PRIMARY ANALYSIS CLINICAL STUDY REPORT ADDENDUM 1 (END OF PART A IMMUNOGENICITY AND SAFETY)

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
Sponsor:	ModernaTX, Inc. 200 Technology Square Cambridge, MA 02139
Sponsor Signatory:	Roderick McPhee, MD, PhD Director, Clinical Development, Infectious Diseases ModernaTX, Inc. Telephone: (b) (6) e-mail: roderick.mcphee@modernatx.com
Drug Development Phase:	2a
Study Initiation Date:	First participant, first visit: 22 May 2020
Analysis Dates:	**Primary Analysis CSR (Day 57 database lock date):** 05 Nov 2020 **CSR Addendum 1 (End of Part A database lock date):** 10 Jun 2021
Sponsor Medical Officer:	Roderick McPhee, MD, PhD
Date of Original Report:	23 Feb 2021
Date of Report Addendum 1:	13 Aug 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;39(20):2791-2799.

Study Period:

Original Report (Primary Analysis [Day 57] CSR):	22 May 2020 (first participant, first visit) to 05 Nov 2020 (database lock date)
Report Addendum 1 (CSR Addendum 1 [End of Part A]):	22 May 2020 (first participant, first visit) Database lock date (10 Jun 2021)

Drug Development Phase: 2a

Objectives and Endpoints: The study objectives and endpoints for Part A are presented in the primary analysis (Day 57) Clinical Study Report (CSR). This End of Part A CSR addendum provides safety (adverse events [AEs] leading to discontinuation from study participation, medically attended AEs [MAAEs], serious AEs [SAEs], vital sign measurements, and assessments for severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] infection) and immunogenicity (binding antibody [bAb] and neutralizing antibody [nAb] titer) results presented through the Participant Decision Clinic Visit (database lock date of 10 Jun 2021).

Methodology: Study mRNA-1273-P201 is an ongoing 3-part, Phase 2a study: Part A, Part B, and Part C. Part A, the Blinded Phase of the study, was a randomized, observer-blind, and placebo-controlled study, with adult participants at least 18 years of age. Two dose levels, 50 µg and 100 µg, were evaluated, and were chosen based in part on initial safety data from the Phase 1 National Institute of Allergy and Infectious Disease (NIAID) Division of Microbiology and Infection Disease (DMID) study of mRNA-1273 (Study 20-0003; NCT04283461). The Phase 2a 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. Each participant was to receive 2 injections of mRNA-1273 or placebo by 0.5 mL intramuscular (IM) injection on Day 1 and Day 29. Part A, Blinded Phase 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 a Participant Decision Clinic Visit (initiation of Part B) or Day 394 (Month 13), whichever was earlier. The End of Part A was defined as the earlier of Visit 9 (Day 394 [Month 13]), the completion of the last participant's last visit under Part A, or initiation of Part B (Participant Decision Clinic Visit). Participants were considered to have completed Part A of the study if they completed the final visit on Day 394 (Month 13) or initiated Part B (from Participant Decision Clinic Visit) of the study.

Given that the primary efficacy endpoint for mRNA-1273 against coronavirus disease 2019 (COVID-19) was met in a separate Phase 3 efficacy study (mRNA-1273-P301 COVE study; NCT04470427) conducted by the Sponsor and mRNA-1273 was authorized under Emergency Use Authorization (EUA) on 18 Dec 2020, this Phase 2a study moved to the Part B, Open-Label Interventional Phase. Transitioning the study to Part B permitted all ongoing study participants to be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA and the option to offer all ongoing study participants an opportunity to schedule a Participant Decision Clinic Visit to know their original treatment assignment (placebo vs. mRNA-1273 [50 µg or 100 µg] vaccine). Part B was designed to offer participants who received placebo in Part A of this study the option to receive 2 injections of open-label mRNA-1273 (100 µg). Participants who received 1 or 2 doses of 50 µg or 100 µg mRNA-1273 in Part A were offered a single booster dose of mRNA-1273 (50 µg) in Part B. All study participants received a Notification Letter summarizing the basis for a COVID-19 vaccine to receive an EUA and were asked to schedule a Participant Decision Clinic Visit. After the Participant Decision Clinic Visit, all participants were to proceed to the open-label Part B of the study and follow the Part B Schedule of Events.

Part C is a proof-of-concept rollover study of approximately 60 participants who were enrolled in Moderna's Phase 3 mRNA-1273-P301 COVE study, have already been unblinded, and have previously received 2 doses of mRNA-1273 at least 6 months earlier. Upon enrollment into Part C of this study, participants were to receive a single IM injection of mRNA-1273.351 (20 µg or 50 µg) or mRNA-1273/mRNA-1273.351 mixture (50 µg total) at least 6 months after receiving the second vaccination in the mRNA-1273-P301 COVE study.

Safety assessments in this CSR addendum included monitoring and recording of the following for each participant:

- AEs leading to discontinuation from study participation
- MAAEs, SAEs, and vital sign measurements
- AEs of interest
- Assessments for SARS-CoV-2 infection

Immunogenicity assessments included the following:

- Serum bAb level against SARS-CoV-2 as measured by enzyme-linked immunosorbent assay (ELISA) specific to the SARS-CoV-2 spike protein (VAC65)
- Serum nAb titer against SARS-CoV-2 as measured by live virus microneutralization (MN) assays

For the detection of immunoglobulin G (IgG) specific to SARS-CoV-2 spike protein modified with 2 proline substitutions within the heptad repeat 1 domain (S-2P) in human serum, an ELISA method has been developed, qualified, and validated by PPD Laboratories (VAC65).

Assessment of nAb was based on a qualified assay (MN assay). For the SARS-CoV-2 MN assay, the vast majority of samples at Baseline, Day 29, Day 43 and Day 57 were tested using the first viral lot. Due to a limited volume of the first viral lot, a new viral lot was bridged into the qualified assay. All samples at Day 209 were tested using the new viral lot.

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.

Diagnosis and Main Criteria for Inclusion and Exclusion: Refer to the primary analysis (Day 57) CSR for the inclusion and exclusion criteria for the study.

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 the study vaccine 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 mRNA-1273 or placebo as 2 injections administered 28 days apart (Day 1 and Day 29).

Statistical Methods: An analysis of safety and immunogenicity data was performed after all participants completed Part A of the study.

