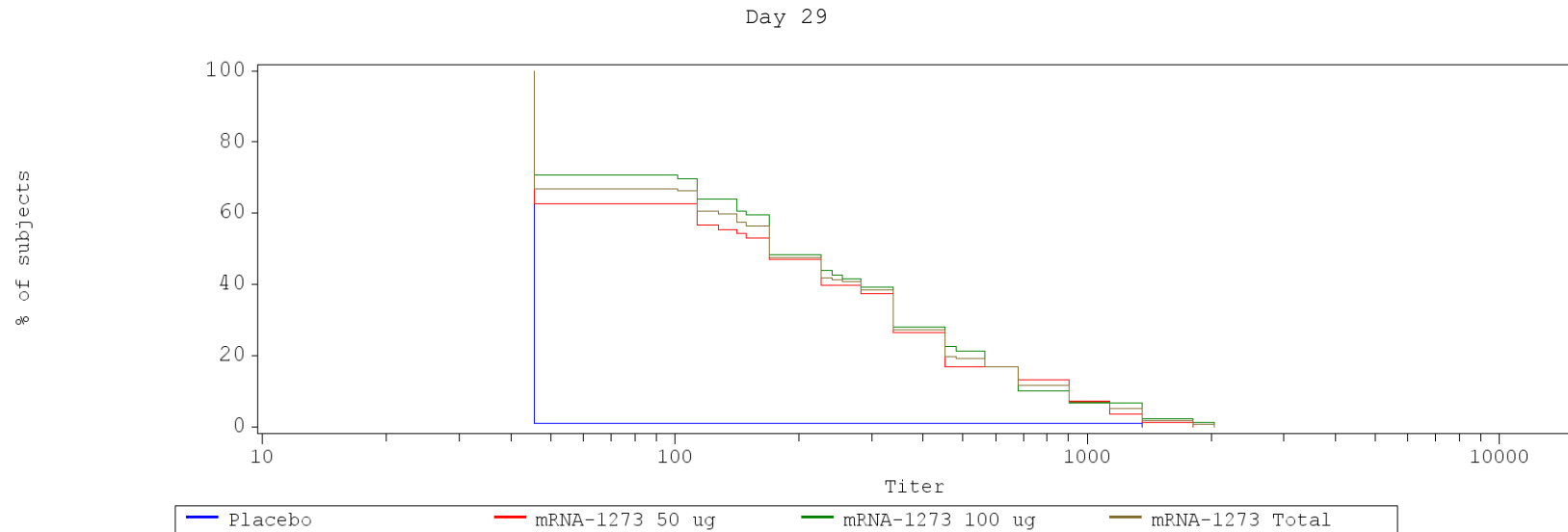
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

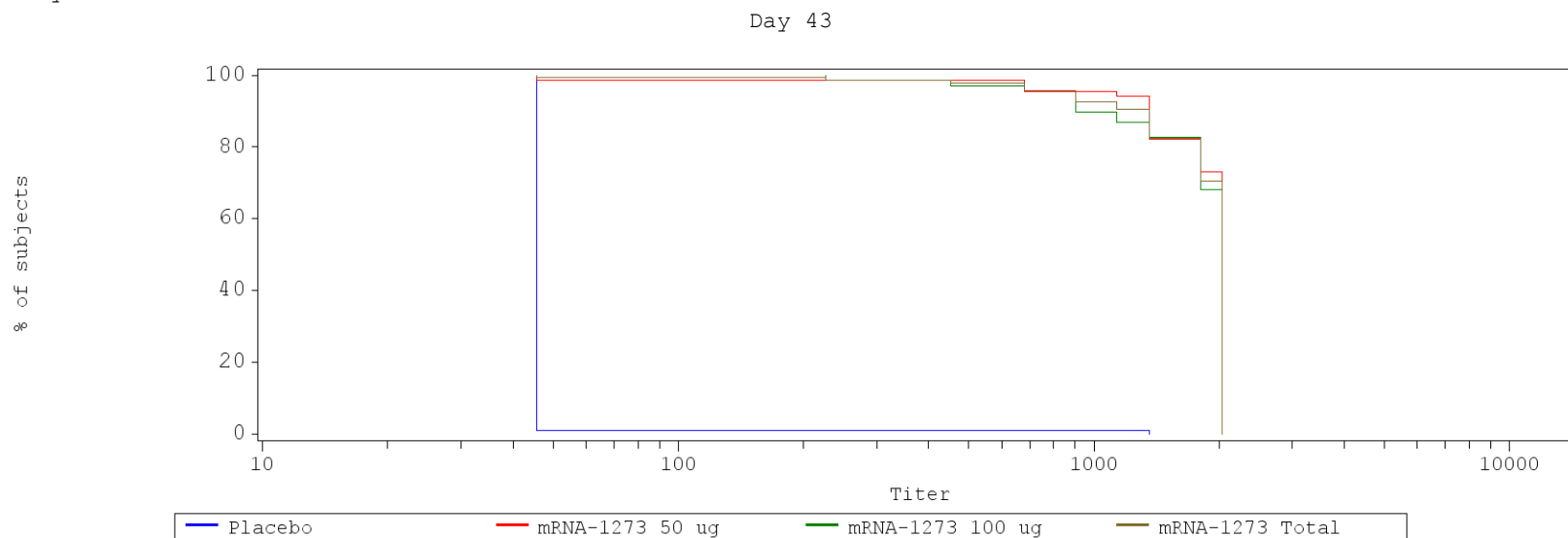
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

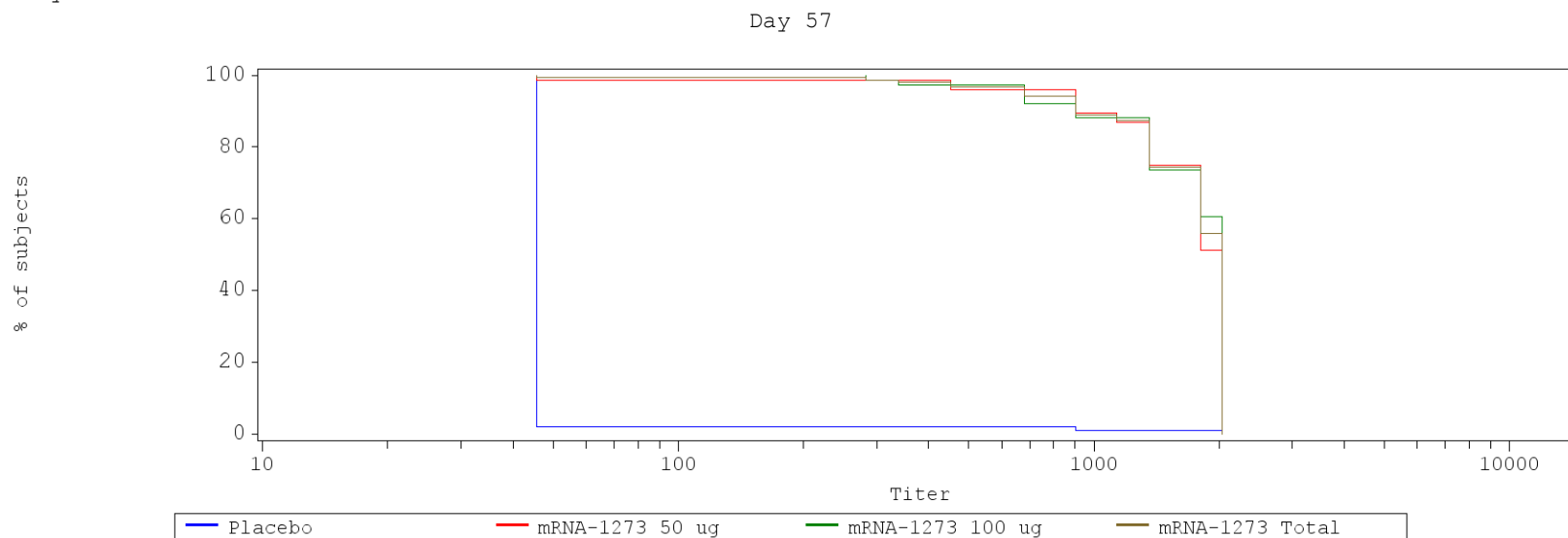
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.

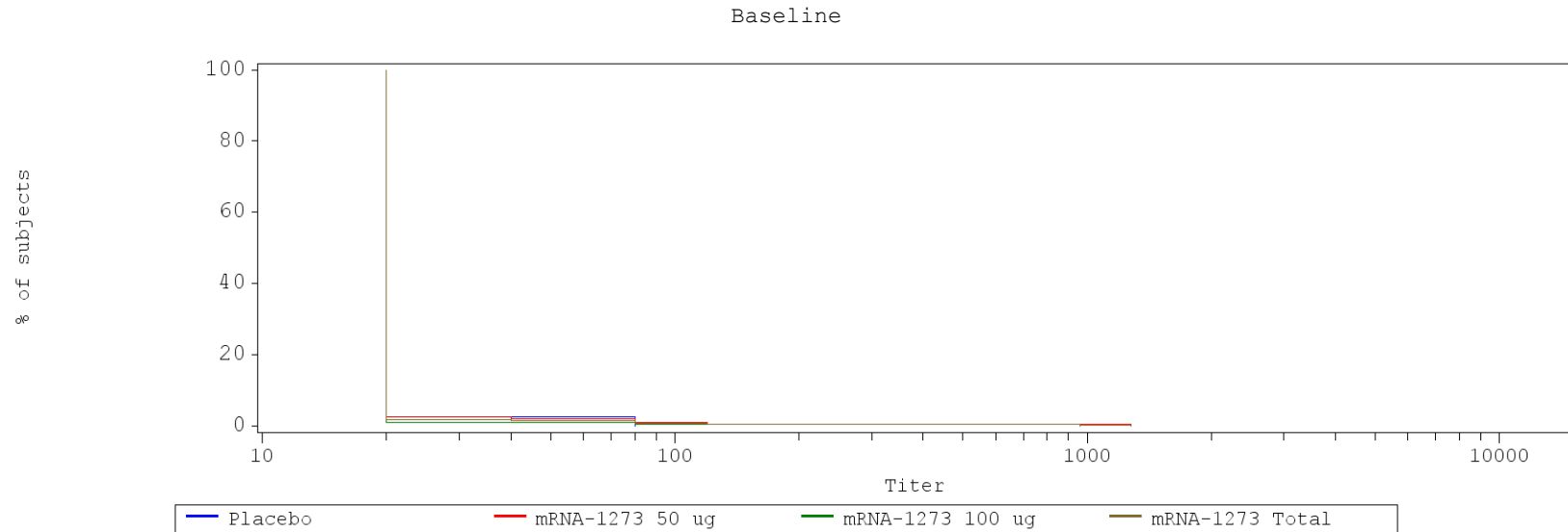
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

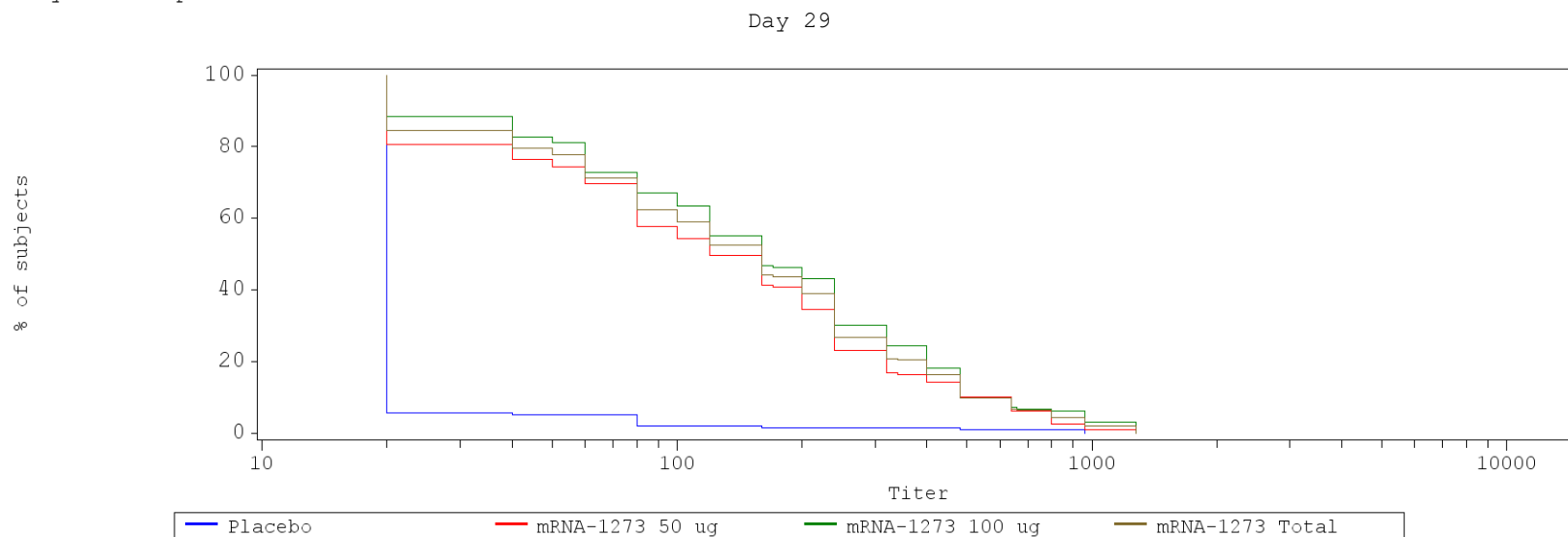
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

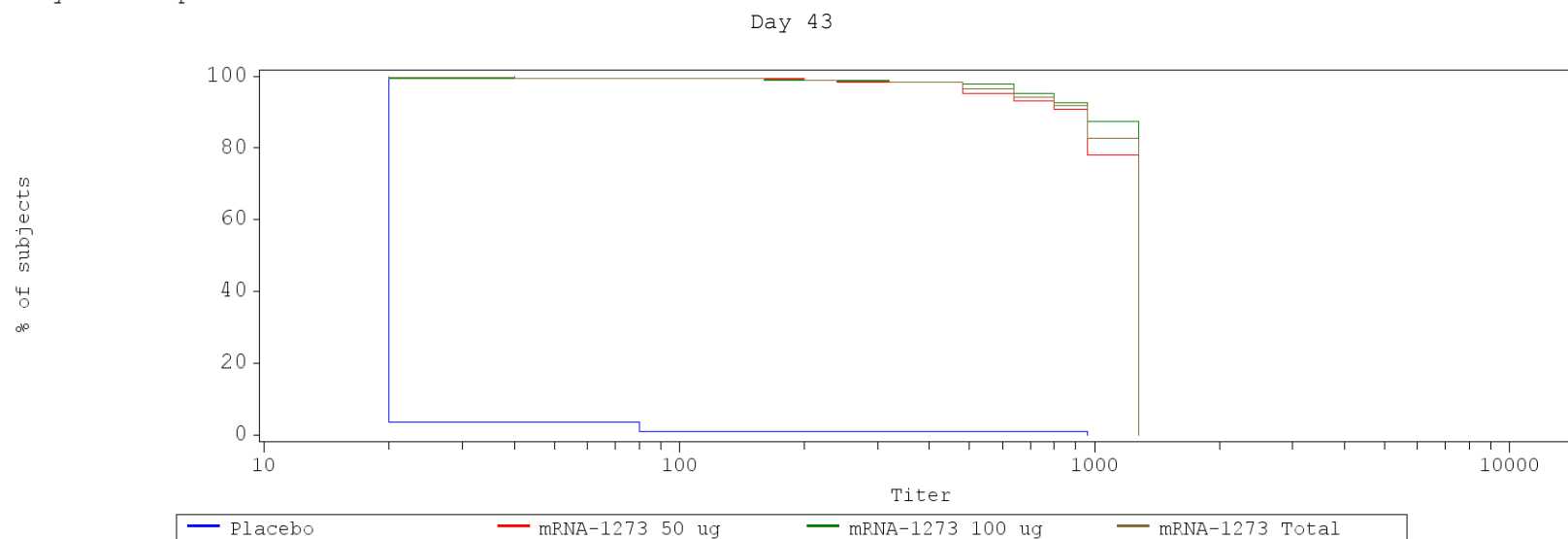
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

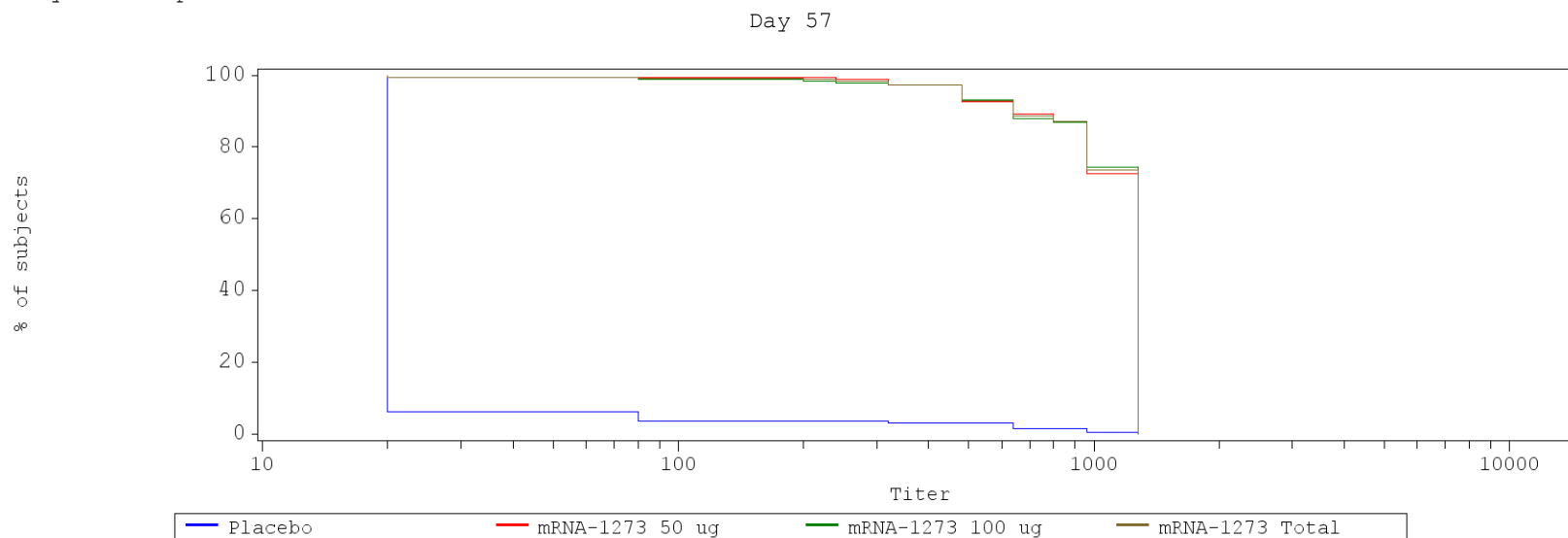
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

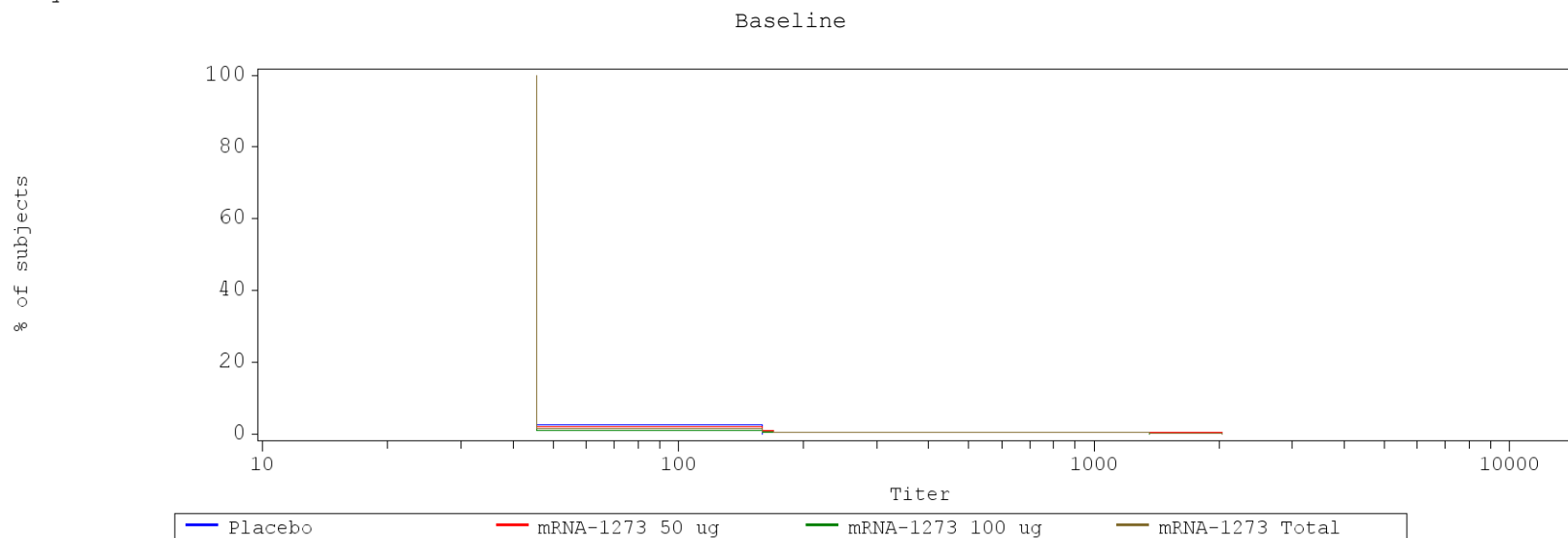
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

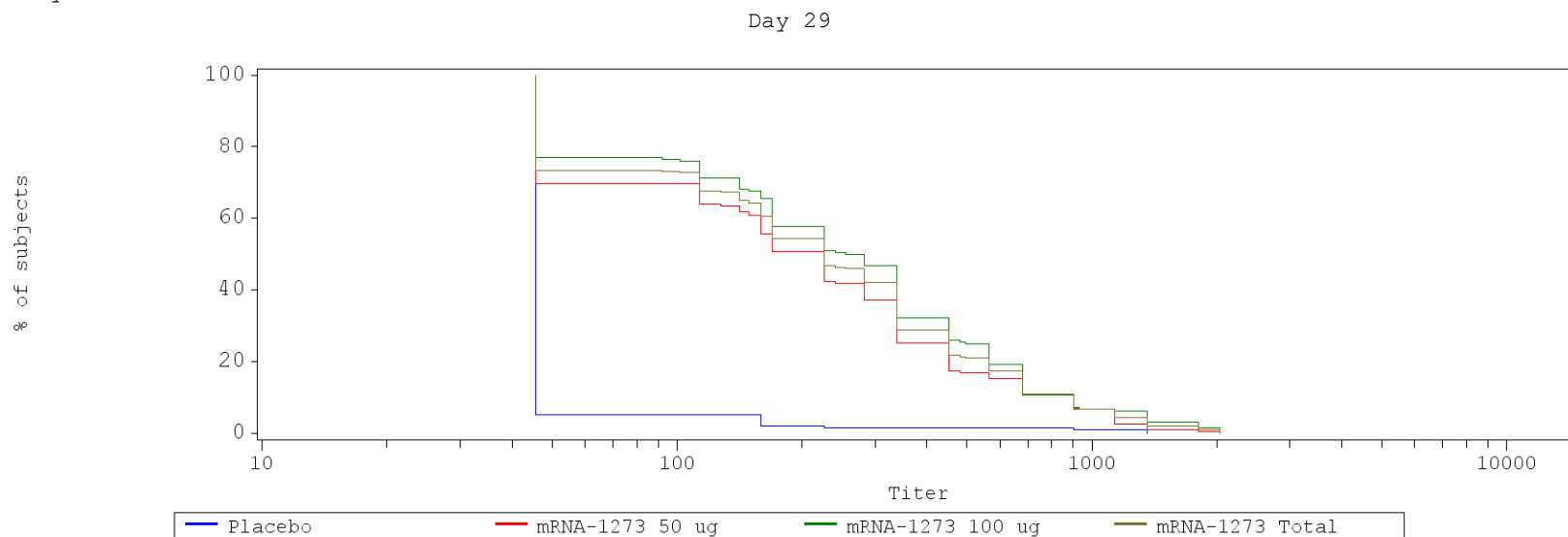
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

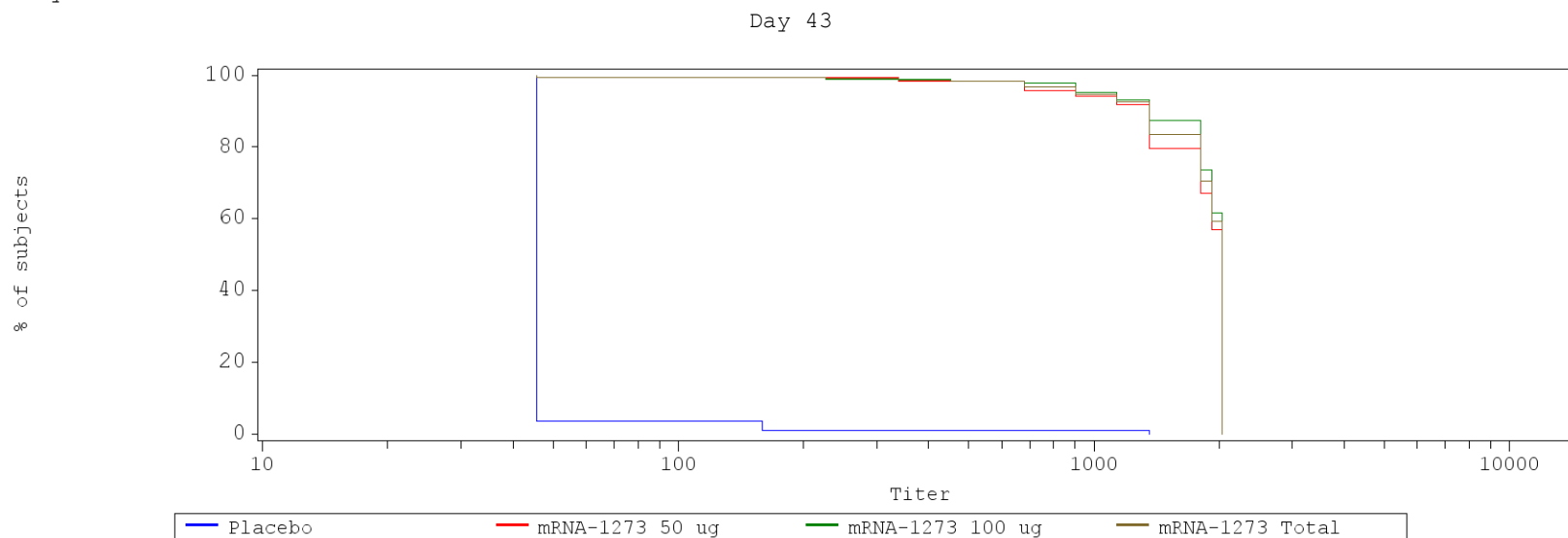
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

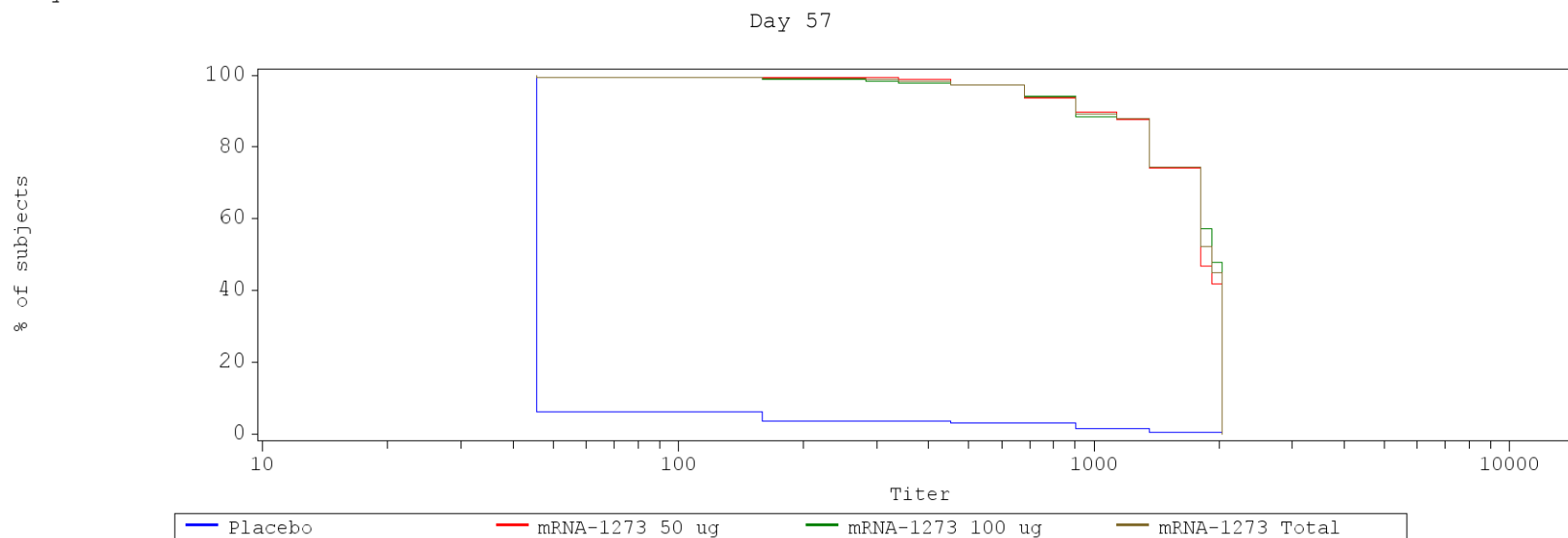
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

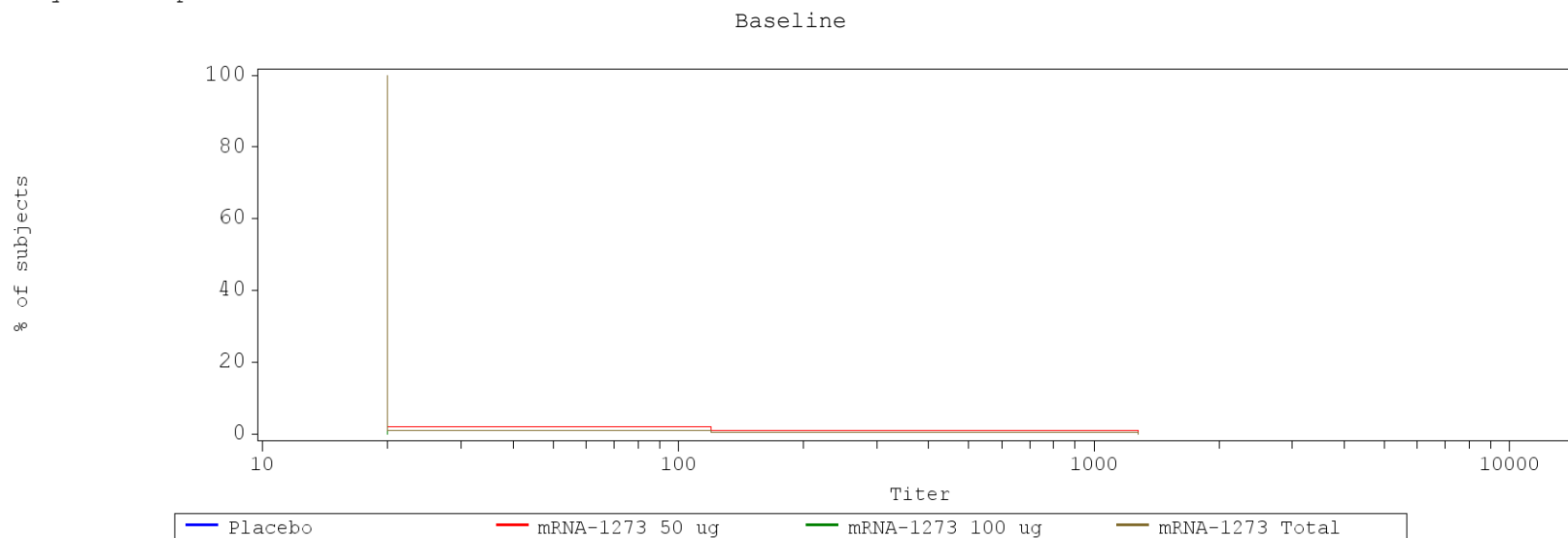
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