For the End of Part A analysis, additional bAb data based on a validated ELISA assay, VAC65 spike IgG antibody, became available. Seroresponse, as measured by VAC65 spike IgG antibody at a participant level, was defined as a change of VAC65 spike IgG antibody titer from below the lower limit of quantification (LLOQ) to equal to or above LLOQ, or a 4.6-times or higher titer ratio in participants with baseline titers ≥ LLOQ. Seroresponse (≥ 4-fold rise) specific to SARS-CoV-2 spike protein measured by ELISA at a participant level was defined as a ≥ 4 × LLOQ for participants with baseline antibody level below the LLOQ, or a 4-times or higher ratio in participants with pre-existing bAb levels.

For VAC65 spike IgG antibody, proportions of participants with fold-rise ≥ 2, fold-rise ≥ 3, and fold-rise ≥ 4 of serum SARS-CoV-2-specific bAb levels from baseline at each post-injection time points were tabulated with 2-sided 95% Clopper-Pearson confidence intervals (CIs), and proportions of participants with seroresponse were presented with 2-sided 95% Clopper-Pearson CIs at each postbaseline timepoint.

To thoroughly characterize all potential AEs of interest, summaries were produced by searching the database using individual Standardized MedDRA Queries (SMQs) for vasculitis, hypersensitivity, arthritis, angioedema, peripheral neuropathy, demyelinating disease of central nervous system, and convulsions.

More than 1 viral lot was used for detection of nAb, and each viral lot led to one set of LLOQ and upper limit of quantification (ULOQ). As a result, the proportions of participants achieving seroresponse and/or ≥ 2-fold, ≥ 3-fold, and ≥ 4-fold increase from baseline and the corresponding CI were not reported.

Summary of Results:

Participant Disposition: In each treatment group, all participants received the first injection of study vaccine and the majority of participants in both age cohorts (> 95%) received the second

injection. The details about participants who discontinued the study vaccine and reasons for discontinuations are summarized in the primary analysis (Day 57) CSR.

Twenty-seven and 18 participants in the mRNA-1273 overall group and placebo group, respectively, discontinued from the study. The most common reasons for study discontinuation were protocol deviation (6/400 [1.5%] participants in the mRNA-1273 overall group and 8/200 [4.0%] participants in the placebo group) and lost to follow-up (12/400 [3.0%] participants in the mRNA-1273 overall group and 7/200 [3.5%] participants in the placebo group). Other reasons for study discontinuation included physician decision (3/400 [0.8%] participants in the mRNA-1273 overall group and no participant in the placebo group), withdrawal of consent (COVID-19 noninfection related; 1/400 [0.3%] participant in the mRNA-1273 overall group and no participant in the placebo group), withdrawal of consent (5/400 [1.3%] participants in the mRNA-1273 overall group and no participant in the placebo group), and other (no participant in the mRNA-1273 overall group and 3/200 [1.5%] participants in the placebo group).

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: Demographic data and baseline characteristics are summarized in the primary analysis (Day 57) CSR (Section 5.4).

Safety: Solicited adverse reactions reported after each injection are presented in the primary analysis (Day 57) CSR (Section 7.1).

In this End of Part A 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) and Cohort 2 (≥ 55 years old). No new safety findings since the primary analysis (Day 57) CSR were identified in this End of Part A analysis.

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

- The incidence of unsolicited treatment-emergent AEs (TEAEs) during Part A was similar between the mRNA-1273 overall group (45.3%) and the placebo group (47.0%). The number of participants who experienced unsolicited TEAEs regardless of causality was 105/200 (52.5%) participants in the mRNA-1273 50 µg group and 76/200 (38.0%) participants in the mRNA-1273 100 µg group. The number of participants who experienced unsolicited TEAEs related to the study vaccine was 19/200 (9.5%)

participants in the mRNA-1273 50 µg and 28/200 (14%) participants in the mRNA-1273 100 µg group.

- The incidence of the most common unsolicited TEAEs was similar between the mRNA-1273 overall and placebo groups except for the AE of COVID-19, where the incidence was notably higher in the placebo group.
- The most common unsolicited TEAEs (incidence ≥ 2%) in the mRNA-1273 overall or placebo groups were COVID-19 (5/400 [1.3%] and 26/200 [13.0%], respectively), headache (25/400 [6.3%] and 8/200 [4.0%], respectively), fatigue (21/400 [5.3%] and 7/200 [3.5%], respectively), arthralgia (11/400 [2.8%] and 4/200 [2.0%], respectively), oropharyngeal pain (8/400 [2.0%] and 4/200 [2.0%], respectively), myalgia (8/400 [2.0%] and 3/200 [1.5%], respectively), upper respiratory tract infection (6/400 [1.5%] and 4/200 [2.0%], respectively), and dermatitis contact (8/400 [2.0%] and 3/200 [1.5%], respectively).
- Of the 6 participants in the overall mRNA-1273 group with confirmed SARS-CoV-2 infection (4 participants in the 50 µg group and 2 participants in the mRNA-1273 100 µg group), only 1 TEAE was reported outside of the Infections and Infestations system organ class (SOC; migraine in 1 participant that was not temporally associated with COVID-19 infection). In the placebo group, the TEAEs reported outside of the Infections and Infestations SOC included hyperestrogenism, depression, oral disorder, rash papular, fatigue, and vitamin D decreased (1 participant each). No meaningful conclusion can be drawn for these participants due to the limited number of cases.
- No deaths occurred during Part A of the study. A total of 7 participants (1.8%) reported SAEs (5 participants [2.5%] in the 50 µg mRNA-1273 group and 2 participants [1.0%] in the 100 µg mRNA-1273 group). No individual preferred term (PT) was reported in more than 1 participant. No SAEs were reported in the placebo group.
- No participants reported unsolicited TEAEs leading to discontinuation from the study during Part A.
- The incidence of MAAEs from Day 1 to End of Part A was similar in the mRNA-1273 overall group (28.0%) and the placebo group (32.0%). The incidence of MAAEs regardless of causality increased during the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (from 39 to 112 participants in the mRNA-1273 overall group and from 17 to 64 participants in the placebo group) which was likely due to the longer duration of follow-up. The incidence of treatment-related MAAEs was similar in the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (8 and 6 participants in the mRNA-1273 group, respectively, and 2 and 1 participants in the placebo group, respectively).

- As identified from analyses of AEs of interest based on an SMQ search of the database, the incidence of hypersensitivity was similar between the mRNA-1273 overall group (3.5%) and placebo group (3.0%). No participants had AEs of interest in the SMQs of vasculitis, demyelination, or convulsions. Two participants in the mRNA-1273 overall group had AEs of interest in the arthritis SMQ (gout in 1 participant and periarthritis in 1 participant). One participant in the placebo group had a TEAE in the peripheral neuropathy SMQ (PT of neuralgia).
- Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed through Day 209 were comparable to those observed at baseline, with no notable trends or differences across groups.