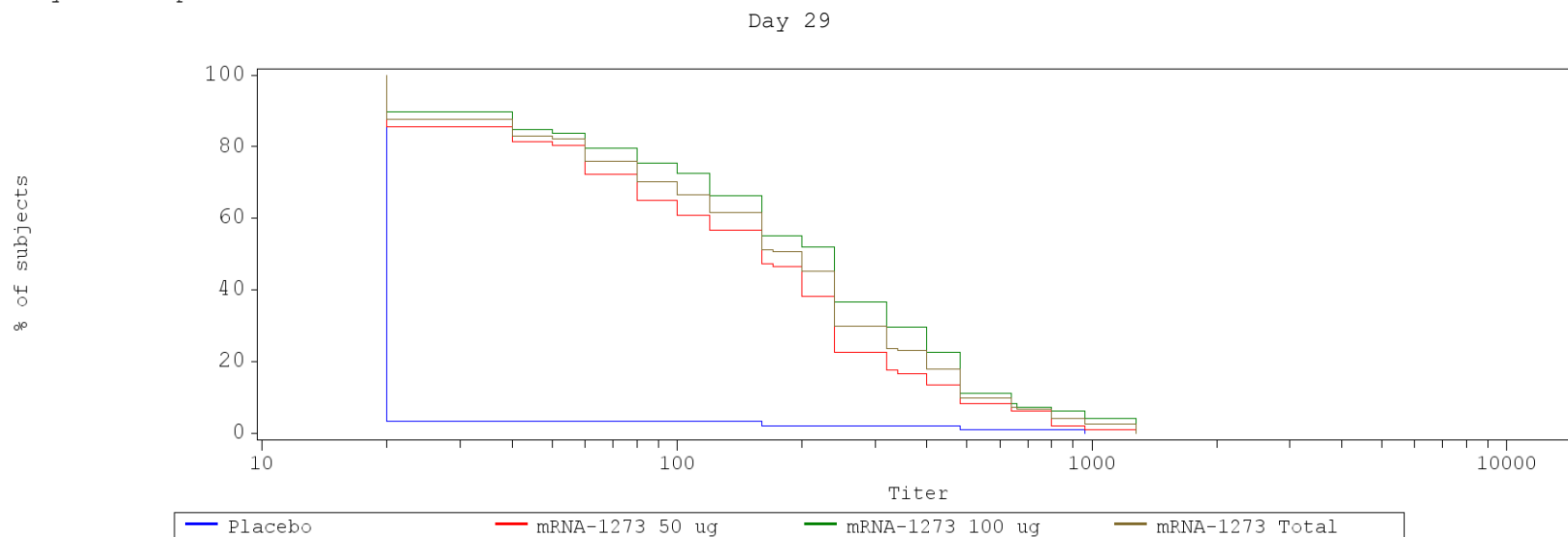
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

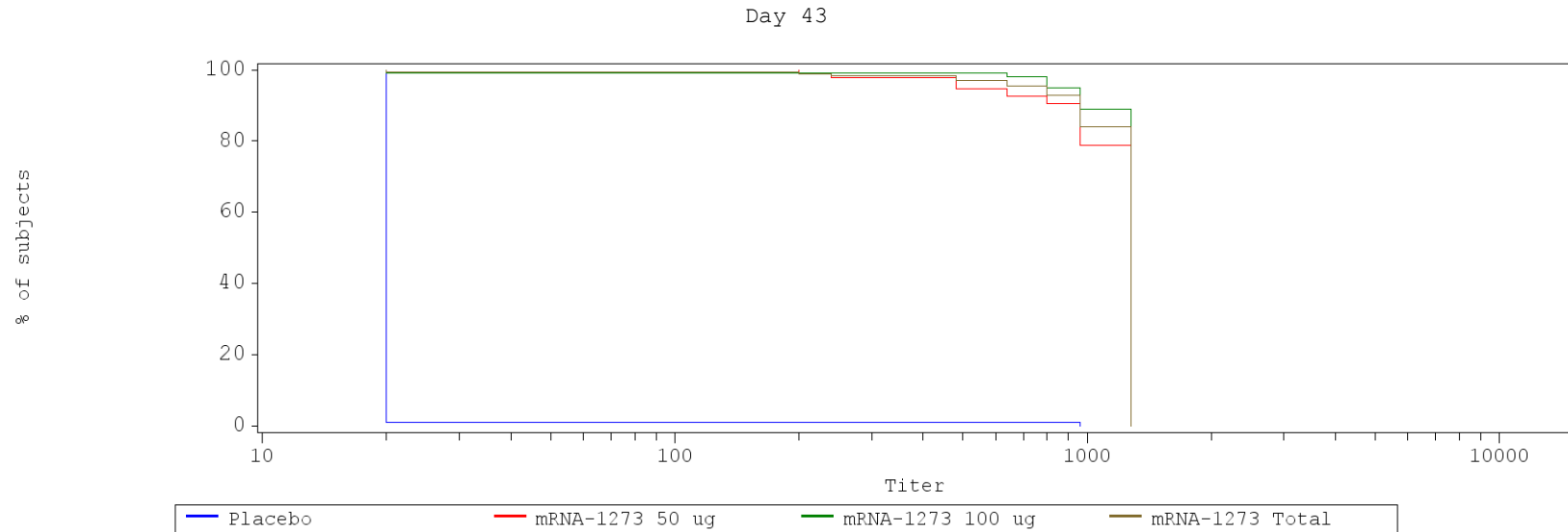
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

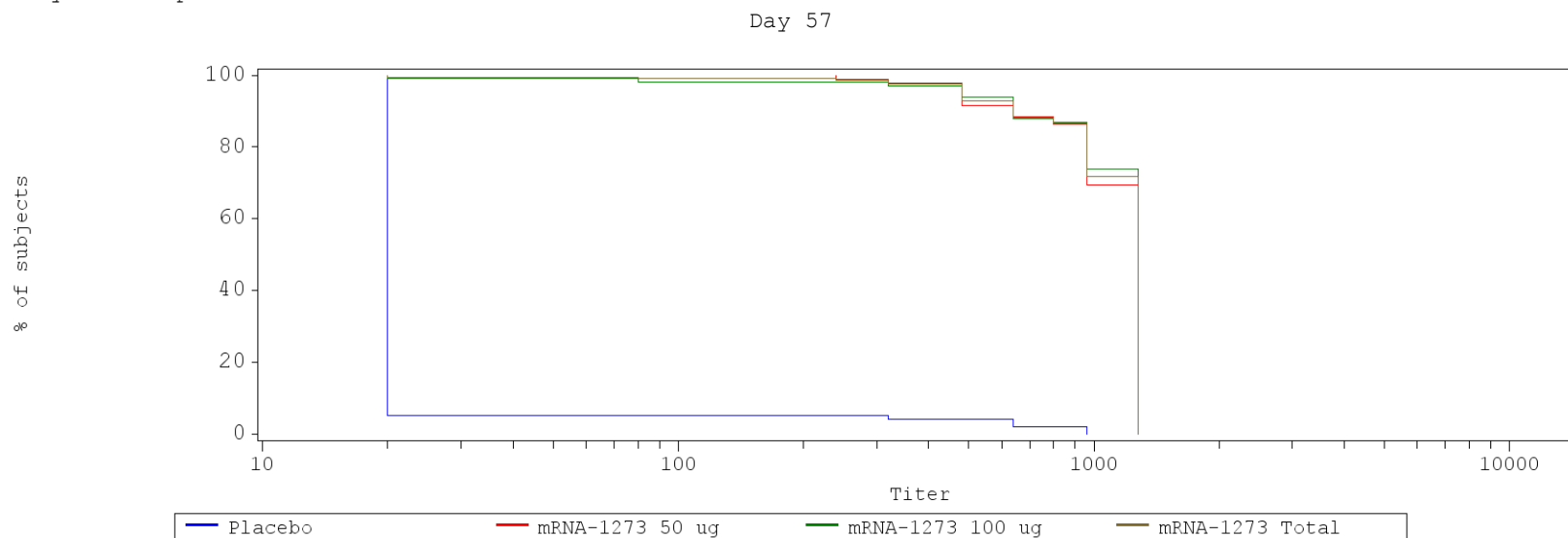
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

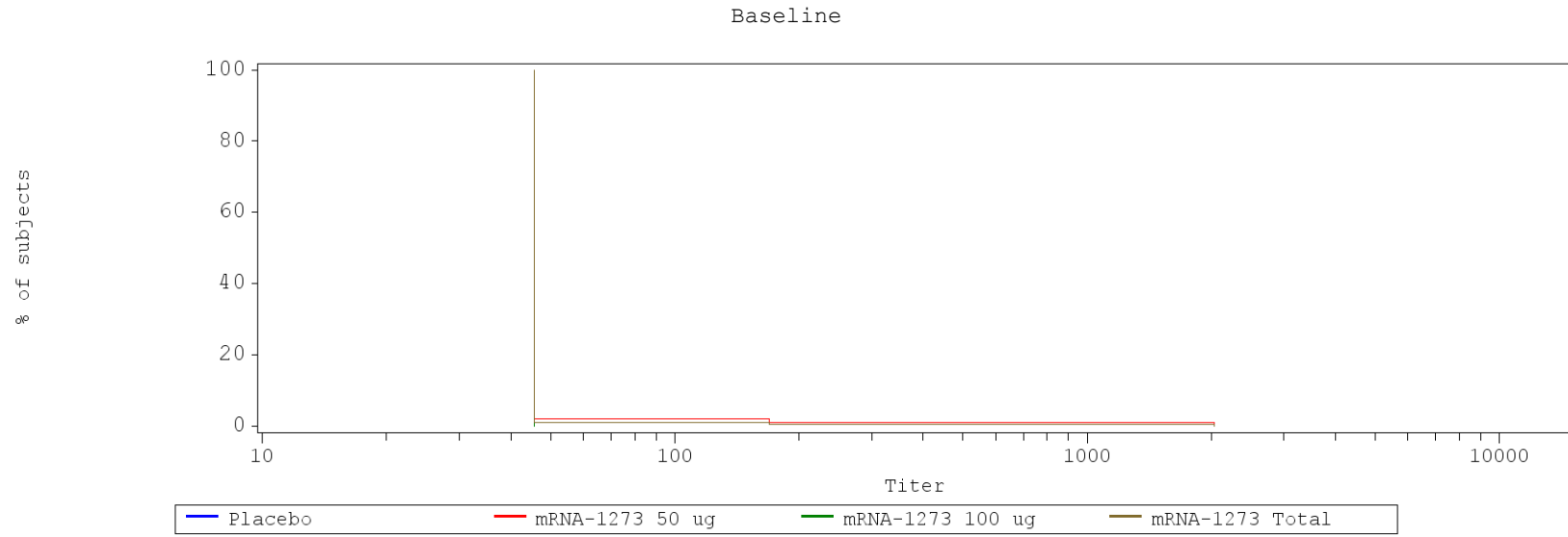
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

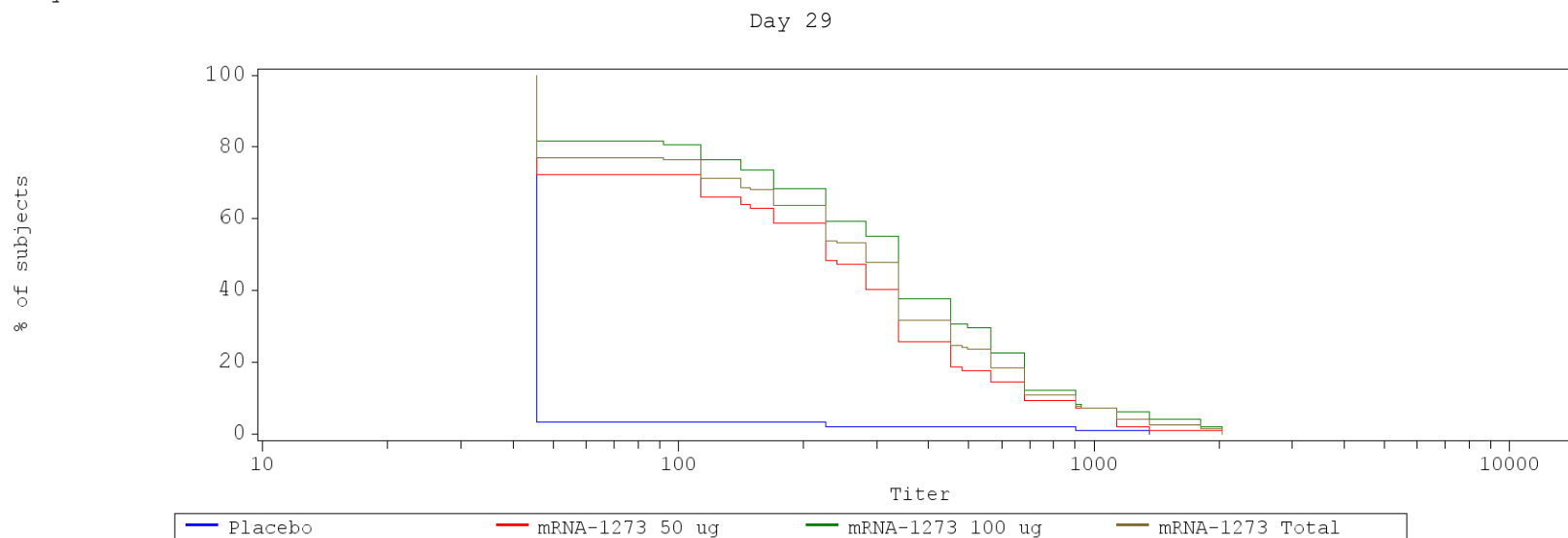
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

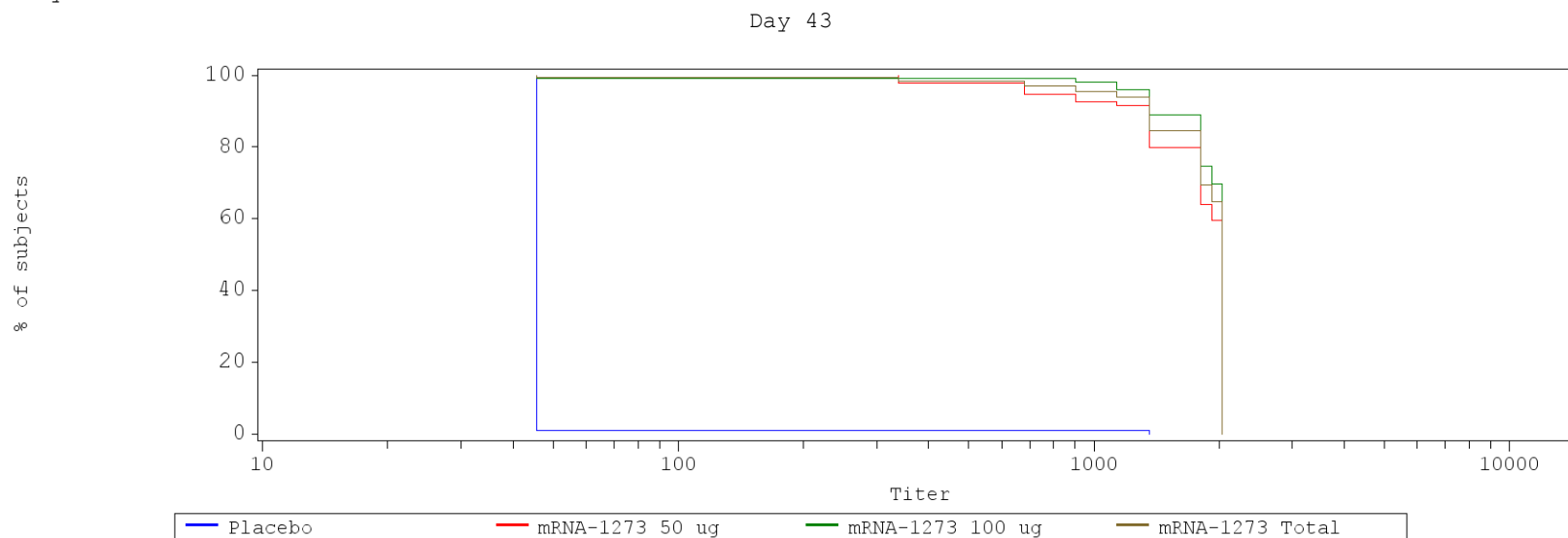
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