Immunogenicity: Data in this End of Part A analysis provided evidence of the robust immunogenicity of both 100 µg and 50 µg dose levels of mRNA-1273 when administered as 2 doses separated by 28 days.

- The time course of bAb response to vaccination was similar in both dose groups: mRNA-1273 induced increases in geometric mean (GM) levels from baseline by Day 29 (28 days after the first injection), and declined from the peak at Day 43 (14 days after the second injection) to Day 209. At Day 209, GM levels remained higher than the levels observed at Day 29 (before the second injection) for both mRNA-1273 100 µg and mRNA-1273 50 µg dose groups.
- The geometric mean fold-rise (GMFR) of bAb response trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at all postbaseline visits. GMFR results showed a robust response in both dose groups, with seroresponse criteria being met in 100% of participants at Day 43 and Day 57.
- Similar trends in bAb response were observed in Cohort 1 (age ≥ 18 and < 55 years) and Cohort 2 (age ≥ 55 years), and GM levels and GMFRs were generally higher in Cohort 1 than Cohort 2 at each postbaseline visit. In both cohorts, seroresponse criteria were met in 100% of participants at Day 43 and Day 57.
- The time course of nAb response to vaccination was similar in both dose groups: mRNA-1273 induced increases in MN_{50} and MN endpoint titer values from baseline by Day 29 (28 days after the first injection) and declined from the peak at Day 43 (14 days after the second injection) to Day 209. The titers at Day 209 remained higher than the values observed at Day 29 (before the second injection) for both 100 µg and 50 µg dose groups.
- Within the mRNA-1273 100 µg group, nAb responses were numerically higher in Cohort 1 than in Cohort 2 at each postbaseline visit.

Overall, the magnitude and kinetics of immune response for both bAb and nAb was consistent across dose groups and age cohorts. Study 201 provided evidence of persistence of immune response through Day 209 (6 months after the second injection of mRNA-1273), which was lower than the peak observed at Day 43 but was higher than that at Day 29 (before the second injection).

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 2 age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).

- Vaccination with mRNA-1273 resulted in robust immune responses to SARS-CoV-2 in participants 18 years and older at both dose levels, and persistence of immune response was observed up to 6 months after the second injection. The titers are numerically higher in participants who received 100 µg compared with 50 µg of mRNA-1273 at Day 209. These results confirm the selection of the 100 µg dose that was brought forward in the pivotal Phase 3 (COVE) study.

Date of This Report: 13 Aug 2021

List of Abbreviations and Definition of Terms

Abbreviation	Definition
AE	adverse event
ANCOVA	analysis of covariance
AR	adverse reaction
bAb	binding antibody
CDC	Centers for Disease Control and Prevention
CI	confidence interval
COVID-19	coronavirus disease 2019
CSR	clinical study report
DMID	Division of Microbiology and Infectious Diseases
eCRF	electronic case report form
eDiary	electronic diary
EUA	emergency use authorization
ELISA	enzyme-linked immunosorbent assay
GM	geometric mean
GMFR	geometric mean fold-rise
GMT	geometric mean titer
HCP	healthcare practitioner
IgG	immunoglobulin G
IM	intramuscular
LLOQ	lower limit of quantification
LOD	limit of detection
MAAE	medically attended adverse event
MN	microneutralization
nAb	neutralizing antibody
NIAID	National Institute of Allergy and Infectious Disease
PCR	polymerase chain reaction
PP	Per-Protocol
PT	preferred term
RT-PCR	reverse transcription polymerase chain reaction
S-2P	spike protein modified with 2 proline substitutions within the heptad repeat 1 domain
SAE	serious adverse event
SAP	Statistical Analysis Plan

Abbreviation	Definition
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	Standardized MedDRA Query
SOC	system organ class
TEAE	treatment-emergent adverse event
TMB	3,3′,5,5′-tetramethylbenzidine
ULOQ	upper limit of quantification

1 Introduction

1.1 Background

Refer to the primary analysis (Day 57) Clinical Study Report (CSR; Section 1.1).

1.2 Nonclinical Studies

A summary of the nonclinical studies conducted for mRNA-1273 is provided in the primary analysis (Day 57) CSR (Section 1.2).

1.3 Clinical Studies

A summary of the clinical studies conducted for mRNA-1273 is provided in the primary analysis (Day 57) CSR (Section 1.3).

Phase 2a Study mRNA-1273-P201 is an ongoing 3-part study. Part A, the blinded Phase, was randomized, observer-blind, and placebo-controlled phase of the study, and evaluated the safety, reactogenicity, and immunogenicity of 2 dose levels (50 and 100 µg) of mRNA-1273 vaccine, each administered in 2 doses 28 days apart, in adult participants at least 18 years of age. Following authorization of a coronavirus disease 2019 (COVID-19) vaccine under Emergency Use Authorization (EUA), the study was amended to provide transition to Part B, the Open-Label Interventional Phase. Part B provided all ongoing study participants to (a) be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA, and (b) the option to offer all ongoing study participants who request unblinding an opportunity to schedule a Participant Decision Clinic Visit to know their original group assignment (placebo vs. mRNA-1273 [50 µg or 100 µg vaccine]) and (c) for study participants who previously received placebo, the option to receive 2 doses of mRNA-1273 (100 µg) vaccine and for study participants who received 1 or 2-doses of the primary series of mRNA-1273 (50 or 100 µg) the option to receive a 50 µg booster dose of mRNA-1273. Part C, a proof-of-concept, Open-Label Interventional part of the study to evaluate a single booster dose of mRNA-1273.351 (50 µg or 20 µg) or mRNA-1273/mRNA-1273.351 mixture (50 µg total), is prompted by the need to proactively prepare for vaccination strategies that induce broader protection against variants of concern such as B.1.351.

The primary analysis (Day 57) CSR, dated 23 Feb 2021, provided the primary analysis of safety and immunogenicity data through Day 57 of Part A and includes a complete description of the study investigational plan and methodology in effect through the 05 Nov 2020 database lock date (mRNA-1273-P201 Protocol Amendment 3). This End of Part A CSR addendum provides safety

and immunogenicity results through the Participant Decision Clinic Visit (database lock date of 10 Jun 2021). No data from the Open-Label Phase have been included in this CSR addendum.

2 Study Objectives and Endpoints

The study objectives and endpoints for Part A are presented in the primary analysis (Day 57) CSR. This End of Part A CSR addendum provides cumulative safety (adverse events [AEs] leading to discontinuation from study participation, medically attended AEs [MAAEs], serious AEs [SAEs], vital sign measurements, and assessments for severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2] infection) and immunogenicity (binding antibody [bAb] and neutralizing antibody [nAb] titer) results through the Participant Decision Clinic Visit (database lock date of 10 Jun 2021).

3 Investigational Plan

3.1 Overall Study Design and Plan

Study mRNA-1273-P201 is an ongoing 3-part, Phase 2a study being conducted in the US: Part A, Part B, and Part C. Part A, the Blinded Phase of the study, was a randomized, observer-blind, and placebo-controlled, with adult participants at least 18 years of age. Two dose levels, 50 µg and 100 µg, were evaluated, based in part on initial safety data from the Phase 1 National Institute of Allergy and Infectious Disease (NIAID) Division of Microbiology and Infection Disease (DMID) study of mRNA-1273 (Study 20-0003; NCT04283461). The Phase 2a study included 2 age cohorts: Cohort 1 ≥ 18 to < 55 years old (300 participants planned) and Cohort 2 ≥ 55 years old (300 participants planned).

Given that the primary efficacy endpoint for mRNA-1273 against COVID-19 was met in a separate Phase 3 efficacy study (mRNA-1273-P301 COVE study; NCT04470427) conducted by the Sponsor and mRNA-1273 was authorized under EUA on 18 Dec 2020, this Phase 2a study moved to Part B, Open-Label Interventional Phase. Transitioning of the study to Part B permitted all ongoing study participants to be informed of the availability and eligibility criteria of any COVID-19 vaccine made available under an EUA and the option to offer all ongoing study participants an opportunity to schedule a Participant Decision Clinic Visit to know their original treatment assignment (placebo vs. mRNA-1273 [50 µg or 100 µg] vaccine). Part B was designed to offer participants who received placebo in Part A of this study the option to receive 2 injections of open-label mRNA-1273 (100 µg) and participants who received 1 or 2 doses of 50 µg or 100 µg mRNA-1273 in Part A were offered a single booster dose of mRNA-1273 (50 µg) in Part B. All study participants received a Notification Letter summarizing the basis for a COVID-19 vaccine to receive an EUA and were asked to schedule a Participant Decision Clinic Visit. After the Participant Decision Clinic Visit (mRNA-1273-P201 Clinical Study Protocol [Table 10]; Appendix 16.1.1), all participants were to proceed to the open-label Part B of the study and follow the Part B Schedule of Events (mRNA-1273-P201 Clinical Study Protocol; Appendix 16.1.1).

Part C is a proof-of-concept rollover study of approximately 60 participants who were enrolled in Moderna's Phase 3 mRNA-1273-P301 COVE study, had already been unblinded, and had previously received 2 doses of mRNA-1273 at least 6 months earlier. Upon enrollment into Part C of this study, participants were to receive a single intramuscular (IM) injection of mRNA-1273.351 (20 µg or 50 µg) or mRNA-1273/mRNA-1273.351 mixture (50 µg total) at least 6 months after receiving the second vaccination in the mRNA-1273-P301 COVE study. mRNA-1273.351 is an mRNA vaccine that is similar to the mRNA-1273 vaccine available under

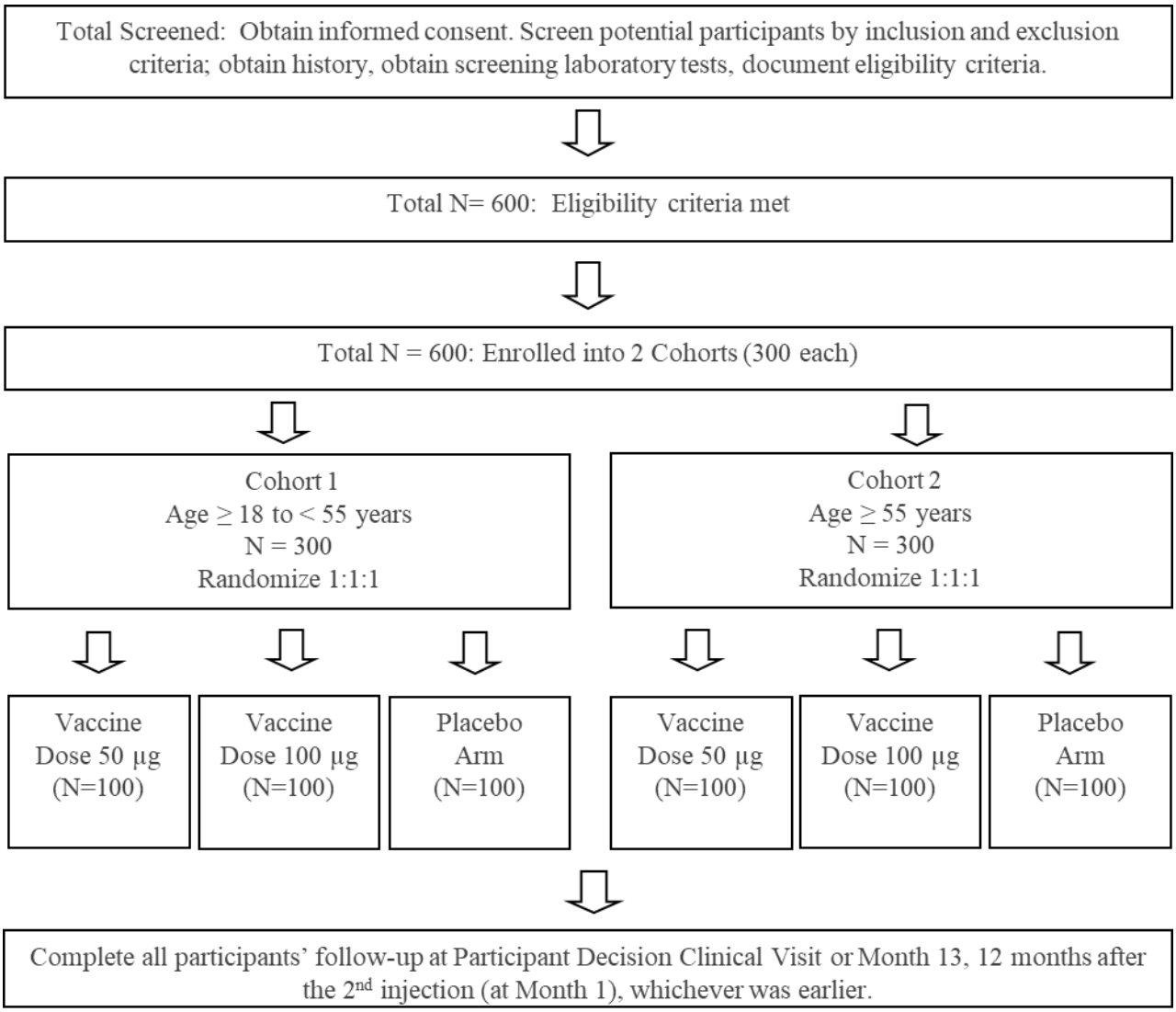
the EUA but in which the mRNA encodes for the S protein of the B.1.351 variant of SARS-CoV-2.