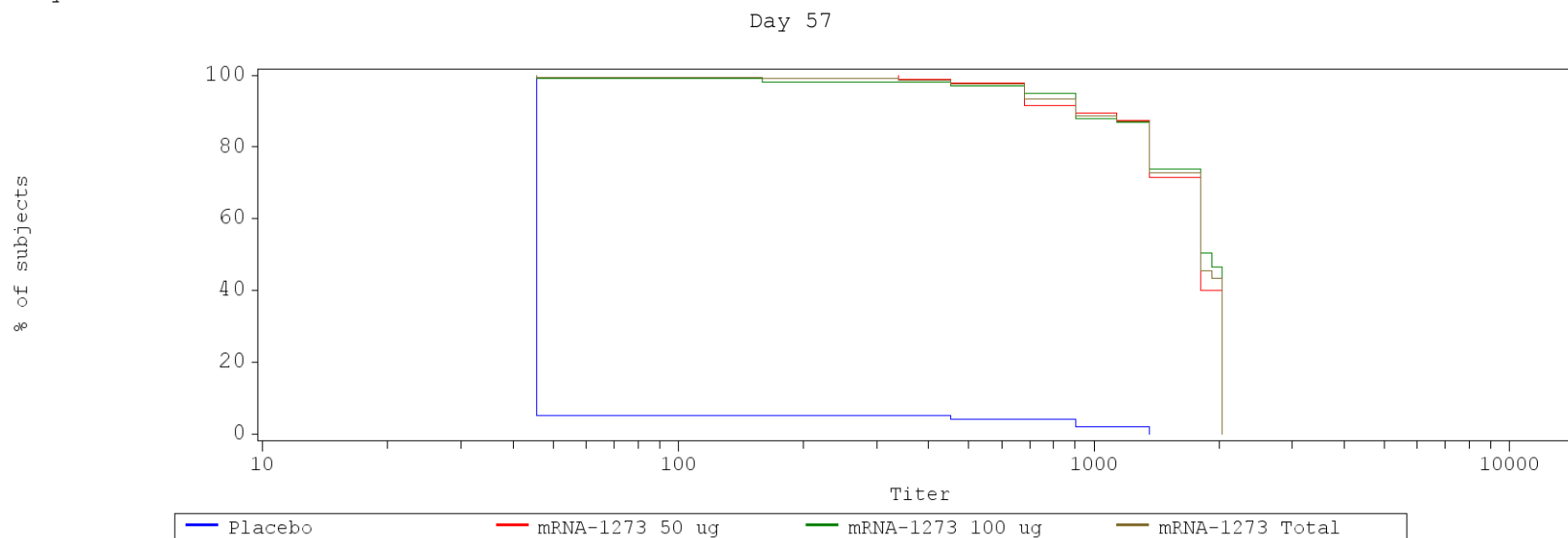
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (≥ 18 and < 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

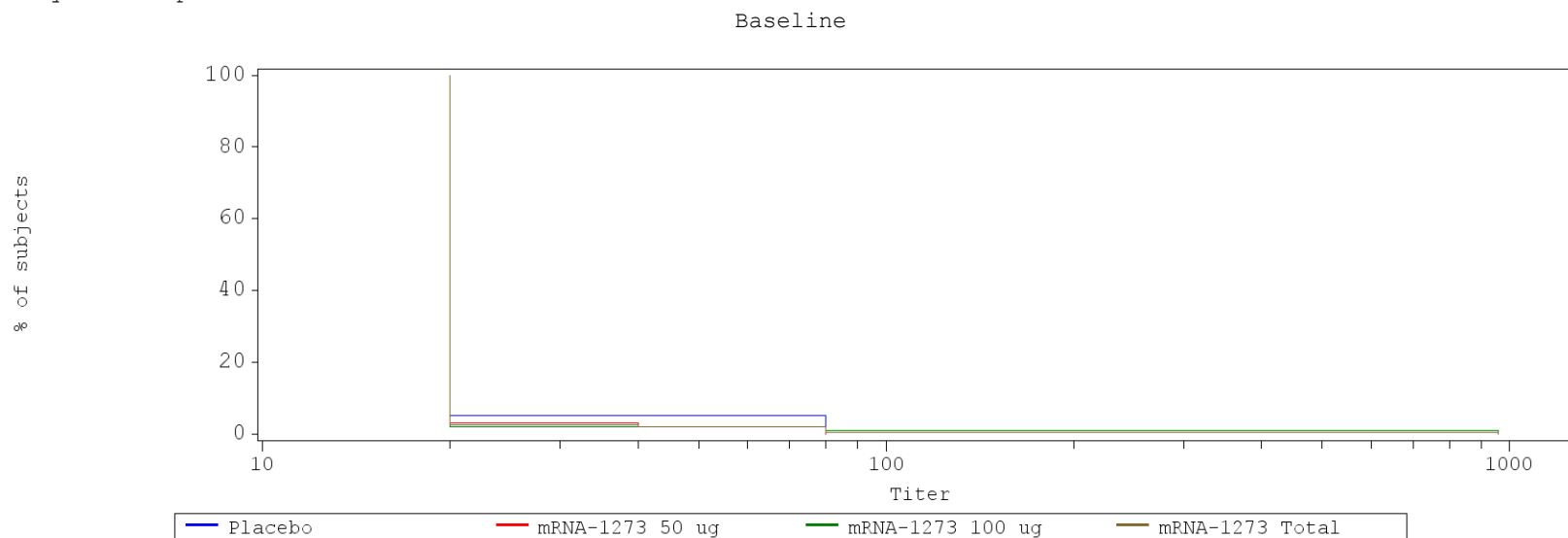
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

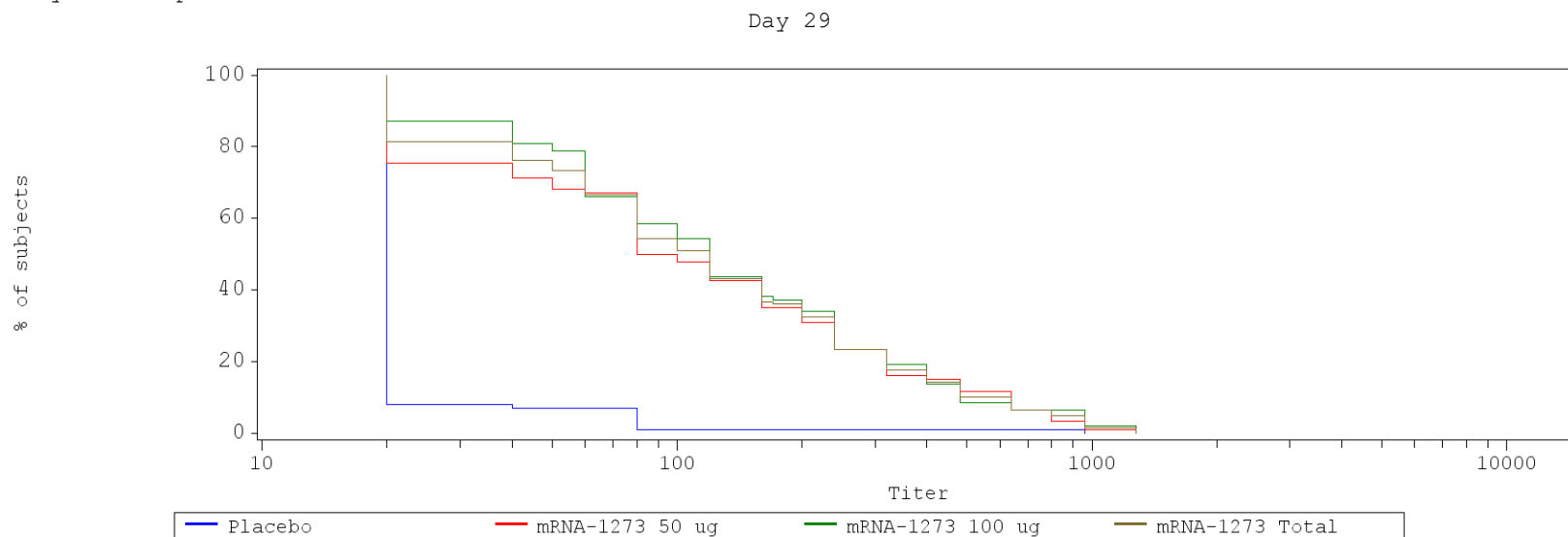
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

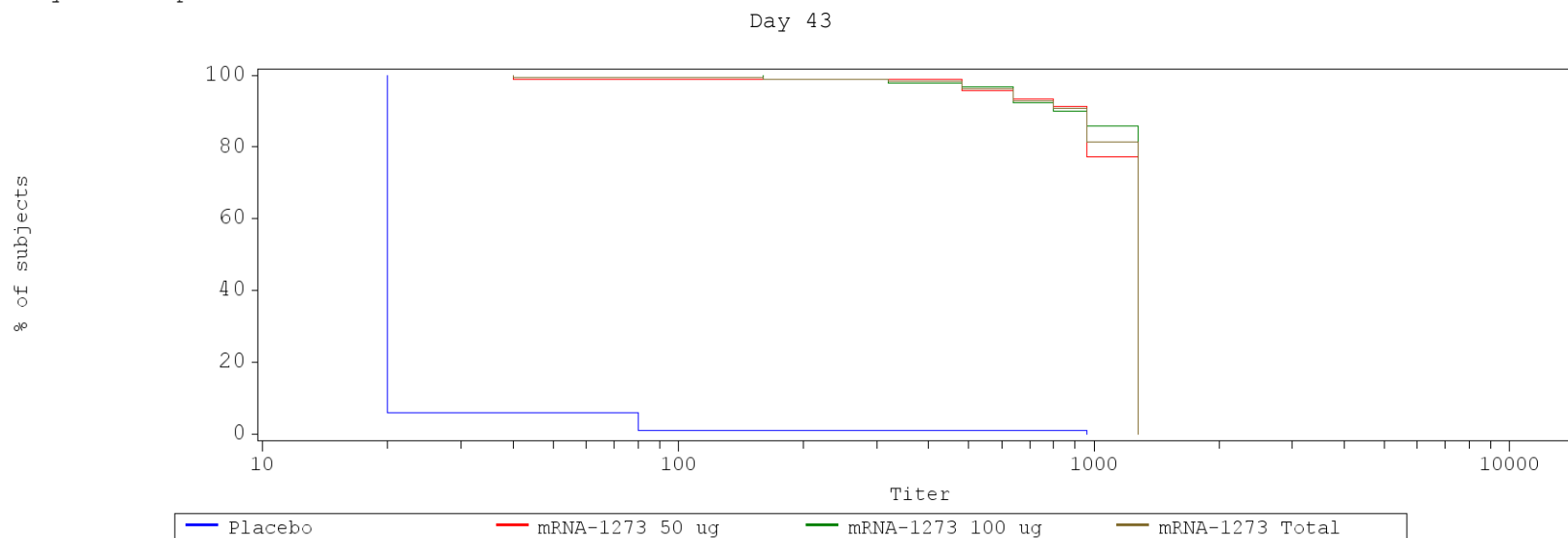
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

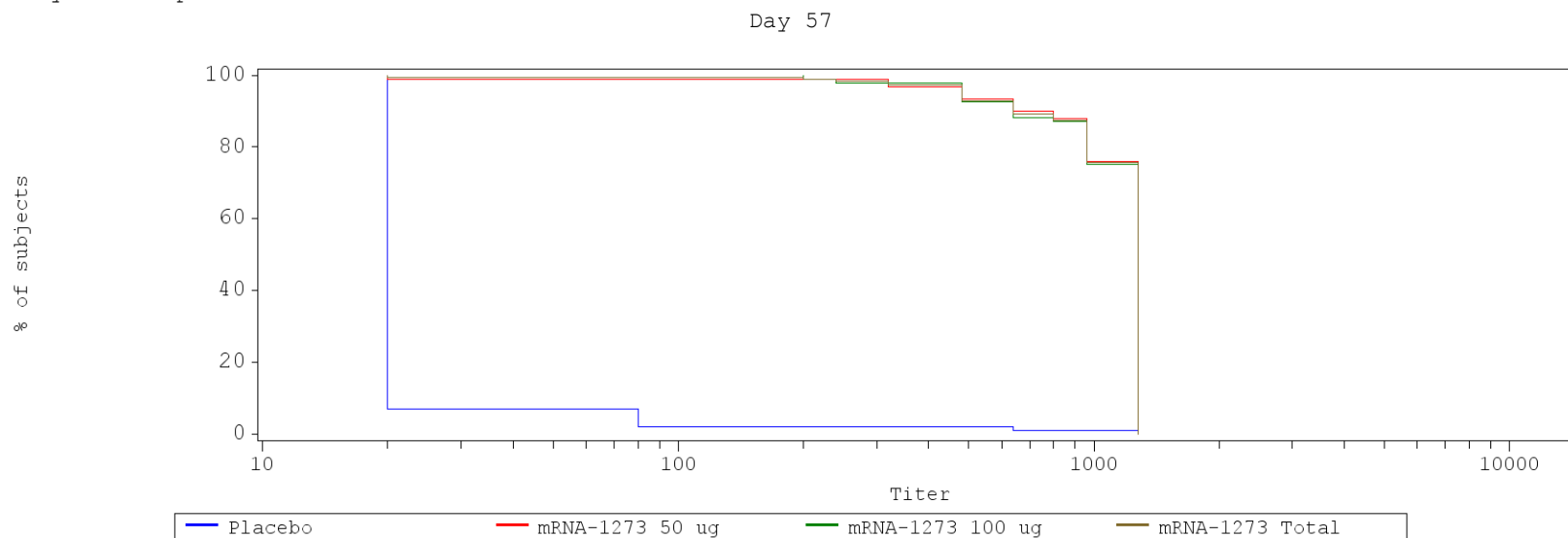
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN Endpoint Titer



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

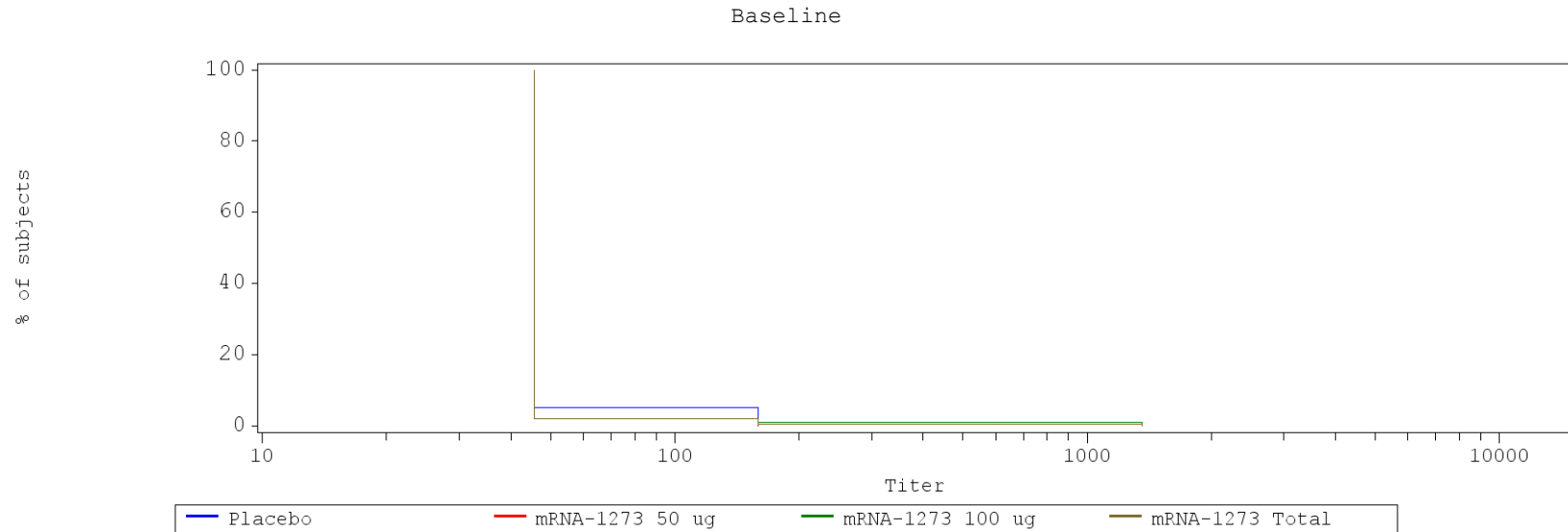
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