Part A, the Blinded Phase

The Blinded Phase of this study was a randomized, observer-blind, and placebo-controlled study in adult participants at least 18 years of age.

Two dose levels, 50 µg and 100 µg, were evaluated, and were chosen based in part on initial safety data from the Phase 1 NIAID DMID study of mRNA-1273 (Study 20-0003; NCT04283461). The Phase 2a study included 2 age cohorts: Cohort 1 included ≥ 18 to < 55 year old participants (300 participants planned) and Cohort 2 included ≥ 55 year old participants (300 participants planned). Eligible participants (approximately 600 planned participants) 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. Each participant was to receive 2 injections of mRNA-1273 or placebo by 0.5 mL IM injection on Day 1 and Day 29. The study schematic of Part A is presented in Figure 1.

Figure 1: Study Flow Schema for Part A



Part A, Blinded Phase 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 a Participant Decision Clinic Visit (initiation of Part B) or Day 394 (Month 13), whichever was earlier. Scheduled participant contact continued approximately every 2 weeks after Day 57 to collect MAAEs, AEs leading to withdrawal from the study, 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 9; 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. Safety telephone calls occurred every 4 weeks from Day 85 through Day 197 and from Day 237 through Day 377. The duration of Part A was approximately 14 months for each participant: a screening period of up to 1 month and the Part A study period of 13 months that included the first dose of vaccine on Day 1 and the second dose on Day 29. The participant's final visit was on Day 394 (Month 13), 12 months after the second dose of vaccine on Day 29 (Month 1), or at the initiation of Part B, whichever was earlier.

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 3.3.1.2).

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 study vaccine. A safety monitoring committee (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 End of Part A was defined as the earlier of Visit 9 (Day 394 [Month 13]), the completion of the last participant’s last visit completed under Part A, or initiation of Part B (Participant Decision Clinic Visit). Participants were considered to have completed Part A of the study if they completed the final visit on Day 394 (Month 13) or initiated Part B (from Participant Decision Clinic Visit) of the study.

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.

The primary analysis (Day 57) CSR, dated 23 Feb 2021, provided the primary analysis of safety and immunogenicity data through Day 57 of Part A and includes a complete description of the study investigational plan and methodology in effect through the 05 Nov 2020 database lock date (mRNA-1273-P201 Protocol Amendment 3). This End of Part A CSR addendum provides safety

and immunogenicity results through the Participant Decision Clinic Visit (database lock date of 10 Jun 2021).

The content of this CSR addendum is based on mRNA-1273-P201 Clinical Study Protocol Amendment 6, dated 28 Apr 2021, and the final mRNA-1273-P201 Statistical Analysis Plan (SAP), dated 03 Jun 2021. The Schedule of Events is provided in the mRNA-1273-P201 Clinical Study Protocol (Table 9, Appendix 16.1.1).

Full details of the investigational plan for Part A are presented in the primary analysis (Day 57) CSR (Section 3).

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 database lock for this CSR addendum, the original mRNA-1273-P201 Clinical Study Protocol, dated 22 Apr 2020, had been amended 6 times. A summary of major changes to Original Protocol based on Amendment 1 to Amendment 3 is included in the primary analysis (Day 57) CSR (Section 3.2.1). Table 1 provides a summary of the major changes impacting Part A based on Amendment 4 to Amendment 6. The original protocol and each amendment, including a summary of changes, are provided in Appendix 16.1.1.

Table 1: Summary of Major Changes Impacting Part A Implemented With Each Amendment

Protocol Amendment	Summary of Major Changes
Amendment 4 (15 Jan 2021)	• Added a "Participant Decision Clinic Visit"; instructions for transitioning to Part B, Open-Label; Schedule of Events for the Participant Decision Clinic Visit; and Schedules of Events for Part B, Open-Label procedures. • Updated status of nonclinical studies, as well as ongoing clinical studies, including this study (mRNA-1273-P201) and the Phase 3 Study mRNA-1273-P301. • Updated the blinding details to clarify that the study site staff, investigators, study monitors, and participants will remain blinded until the initiation of Open-Label Part B. • Clarified that while the pause-triggering rules that had been in effect for Part A will not be applicable for Part B, participants will continue to be monitored for the pause rule criteria.

Protocol Amendment	Summary of Major Changes
Amendment 5 (19 Feb 2021)	• Specified that Part B and Part C of the study will be open-label. • Clarified that patients in Part A will have the opportunity to enter Part B provided they meet the eligibility criteria. • Inclusion and exclusion criteria were updated. • The definitions and reporting procedures for AEs consistent with anaphylaxis were added.
Amendment 6 (28 Apr 2021)	• Clarified the definition of End of Part A. • Added an analysis of safety and immunogenicity at the end of Part A.

Abbreviations: AEs = adverse events; 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 Study Assessments

3.3.1 Safety Assessments (Part A)

Reactogenicity was measured by the occurrence of solicited local (injection site) and systemic ARs from the time of each vaccination through 7 days post each vaccination and until resolution if persisting beyond Day 7. Unsolicited non-serious AEs were captured from Day 1 through 28 days after each dose up to Day 57 (-3/+7 days). These assessments along with AEs leading to discontinuation from dosing and/or study participation, MAAEs, and SAEs up to Day 57 are described in the primary analysis (Day 57) CSR.

Safety assessments in this CSR addendum included monitoring and recording of the following for each participant through End of Part A:

- AEs leading to discontinuation from study participation
- MAAEs (including clinically significant physical examination finding), SAEs, and vital sign measurements
- AEs of interest
- Assessments for SARS-CoV-2 infection

3.3.1.1 Serious Adverse Events and Medically Attended Adverse Events

The AE and SAE definitions are provided in the mRNA-1273-P201 Clinical Study Protocol Section 3.4.8.1 and Section 3.4.8.3 (Appendix 16.1.1). A treatment-emergent AE (TEAE) was defined as any event not present before exposure to vaccine or any event already present that worsened in intensity or frequency after exposure.

An MAAE was an AE that led to an unscheduled visit to a healthcare practitioner (HCP). This included visits to a study site for unscheduled assessments (eg, rash assessment, abnormal laboratory follow-up, SARS-CoV-2 infection [Section 3.3.1.2]) 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 electronic case report form (eCRF).

Anaphylaxis is an acute hypersensitivity reaction with multi-organ-system involvement that can present as, or rapidly progress to, a severe life-threatening reaction. It may occur following exposure to allergens from a variety of sources. All suspected cases of anaphylaxis were to be recorded as MAAEs and reported as SAEs, based on criteria for a medically important event, unless the event met other serious criteria. Further details on the characterization of anaphylaxis is provided in mRNA-1273-P201 Clinical Study Protocol Section 3.4.8.8 (Appendix 16.1.1).

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 3.4.8 (Appendix 16.1.1).

In Part A, both MAAEs and SAEs were captured from Day 1 through the Participant Decision Clinic Visit (initiation of Part B) or Day 394, whichever was earlier, as specified in the mRNA-1273-P201 Clinical Study Protocol Section 3.4.8.7 (Appendix 16.1.1).

At every study site visit or telephone contact, participants were asked a standard question to elicit any medically-related changes in their well-being. 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.

3.3.1.2 Assessment of SARS-CoV-2 Infection

The incidence of confirmed SARS-CoV-2 infection was an exploratory endpoint.

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 9; 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 reverse transcription polymerase chain reaction (RT-PCR) if a participant experienced any of the following:

- Signs or symptoms of SARS-CoV-2 infection as defined by the Centers for Disease Control and Prevention (CDC) (CDC 2020)
- 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 3.4.1 (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 3.3.1.1) along with relevant concomitant medications and details about severity, seriousness, and outcome.

3.3.1.3 Pregnancy

In Part A, a point-of-care urine pregnancy test was to be performed at the Screening Visit (Day 0) and before each vaccine administration. At any time, a pregnancy test either via blood or point-of-care urine could have been performed, at the discretion of the investigator. Pregnancies that were not detected by pregnancy test at protocol-defined timepoints but were reported to the sites were captured in the safety database. Any pregnancy that occurred in participants after

enrollment was to be 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 3.4.8.8 (Appendix 16.1.1).

3.3.1.4 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 9) and as described in mRNA-1273-P201 Clinical Study Protocol Section 3.4.9 (Appendix 16.1.1).

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 13; 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.

3.3.1.5 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 9; 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 an 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.

3.3.2 Immunogenicity Assessments (Part A)

Blood samples for immunogenicity assessments were collected at the time points indicated in the Schedule of Events (mRNA-1273-P201 Clinical Study Protocol Table 9; Appendix 16.1.1). The following were the immunogenicity assessment performed:

- Serum bAb level against SARS-CoV-2 as measured by enzyme-linked immunosorbent assay (ELISA) specific to the SARS-CoV-2 spike protein (VAC65)
- Serum nAb titer against SARS-CoV-2 as measured by live virus microneutralization (MN) assays

The analyses for exploratory endpoints are not included in this CSR addendum.

Sample collection, including backup samples, is described in mRNA-1273-P201 Clinical Study Protocol Section 3.4.5 (Appendix 16.1.1). Procedures for 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 (primary CSR [Day 57] Section 3.3).

For participants who provided consent, serum from immunogenicity testing may be used for future research.

Detection of IgG Specific to SARS-CoV-2 Spike Protein in Human Serum (VAC65)

This quantitative ELISA was designed to detect the immunoglobulin G (IgG) antibody to the SARS-CoV-2 virus spike protein modified with 2 proline substitutions within the heptad repeat 1 domain (S-2P) in human serum. Microtiter plates were coated with commercially available SARS-CoV-2 full-length S-2P glycoprotein and serum containing the SARS-CoV-2 IgG antibody was added. Bound antigen-antibody complex was detected using purified goat anti-human IgG horseradish peroxidase (HRP) conjugate. Color development occurred during the addition of 3,3',5,5'tetramethylbenzidine (TMB) substrate and color intensity was measured spectrophotometrically (450 nm). The intensity of the color was directly proportional to the IgG antibody concentration. Quantitation of the human IgG antibody to SARS-CoV-2, or antibody concentration (AU/mL), was determined by interpolation from a standard curve analyzed on each assay plate. The limit of detection was 0.24 AU/mL, the lower limit of quantification (LLOQ) was 1 AU/mL at 1:500 dilution, and the upper limit of quantification (ULOQ) was 205.2 AU/mL at the 1:5,000 dilution.

SARS-CoV-2 Microneutralization Assay

The details of the SARS-CoV-2 MN assay method are described in the primary analysis (Day 57) CSR.

For the SARS-CoV-2 MN assay, the vast majority samples at Baseline, Day 29, Day 43, and Day 57 were tested using the first viral lot. Due to a limited volume of the first viral lot, a new viral lot was bridged into the qualified assay. All samples at Day 209 were tested using the new viral lot.

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

4.1 Statistical Methods

An analysis of safety and immunogenicity data was performed after all participants completed Part A of the study. After the EUA of mRNA-1273, the study protocol was amended to allow all participants to transition to Part B of the study (Section 3). Therefore, a planned analysis at End of Part A has been added in Amendment 6. The statistical analysis plan has been amended to incorporate this change. The majority of the details about statistical methods and sample size considerations for Part A are described in the primary analysis (Day 57) CSR (Section 4).

For the End of Part A analysis, additional bAb data based on a validated ELISA assay, VAC65 spike IgG antibody, become available. Seroresponse, as measured by VAC65 spike IgG antibody at a participant level, was defined as a change of VAC65 spike IgG antibody titer from below the LLOQ to equal to or above LLOQ, or a 4.6-times or higher titer ratio in participants with baseline titers ≥ LLOQ. Seroresponse (≥ 4-fold rise) specific to SARS-CoV-2 spike protein measured by ELISA at a participant level was defined as a ≥ 4 × LLOQ for participants with baseline antibody level below the LLOQ, or a 4-times or higher ratio in participants with pre-existing bAb levels.