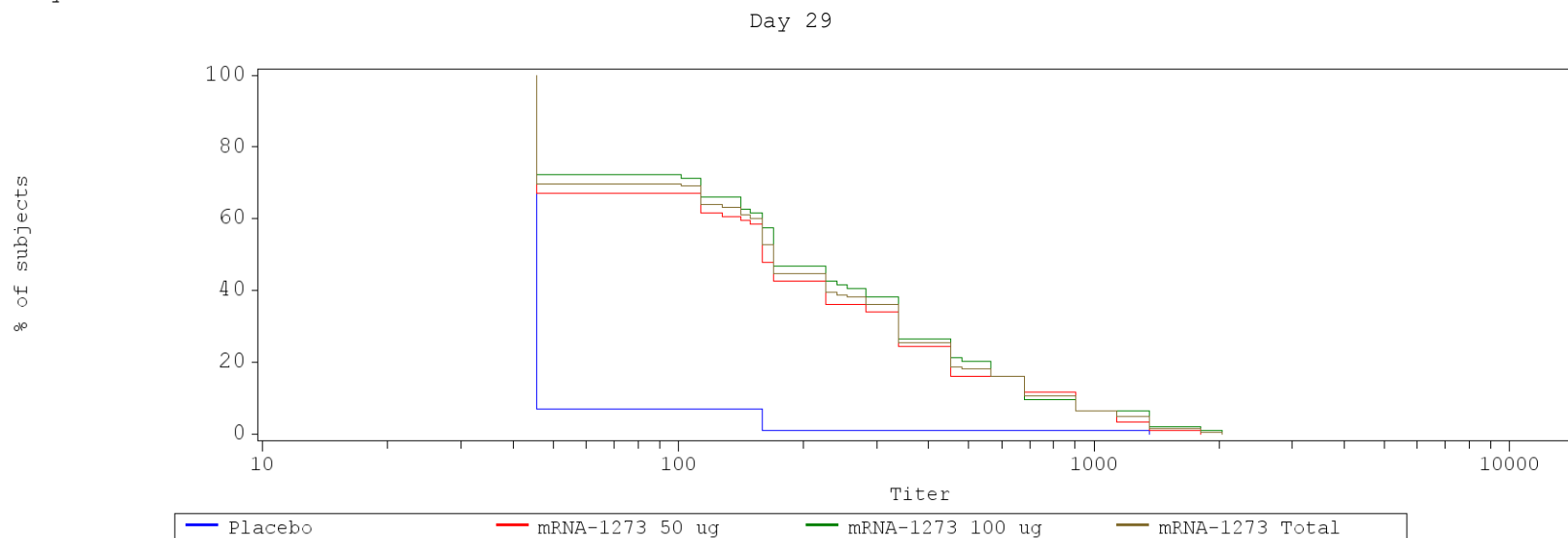
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

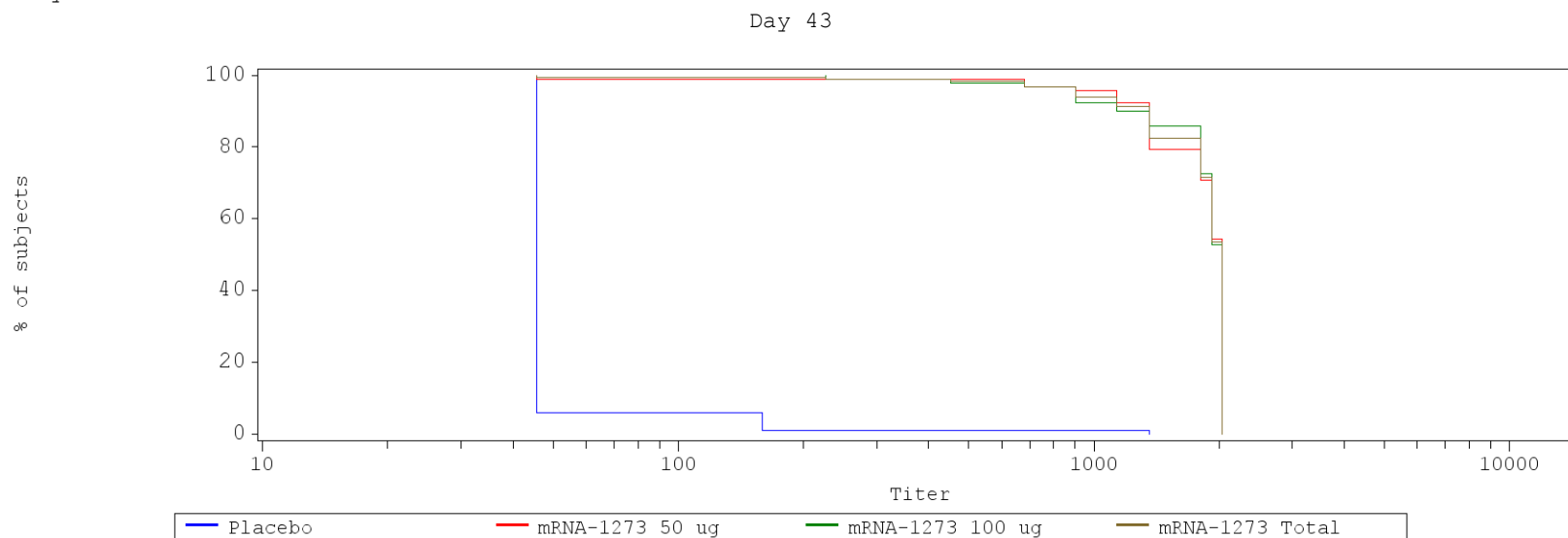
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

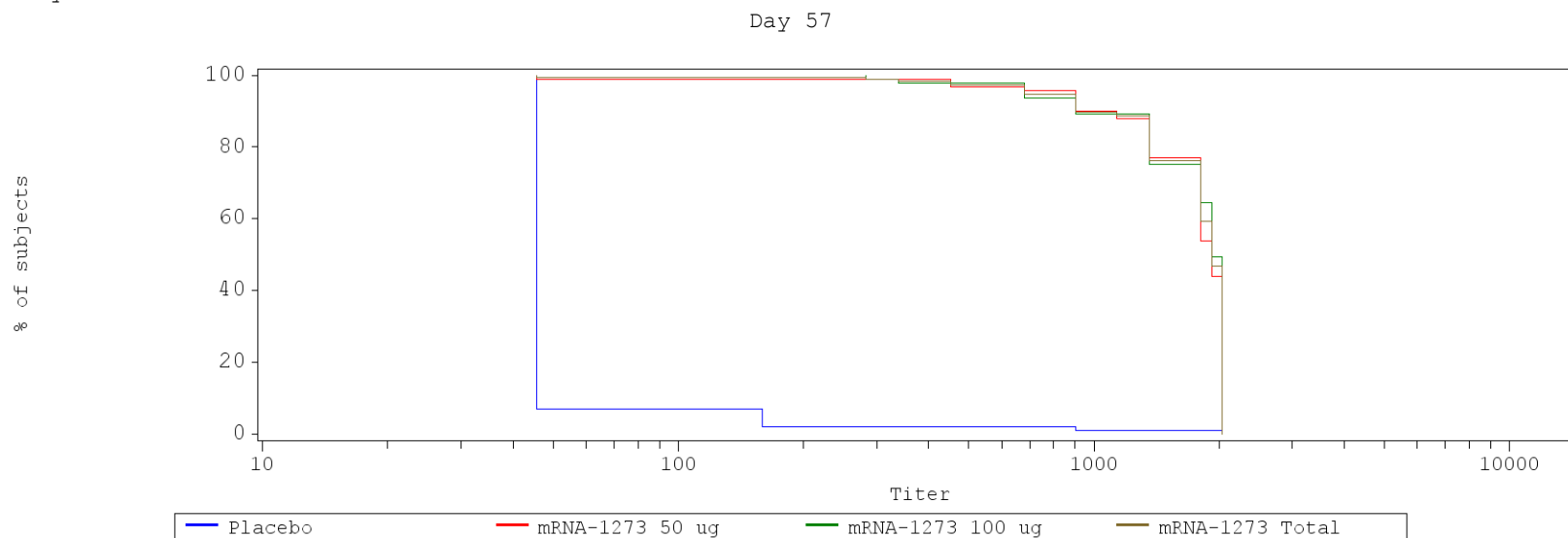
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

Figure 14.2.6.2.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (≥ 55 Years)
Antibody: MN50



nAb = Neutralizing antibody.

Note: Percentages are based on the number of subjects in the Full Analysis Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402060202.sas 19NOV2020 05:16 Database Lock Date: 05NOV2020

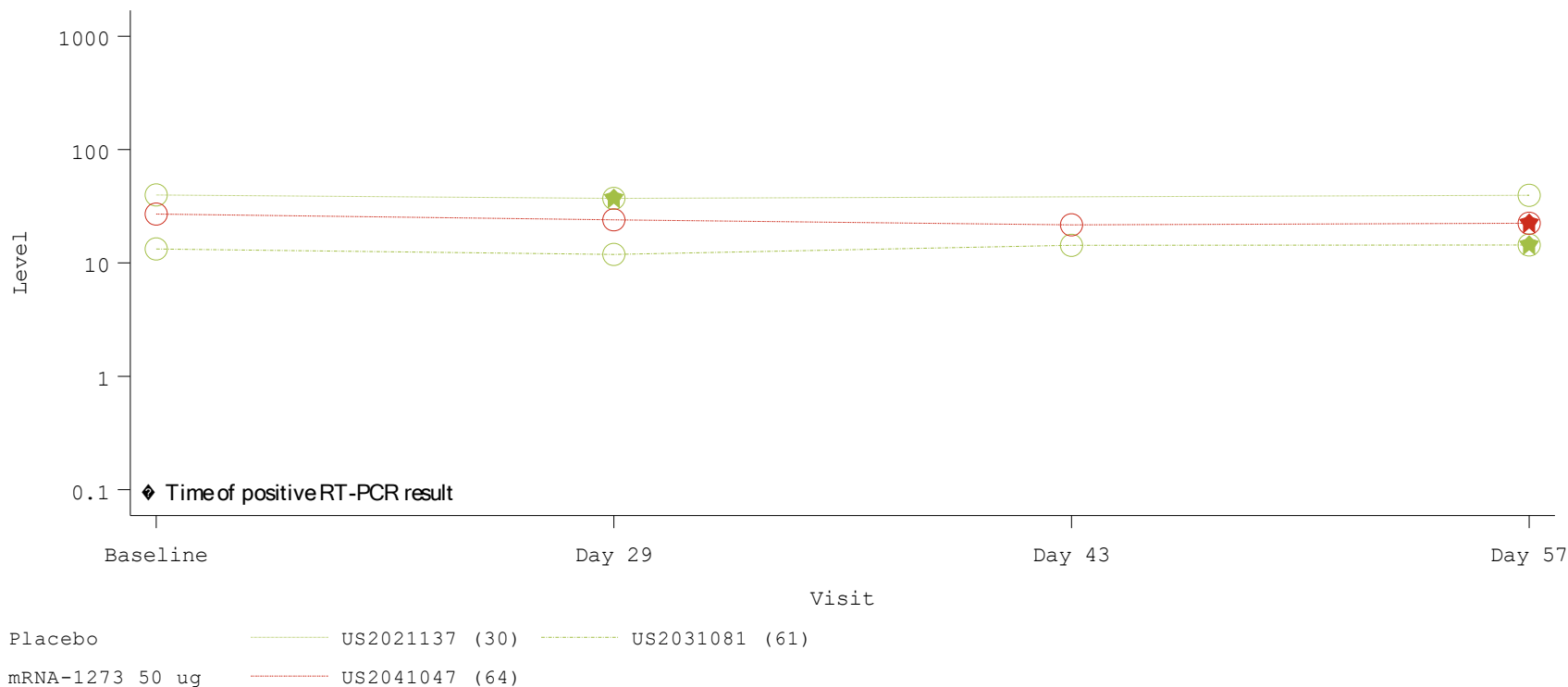
Figure 14.2.7.1

Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)



bAb = Binding antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020701.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

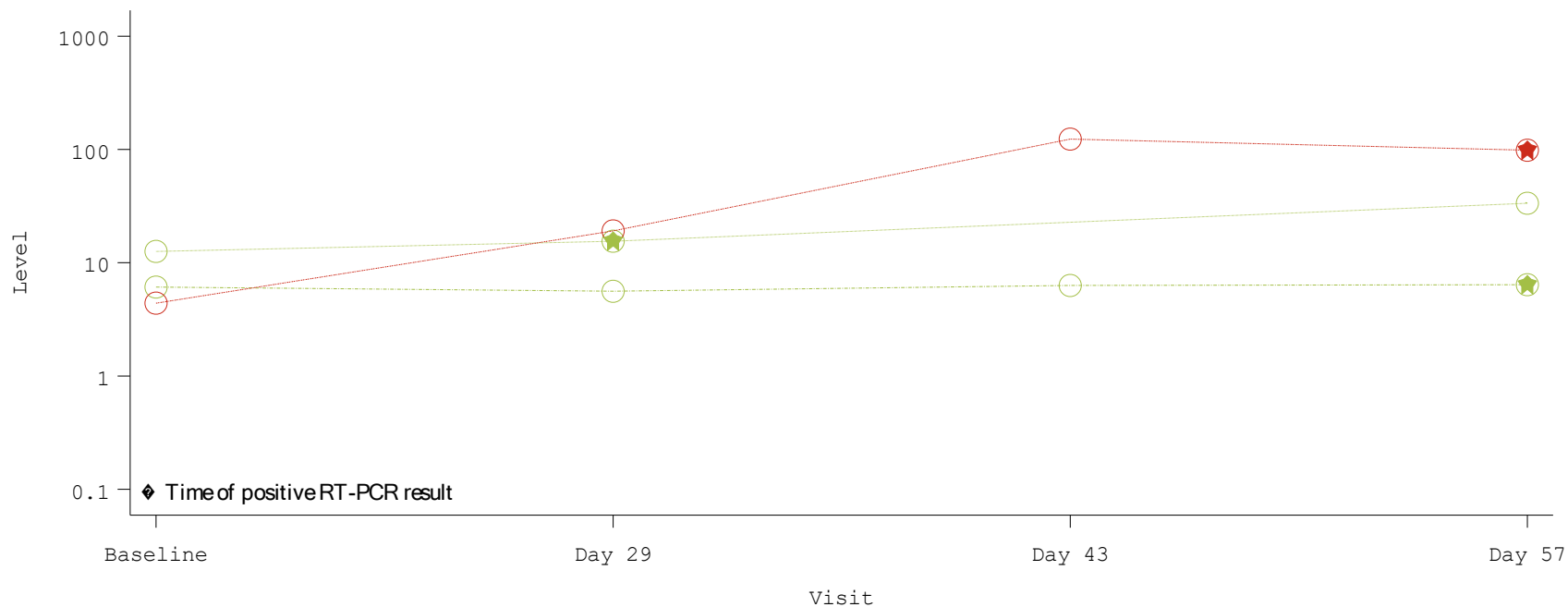
Figure 14.2.7.1

Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)