For VAC65 spike IgG antibody, proportions of participants with fold-rise ≥ 2, fold-rise ≥ 3, and fold-rise ≥ 4 of serum SARS-CoV-2-specific bAb levels from baseline at each post-injection time points were tabulated with 2-sided 95% Clopper-Pearson confidence intervals (CIs), and proportions of participants with seroresponse were presented with 2-sided 95% Clopper-Pearson CIs at each postbaseline timepoint.

To thoroughly characterize all potential AEs of interest, summaries were produced by searching the database using individual Standardized MedDRA Queries (SMQs) for vasculitis, hypersensitivity, arthritis, angioedema, peripheral neuropathy, and demyelinating disease of central nervous system, and convulsions.

The final mRNA-1273-P201 SAP, version 4.0, dated 03 Jun 2021, is provided in Appendix 16.1.9.

4.1.1 Changes in the Planned Analysis

Assessment of nAb was based on a qualified assay (MN assay). More than 1 viral lot was used for detection of nAb (Section 3.3.2), and each viral lot led to one set of LLOQ and ULOQ (as

noted in footnote of Table 10). As a result, the proportions of participants achieving seroresponse and/or ≥ 2-fold, ≥ 3-fold, and ≥ 4-fold increase from baseline and the corresponding CIs were not reported.

5 Study Populations

5.1 Disposition of Participants

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 2).

In each treatment group, all participants received the first injection of the study vaccine and the majority of participants in both age cohorts (> 95%) received the second injection. The details about participants who discontinued the study vaccine and reasons for discontinuations are summarized in the primary analysis (Day 57) CSR (Section 5.1).

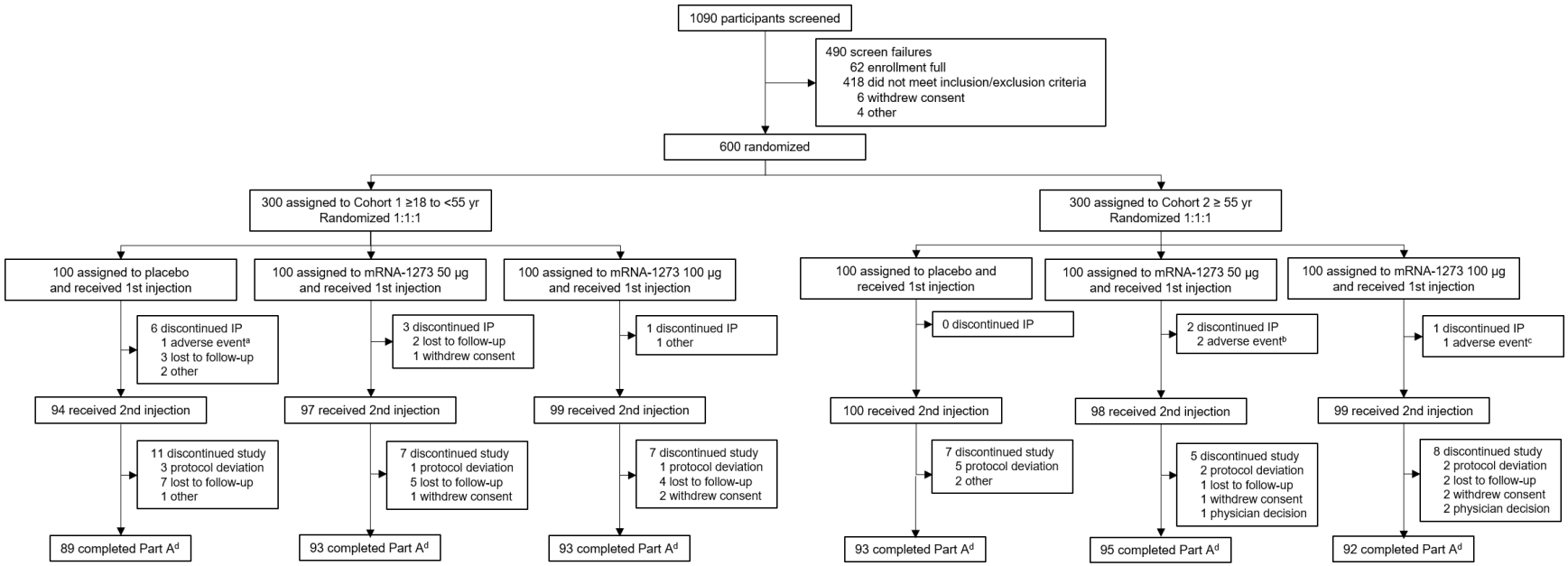
The majority (555/600 [92.5%] participants) of the participants completed Part A: 373/400 (93.3%) participants in the mRNA-1273 overall group and 182/200 (91.0%) participants in the placebo group. Among the participants who discontinued the study (27/400 [6.8%] participants in the mRNA-1273 overall group and 18/200 [9.0%] participants in the placebo group), the most common reasons for discontinuation were protocol deviation (6/400 [1.5%] participants in the mRNA-1273 overall group and 8/200 [4.0%] participants in the placebo group) and lost to follow-up (12/400 [3.0%] participants in the mRNA-1273 overall group and 7/200 [3.5%] participants in the placebo group). The most commonly reported reason for protocol deviation included request for unblinding due to availability of COVID-19 vaccines under EUA or receipt of the COVID-19 vaccine outside the trial (Listing 16.2.1.1). Other reasons for study discontinuation included physician decision (3/400 [0.8%] participants in the mRNA-1273 overall group and no participant in the placebo group), withdrawal of consent (COVID-19 noninfection related; 1/400 [0.3%] participant in the mRNA-1273 overall group and no participant in the placebo group), withdrawal of consent (5/400 [1.3%] participants in the mRNA-1273 overall group and no participant in the placebo group), and other (no participant in the mRNA-1273 overall group and 3/200 [1.5%] participants in the placebo group).

Age Cohorts

Overall, 25/300 (8.3%) participants and 20/300 (6.7%) discontinued the study in Cohort 1 (≥ 18 and < 55 years) and Cohort 2 (≥ 55 years), respectively. A slightly numerically higher proportion of participants discontinued the study due to loss to follow-up in Cohort 1 (16/300 [5.3%] participants) than in Cohort 2 (3/300 [1.0%] participants); this trend was observed in all vaccination groups between the age cohorts (Table 14.1.1.1).

An overview of participant disposition in this study is shown in Figure 2.

Figure 2: Participant Disposition



Abbreviations: COVID-19 = coronavirus disease 2019; IP = investigational product; SARS-CoV-2 = severe acute respiratory syndrome coronavirus that causes COVID-19.