Placebo US2021137 (30) US2031081 (61)

mRNA-1273 50 ug US2041047 (64)

bAb = Binding antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020701.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

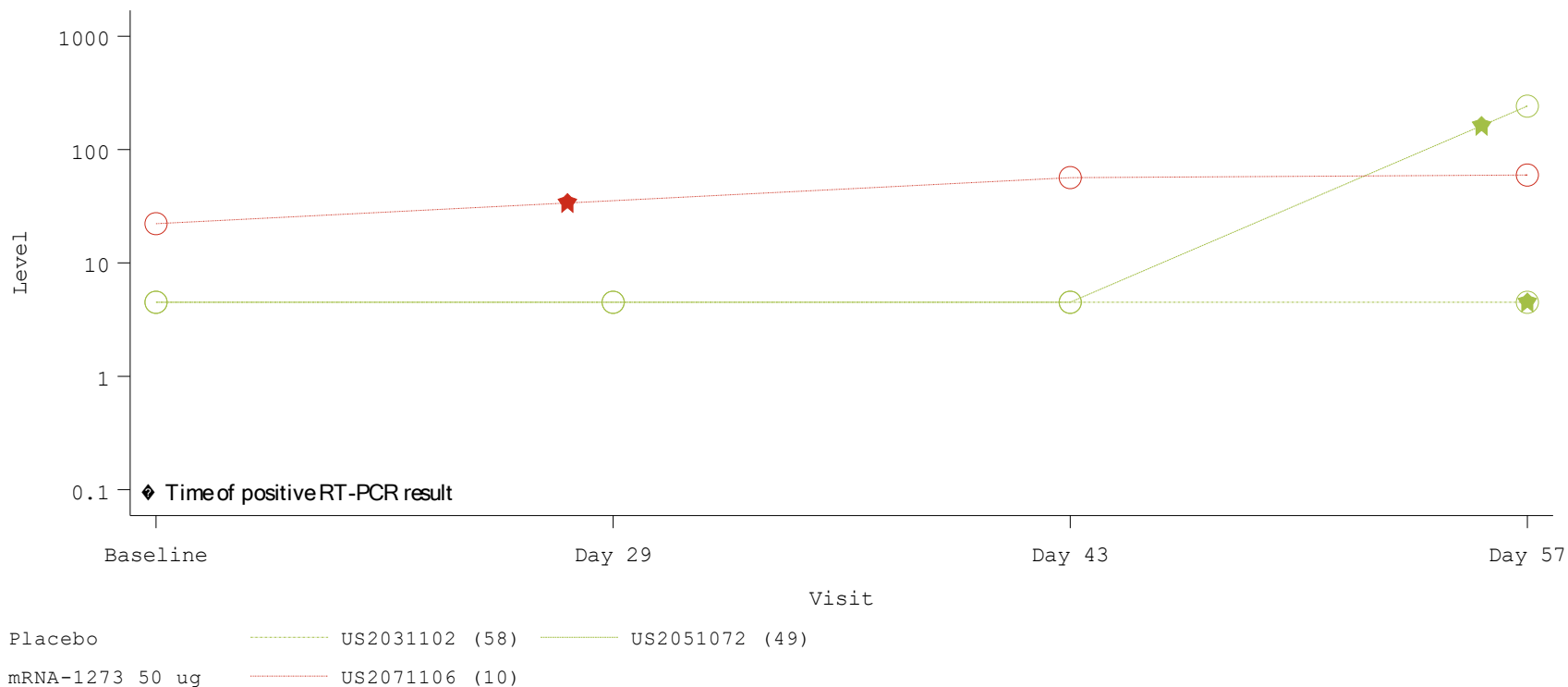
Figure 14.2.7.1

Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (Age >= 55)

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) (LLOQ: 9, ULOQ: 33000)



bAb = Binding antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

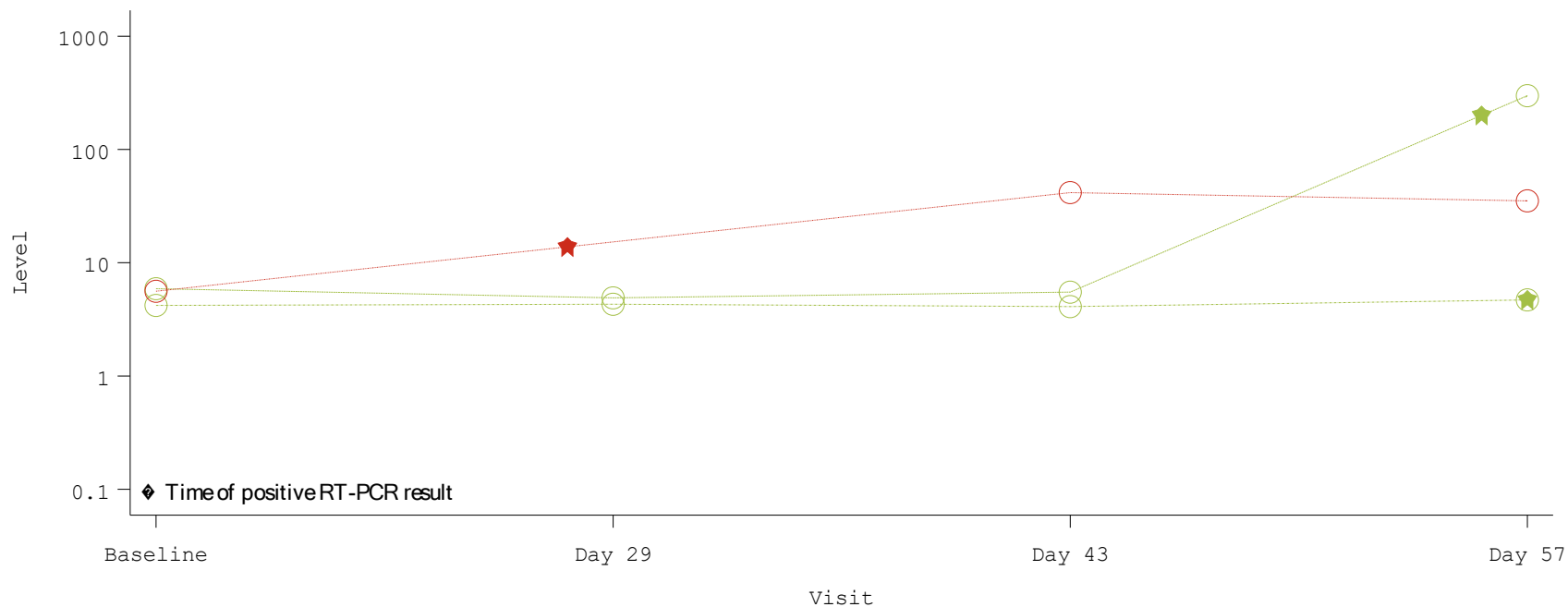
Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020701.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

Figure 14.2.7.1

Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (Age >= 55)

Antibody: VAC58 Spike IgG Antibody (ug/mL) (LLOQ: 3.9, ULOQ: 487)



bAb = Binding antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl4020701.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

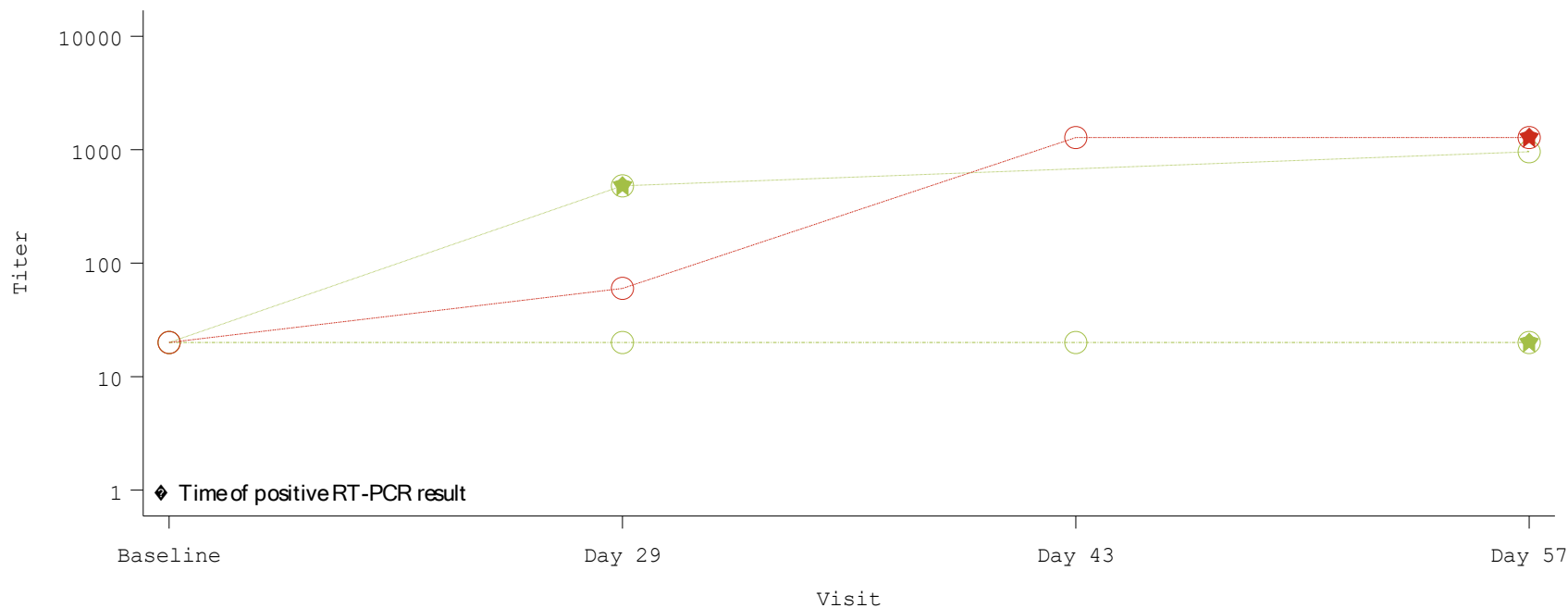
Figure 14.2.7.2.1

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: MN Endpoint Titer



Placebo US2021137 (30) US2031081 (61)
mRNA-1273 50 ug US2041047 (64)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070201.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

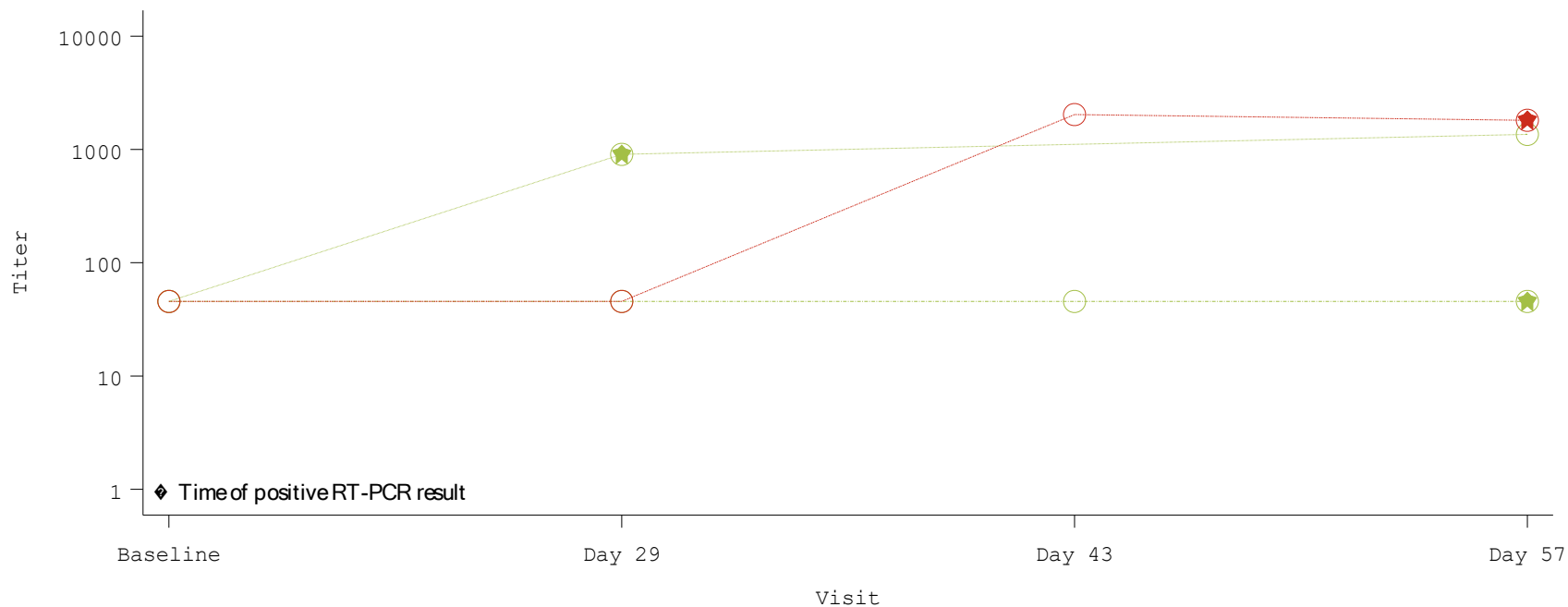
Figure 14.2.7.2.1

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: MN50



Placebo US2021137 (30) US2031081 (61)
mRNA-1273 50 ug US2041047 (64)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070201.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

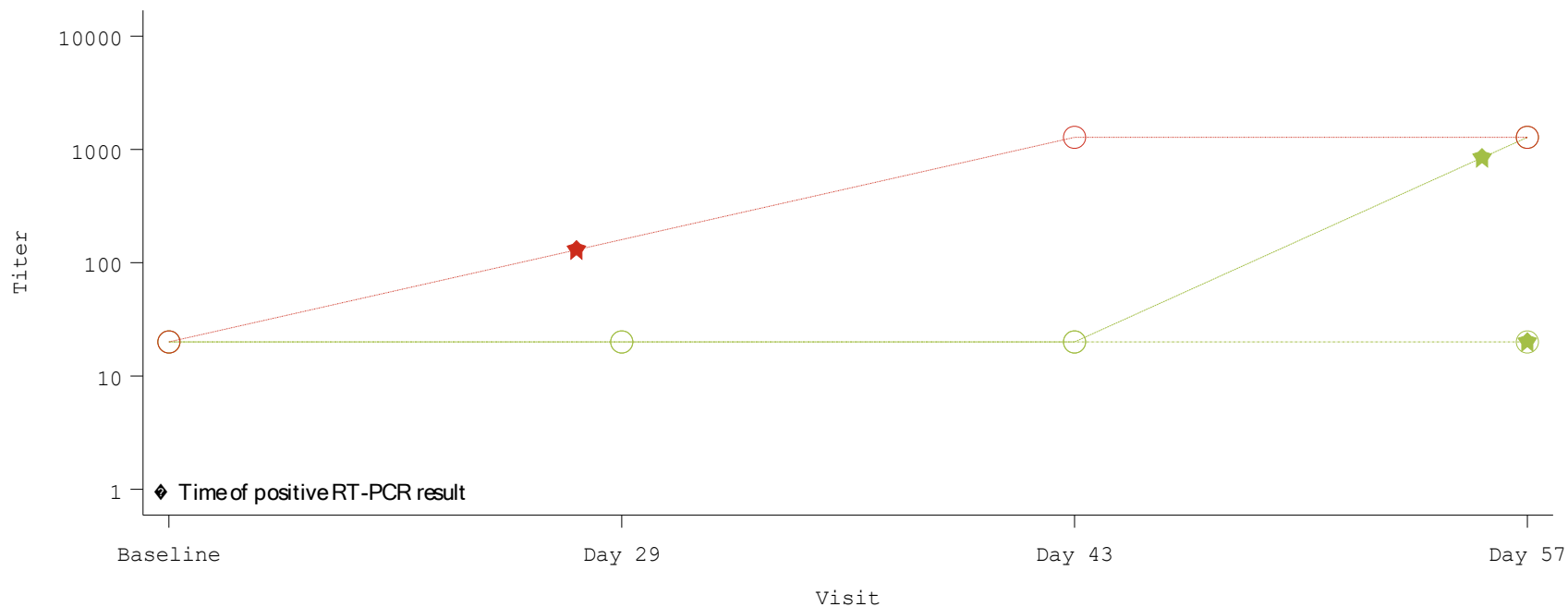
Figure 14.2.7.2.1

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (Age >= 55)

Antibody: MN Endpoint Titer



Placebo US2031102 (58) US2051072 (49)
mRNA-1273 50 ug US2071106 (10)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

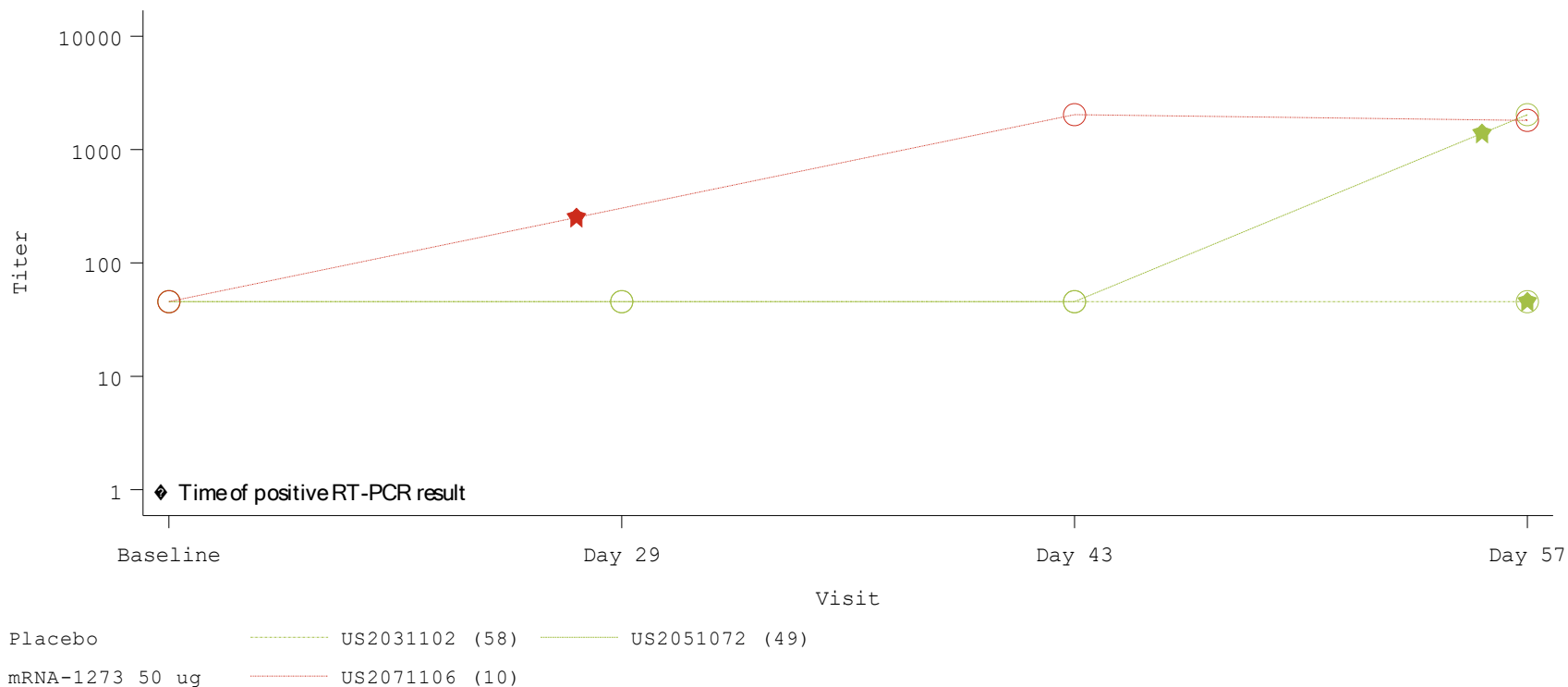
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070201.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

Figure 14.2.7.2.1

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (Age >= 55)
Antibody: MN50



nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070201.sas 19NOV2020 20:44 Database Lock Date: 05NOV2020

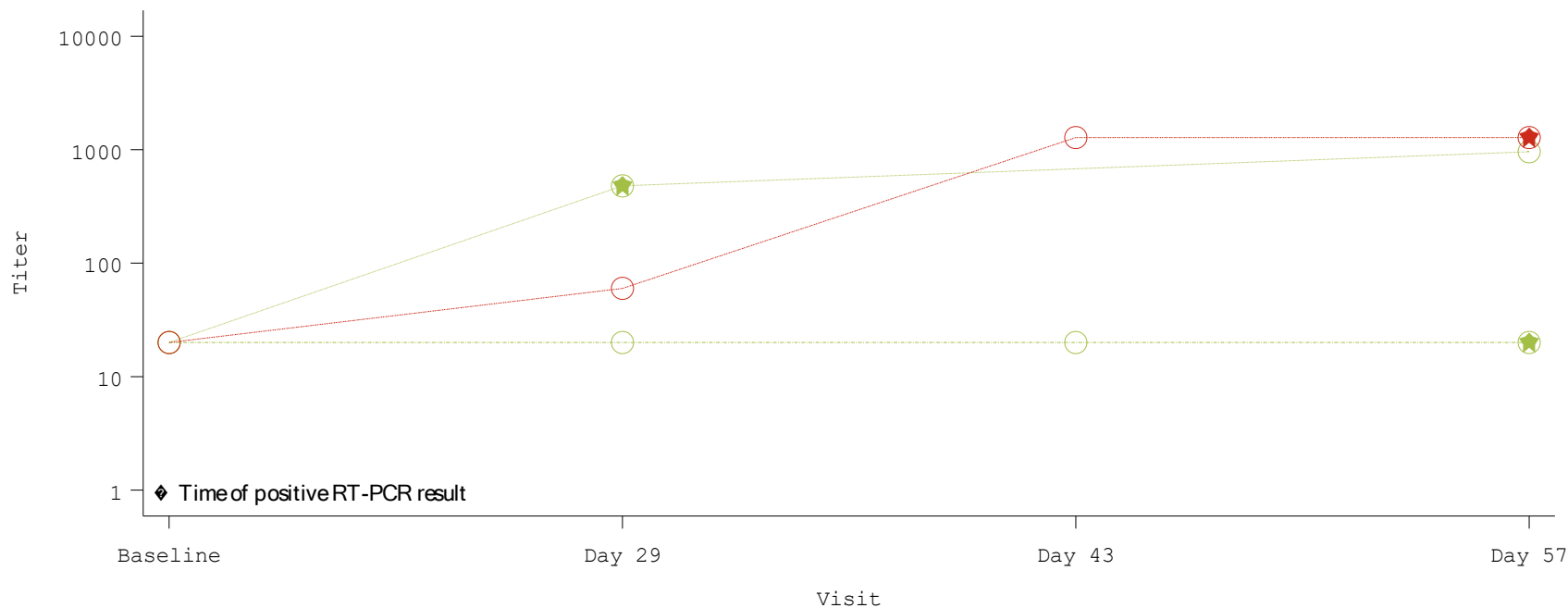
Figure 14.2.7.2.2

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: MN Endpoint Titer



Placebo US2021137 (30) US2031081 (61)
mRNA-1273 50 ug US2041047 (64)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070202.sas 19NOV2020 20:45 Database Lock Date: 05NOV2020

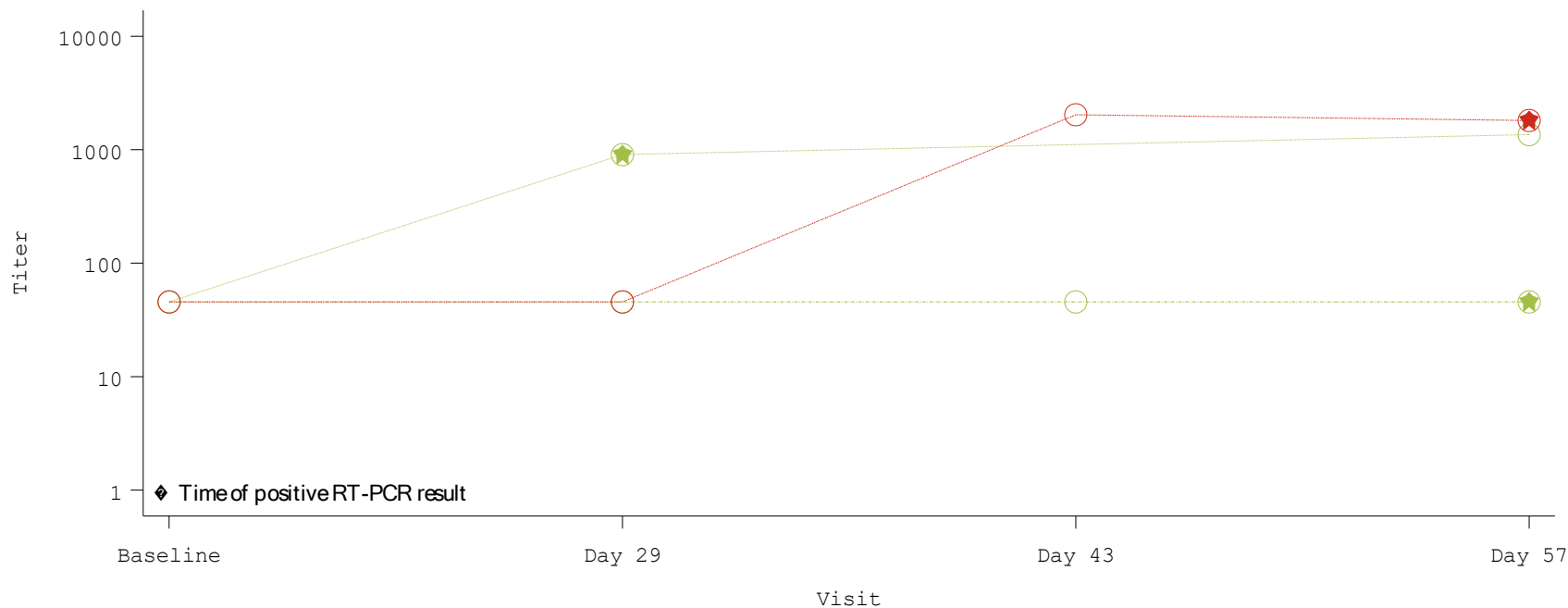
Figure 14.2.7.2.2

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (Age ≥ 18 and age < 55)

Antibody: MN50



Placebo US2021137 (30) US2031081 (61)
mRNA-1273 50 ug US2041047 (64)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by $0.5 \times \text{LLOQ}$. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070202.sas 19NOV2020 20:45 Database Lock Date: 05NOV2020

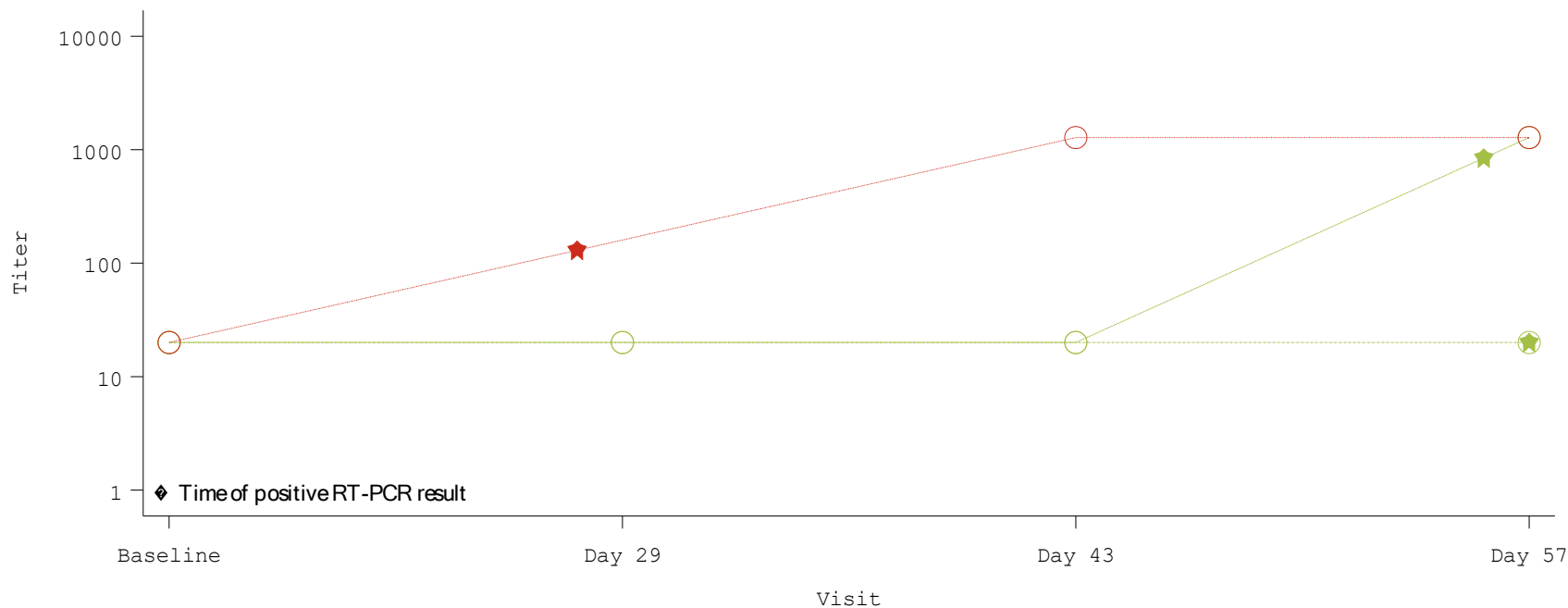
Figure 14.2.7.2.2

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (Age >= 55)

Antibody: MN Endpoint Titer



Placebo US2031102 (58) US2051072 (49)
mRNA-1273 50 ug US2071106 (10)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070202.sas 19NOV2020 20:45 Database Lock Date: 05NOV2020

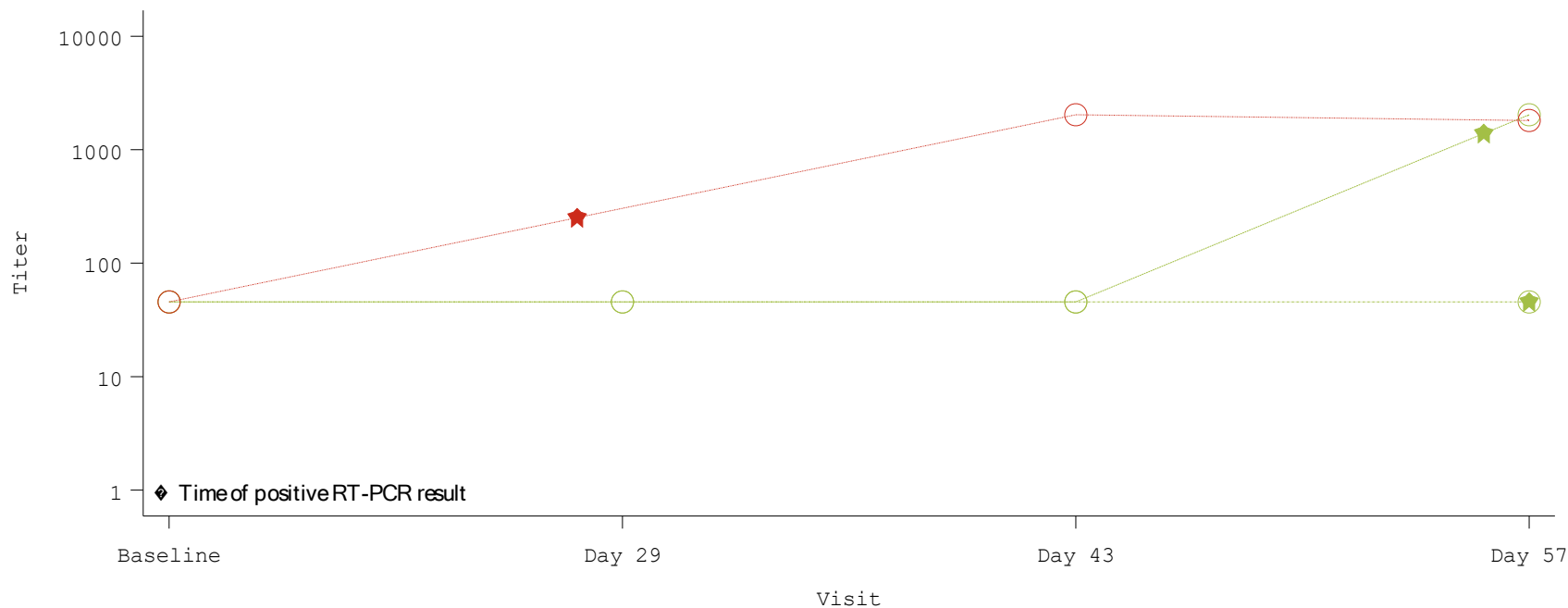
Figure 14.2.7.2.2

Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19

Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (Age >= 55)

Antibody: MN50



Placebo US2031102 (58) US2051072 (49)
mRNA-1273 50 ug US2071106 (10)

nAb = Neutralizing antibody.

Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.

For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

Program: \Moderna MODMRNA1273P201_U\Primary Analysis\TLF\fl402070202.sas 19NOV2020 20:45 Database Lock Date: 05NOV2020

15 Narratives of Deaths, Other Serious Adverse Events, and Certain Other Clinically Meaningful Adverse Events

Participant Number	Death	Other SAE	Unsolicited AE Leading to Discontinuation	Pregnancy
US2081123		X	X	
US2021094			X	
US2071106			X ^a	

Abbreviations: AE=adverse event; SAE= serious adverse event; TEAE=treatment-emergent adverse event.

^a The participant discontinued due to other reasons (positive COVID-19 test result) on Day 6; however, the action taken with investigational product for the TEAE of COVID-19 was erroneously captured as dose not changed.

Participant Number:	US2081123
Vaccination Cohort:	Cohort 2 (≥ 55 years)
Vaccination Group:	50 μ g mRNA-1273
First Dose of Vaccine:	30 Jun 2020
Second Dose of Vaccine:	Not administered
Reason for Narrative:	SAE, AE leading to withdrawal from study vaccine

MedDRA				
Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia	Severe	Not related	01 Aug 2020 – 26 Aug 2020	Resolved

Abbreviations: AE=adverse event; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities Version 23.0; SAE=serious adverse event.

Participant US2081123 was a 65-year-old White male who signed the ICF on 25 Jun 2020, was included in Cohort 2, and was randomly assigned to 50 μ g mRNA-1273 on 30 Jun 2020. The participant received the first dose of 50 μ g mRNA-1273 in the left arm on 30 Jun 2020 (Day 1). The second dose on Day 29 was not administered. The participant was not a sentinel participant. The participant's baseline SARS-CoV-2 status was negative.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions included the following: spinal osteoarthritis (2000–ongoing), spinal stenosis (2000–ongoing), attention deficit hyperactivity disorder (2003–ongoing), depression (2008–ongoing), and erectile dysfunction (2018–ongoing).

Prior/Concomitant Medications and Procedures

The participant was taking the relevant prior and/or concomitant medications and underwent the relevant concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Duloxetine hydrochloride	2015 – Ongoing	Depression/osteoarthritis
Vitamins NOS	2015 – Ongoing	Supplement
Methylphenidate	Mar 2020 – Ongoing	Attention deficit hyperactivity disorder
Ibuprofen	25 Jul 202 – 01 Aug 2020	Pain – SAE of bilateral atypical infection
Paracetamol	25 Jul 2020 – Ongoing	Pain associated with SAE of pneumonia
Enoxaparin	01 Aug 2020 – 04 Aug 2020	Prophylactic for deep vein thrombosis
Loperamide	01 Aug 2020 – 04 Aug 2020	Diarrhea related to

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
		pneumonia
Azithromycin	01 Aug 2020 – 05 Aug 2020	Pneumonia
Ceftriaxone	01 Aug 2020 – 05 Aug 2020	Pneumonia
Butalbital; caffeine; paracetamol	04 Aug 2020 – 05 Aug 2020	Tension headaches related to pneumonia
Benzonatate	05 Aug 2020 – 10 Aug 2020	Pneumonia
Guaifenesin	05 Aug 2020 – 04 Sep 2020	Pneumonia
Levofloxacin	06 Aug 2020 – 08 Aug 2020	Sepsis related to pneumonia
Chest x-ray	29 Jul 2020	Diagnostic
SARS-CoV-2 nasal swab	01 Aug 2020	Adverse event
Chest x-ray	01 Aug 2020	Adverse event
Creatine kinase	17 Aug 2020	Adverse event
Epstein Barr virus antibody panel	17 Aug 2020	Adverse event
Urea nitrogen test	17 Aug 2020	Adverse event
Chest x-ray	20 Aug 2020	Adverse event
Alkaline phosphatase test	24 Aug 2020	Adverse event
Complete blood count	24 Aug 2020	Adverse event
Creatinine test	24 Aug 2020	Adverse event
Gamma-glutamyl transferase test	24 Aug 2020	Adverse event
Liver function test	24 Aug 2020	Adverse event

Abbreviations: NOS=not otherwise specified; SAE=serious adverse event.

Medications are coded using WHO Drug Dictionary Version Mar 2020.

Unsolicited Nonserious Adverse Events

No relevant unsolicited nonserious events were reported at the time of event onset.

Event Details

On 01 Aug 2020, the participant reported a grade 3 severe SAE of pneumonia. According to the safety database, on 25 Jul 2020, the participant was seen by the investigator for symptoms of headache, cough, body aches all over, weakness, and fever. He was tested via nasal swab for COVID-19. Oral paracetamol and oral ibuprofen were given for pain associated with bilateral pneumonia. On 29 Jul 2020, the subject had an unscheduled site visit because he was not feeling well and continued to experience the above-mentioned symptoms. The second IP injection was not administered. Vital signs included blood pressure 114/64 mm Hg, oral temperature 99.8°F, heart rate 68 beats per minute, and respiratory rate 19 breaths per minute. A nondiagnostic chest x-ray revealed possible pneumonia. On the same day, the result from the COVID-19 test performed on 25 Jul 2020 was negative. A second nasal swab for COVID-19 was negative, and a

complete blood count was performed. On 01 Aug 2020, the participant went to the emergency department for cough with productive sputum, elevated fever, urinary issues, body aches, joint pain, and generalized weakness. He was also experiencing increased confusion that had been ongoing for 2 days and reported being sick for 10 days. The participant's breathing was normal, without wheezing or respiratory distress. Vital signs included body temperature of 97.8°F, blood pressure 116/96 mm Hg, pulse 67 beats per minute, respiratory rate 21 breaths per minute, and oxygen saturation 95%. Laboratory results included white blood cell count 13.4 K/ μ L (reference range 4.0 to 10.0), absolute lymphocytes 0.94 K/ μ L (reference range 1.20 to 3.70), absolute monocytes 0.94 K/ μ L (reference range 0.20 to 0.80), absolute basophils 0.13 K/ μ L (reference range 0.00 to 0.10), red blood cell count 3.52 M/ μ L (reference range 4.63 to 6.08), hemoglobin 11.0 g/dL (reference range 13.7 to 17.5), and hematocrit 33.7% (reference range 40.1 to 51.0). Urinalysis and blood cultures were negative. A nasopharyngeal rapid PCR test for SARS-CoV-2 was negative. A chest x-ray revealed bilateral heterogeneous pulmonary opacities, with the right side being greater than the left side, without effusions, which was suggestive of a bilateral atypical infection. An electrocardiogram revealed mild bradycardia. Due to leukocytosis with bandemia and the chest x-ray results, the participant was considered to be septic secondary to the event of community-acquired double pneumonia and was admitted to the hospital. Treatment for the pneumonia included a 5-day course of intravenous azithromycin, ceftriaxone, and fluids. The participant was also treated with oral loperamide for diarrhea related to pneumonia and with butalbital/caffeine/paracetamol for tension headaches related to pneumonia. The subject was discharged from the hospital on 05 Aug 2020 in stable condition and was prescribed a 7-day course of oral levofloxacin for sepsis related to pneumonia and oral guaifenesin and benzonatate for pneumonia. On 11 Aug 2020, at Day 29 visit, central laboratory results included platelet count 901 K/uL (reference range 140 to 400) and alkaline phosphatase 477 U/L (reference range 35 to 144) and the nonserious AEs of increased platelet count and increased blood alkaline phosphatase were reported. On 20 Aug 2020, a 2-view chest x-ray revealed persistent right lower lobe airspace disease compatible with pneumonia, slightly decreased from the prior study. On 26 Aug 2020, the participant was seen for a follow-up visit with a primary provider. The participant reported resolution of weakness and fatigue, and the laboratory results had normalized or were improving.

The second IP dose was withdrawn due to the pneumonia.

The event of pneumonia was considered to be resolved on 26 Aug 2020. The investigator assessed the event of pneumonia to be not related to the IP. The Sponsor agreed with the investigator's assessment. The events of increased platelet count and increased blood alkaline phosphatase were considered to be resolved on 08 Sep 2020. The investigator assessed the events

to be not related to the IP. The participant was continuing in the study at the time of the database lock.

Participant Number:	US2021094
Vaccination Cohort:	Cohort 1 (≥ 18 to < 55 years)
Vaccination Group:	Placebo
First Dose of Vaccine:	05 Jun 2020
Second Dose of Vaccine:	Not administered
Reason for Narrative:	AE leading to withdrawal from study vaccine

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19	Moderate	Not related	06 Jul 2020 – 23 Jul 2020	Resolved

Abbreviations: AE=adverse event; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2021094 was a 53-year-old White male who signed the ICF on 28 May 2020, was included in Cohort 1, and was randomly assigned to placebo on 05 Jun 2020. The participant received the first dose of placebo in the left arm on 05 Jun 2020 (Day 1). The second dose on Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

Nasopharyngeal swab test for SARS-CoV-2 infection by PCR showed a positive result on 06 Jul 2020. The participant was exposed to SARS-CoV-2 infection or COVID-19 on 20 Jun 2020 for 1 day due to social setting and was asymptomatic. SARS-CoV-2-specific serum nAbs and serum bAbs measured by ELISA specific to the SARS-CoV-2 spike protein were not assessed after Day 1.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions included the following: seasonal allergy (1986–ongoing), vasectomy (1997), hyperlipidemia (2012–ongoing), inguinal hernia (2015), and inguinal hernia repair (2015).

Prior/Concomitant Medications and Procedures

The participant was taking the relevant prior and/or concomitant medications and underwent the relevant concomitant procedures presented in the following table:

Medication/Procedure Term	Start Date – Stop Date/Ongoing	Indication
Simvastatin	2012 – Ongoing	Hyperlipidemia
Ibuprofen/pseudoephedrine hydrochloride	29 Jun 2020 – 30 Jun 2020	Sinus pressure/headache

Medications are coded using WHO Drug Dictionary Version Mar 2020.

Unsolicited Nonserious Adverse Events

Relevant unsolicited nonserious events near the time of event onset included the following: cough and sinus headache.

Event Details

On 06 Jul 2020, the participant reported a moderate AE of COVID-19. The participant was exposed on 20 Jun 2020 at a social setting.

The second IP dose was withheld due to the COVID-19. On 13 Jul 2020, the IP dose was discontinued due to COVID-19 infection.

The event of COVID-19 was considered to be resolved on 23 Jul 2020. The investigator assessed the event of COVID-19 to be not related to the IP. The participant was continuing in the study at the time of the database lock.

Participant Number: US2071106
Vaccination Cohort: Cohort 2 (≥ 55 years)
Vaccination Group: 50 μ g mRNA-1273
First Dose of Vaccine: 06 Jul 2020
Second Dose of Vaccine: Not administered
Reason for Narrative: AE leading to withdrawal from study vaccine ^a

MedDRA				
Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
COVID-19	Mild	Not related	11 Jul 2020 – 20 Jul 2020	Resolved

Abbreviations: AE=adverse event; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities Version 23.0.

^a The participant discontinued due to other reasons (positive COVID-19 test result) on Day 6; however, the action taken with IP for the TEAE of COVID-19 was erroneously captured as dose not changed.

Participant US2071106 was a 64-year-old White male who signed the ICF on 01 Jul 2020, was included in Cohort 2, and was randomly assigned to 50 μ g mRNA-1273 on 06 Jul 2020. The participant received the first dose of 50 μ g mRNA-1273 in the left arm on 06 Jul 2020 (Day 1). The second dose on Day 29 was not administered. The participant's baseline SARS-CoV-2 status was negative.

A local diagnostic test (swabbed material; type of test unknown) showed a positive COVID-19 result on 15 Jul 2020. The participant was exposed to SARS-CoV-2 infection or COVID-19 on 11 Jul 2020 for 2 days from a family member. SARS-CoV-2-specific serum nAbs against SARS-CoV-2 and serum bAbs measured by ELISA specific to the SARS-CoV-2 S protein and nucleocapsid antigen were detected on 13 Aug 2021 and had increased relative to Day 1. Routine nasopharyngeal swap test on 26 Aug 2020 was negative.

Medical History/Ongoing Medical Conditions

The participant's medical history and ongoing medical conditions included the following: hypercholesterolemia (1995–ongoing) and vasectomy (2000).

Prior/Concomitant Medications and Procedures

The participant received ibuprofen as needed from 13 Jul 2020 to 15 Jul 2020 for COVID-19 symptoms.

Unsolicited Nonserious Adverse Events

No other relevant unsolicited nonserious events were reported at the time of event onset.

Event Details

On 11 Jul 2020, the participant reported a mild TEAE of COVID-19. On 11 Jul 2020, the IP dose was discontinued due to other reasons (COVID-19 positive); however, the action taken with IP for the TEAE of COVID-19 was erroneously captured as dose not changed.

The event of COVID-19 was considered to be resolved on 20 Jul 2020. The investigator assessed the event of COVID-19 to be not related to the IP. The participant was continuing in the study at the time of the database lock.

16 Appendices

16.1 Study Information

- 16.1.1 Protocol and Protocol Amendments
- 16.1.2 Sample Case Report Form (Unique Pages Only)
- 16.1.3 List of IRBs (Plus the Name of the Committee Chair if Required by the Regulatory Authority) and Representative Written Information for Participant and Sample Consent Forms
- 16.1.4 List and Description of Investigators and Other Important Participants in the Study, Including Brief (One Page) Curricula Vitae or Equivalent Summaries of Training and Experience Relevant to the Performance of the Study
- 16.1.5 Signatures of Sponsor's Responsible Medical Officer, Depending on the Regulatory Authority's Requirement, and Signature of Responsible Biostatistician
- 16.1.6 Listing of Participants Receiving Investigational Product/Investigational Product(s) From Specific Batches, Where More Than One Batch Was Used
- 16.1.7 Randomization Scheme and Codes (Participant Identification and Treatment Assigned)
- 16.1.8 Audit Certificates (if available)
- 16.1.9 Documentation of Statistical Methods
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- 16.1.11 Publications Based on the Study
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- 16.1.13 Standardized MedDRA Queries (Version 23.0)

16.2 Participant Data Listings

- 16.2.1 Discontinued Participants
- 16.2.2 Protocol Deviations
- 16.2.3 Participants Excluded From the Efficacy Analysis
- 16.2.4 Demographic Data
- 16.2.5 Compliance or Drug Concentration Data (or both, if available)
- 16.2.6 Immunogenicity Data
- 16.2.7 Adverse Event Listings (Each Participant)
- 16.2.8 Listing of Individual Laboratory Measurements by Participant, When Required by Regulatory Authorities

16.3 Case Report Forms (CRFs)

16.3.1 CRFs for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

16.3.2 Other CRFs Submitted (only if applicable)

16.4 Individual Participant Data Listings