Note: The "other" reasons for study vaccine discontinuation were false-positive COVID-19 infection results.

[a] COVID-19 infection.

[b] COVID-19 infection in 1 participant and serious treatment-emergent adverse event of pneumonia that occurred > 28 days after IP administration and led to IP discontinuation in 1 participant.

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

[d] Completed Part A is defined as a participant who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

Source: Table 14.1.1.1, Listing 16.2.1.1, and Listing 16.2.7.7, and mRNA-1273-P201 primary analysis (Day 57) CSR (Figure 3).

Table 2: Participant Disposition (Randomized Set)

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) 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)	1 (0.5)	0	1 (0.3)	2 (0.3)
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)	0	1 (0.5)	1 (0.3)	3 (0.5)
Completed end of Part A[a]	182 (91.0)	188 (94.0)	185 (92.5)	373 (93.3)	555 (92.5)
Discontinued from study	18 (9.0)	12 (6.0)	15 (7.5)	27 (6.8)	45 (7.5)
Reason for discontinuation of study					
Adverse event (COVID-19 infection)	0	0	0	0	0
Adverse event (other)	0	0	0	0	0

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	**50 µg (N=200) n (%)**	**100 µg (N=200) n (%)**	**Total (N=400) n (%)**	**Overall (N=600) n (%)**
Death	0	0	0	0	0
Lost to follow-up	7 (3.5)	6 (3.0)	6 (3.0)	12 (3.0)	19 (3.2)
Physician decision	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.5)
Pregnancy	0	0	0	0	0
Protocol deviation	8 (4.0)	3 (1.5)	3 (1.5)	6 (1.5)	14 (2.3)
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	1 (0.5)	4 (2.0)	5 (1.3)	5 (0.8)
Other	3 (1.5)	0	0	0	3 (0.5)

Percentages are based on the number of randomized subjects.

[a] Completed Part A is defined as a subject who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

Source: Table 14.1.1.1.

5.2 Study Analysis Sets

All 600 participants in the Randomized Set received the study vaccine and were included in the Safety Set.

The analysis set for nAb at the primary analysis was the per-protocol (PP) Set for SARS-CoV-2-specific nAb from the First Lot (546/600 [91.0%]; Table 3), while the immunogenicity results for nAb in this CSR addendum are provided based on PP Set for SARS-CoV-2-specific nAb from All Lots (560/600 [93.3%]).

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 a decreasing trend noted from the Day 29 to Day 209 analyses. 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 All Lot (374/400 [93.5%] and 186/200 [93.0%], respectively), with decreasing trend observed from the Day 29 to Day 209 analyses.

Table 3: Number of Participants in Each Analysis Set (Randomized Set)

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) 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	197 (98.5)	198 (99.0)	197 (98.5)	395 (98.8)	592 (98.7)
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)
Day 209	185 (92.5)	182 (91.0)	185 (92.5)	367 (91.8)	552 (92.0)
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)
Day 209	0	0	0	0	0
Full analysis set for SARS-CoV-2-specific nAb from all lots	197 (98.5)	198 (99.0)	198 (99.0)	396 (99.0)	593 (98.8)
Day 29	194 (97.0)	196 (98.0)	194 (97.0)	390 (97.5)	584 (97.3)
Day 57	196 (98.0)	194 (97.0)	198 (99.0)	392 (98.0)	588 (98.0)
Day 209	186 (93.0)	185 (92.5)	186 (93.0)	371 (92.8)	557 (92.8)
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)

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) n (%)
Day 209	154 (77.0)	170 (85.0)	174 (87.0)	344 (86.0)	498 (83.0)
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)
Day 209	0	0	0	0	0
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)	184 (92.0)	187 (93.5)	371 (92.8)	555 (92.5)
Day 57	175 (87.5)	176 (88.0)	177 (88.5)	353 (88.3)	528 (88.0)
Day 209	153 (76.5)	171 (85.5)	174 (87.0)	345 (86.3)	498 (83.0)

Abbreviations: 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).

[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 post-injection 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 post--injection results available for at least one assay component at the corresponding visit.

Source: Table 14.1.2.

5.3 Protocol Deviations

The most common (≥ 2% of participants) major protocol deviations in the Randomization Set were study procedure/assessments (173/600 [28.8%] participants), visit scheduling (169/600 [28.2%] participants), missing endpoint assessments (32/600 [5.3%]), investigator record keeping source documents (20/600 [3.3%] participants), and informed consent form process/timing (20/600 [3.3%] participants; Table 4). The incidence of each common major deviation was comparable for participants who received mRNA-1273 (50 or 100 µg) and placebo.

The common reasons for study procedure/assessments and visit scheduling were related to the safety call, where safety follow-up calls performed out of window was the most common reason for protocol deviation related to study procedure/assessments, and safety call not completed as outlined in the Schedule of Events beginning at Day 85 was the most common reason for protocol deviation related to visit scheduling (Listing 16.2.2.2).

Table 4: Major Protocol Deviations (Randomized Set)

	Overall				
		mRNA-1273			
Deviation Type	**Placebo (N=200) n (%)**	**50 µg (N=200) n (%)**	**100 µg (N=200) n (%)**	**Total (N=400) n (%)**	**Overall (N=600) n (%)**
Concomitant medication	3 (1.5)	3 (1.5)	3 (1.5)	6 (1.5)	9 (1.5)
Exclusion criteria	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)	10 (1.7)
ICF process/timing	4 (2.0)	7 (3.5)	9 (4.5)	16 (4.0)	20 (3.3)
Inclusion criteria	2 (1.0)	0	0	0	2 (0.3)
Informed consent	2 (1.0)	1 (0.5)	0	1 (0.3)	3 (0.5)
Investigator record keeping source documents	6 (3.0)	8 (4.0)	6 (3.0)	14 (3.5)	20 (3.3)
Investigator safety reporting (CRF)	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.7)
Missing endpoint assessments	11 (5.5)	11 (5.5)	10 (5.0)	21 (5.3)	32 (5.3)
Study procedures/assessments	60 (30.0)	61 (30.5)	52 (26.0)	113 (28.3)	173 (28.8)
Study treatment administration/dispense	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)	11 (1.8)
Visit scheduling	50 (25.0)	68 (34.0)	51 (25.5)	119 (29.8)	169 (28.2)

Abbreviations: ICF = informed consent form; CRF = case report form
Source: Table 14.1.1.4.

5.4 Demographics and Other Baseline Characteristics

Demographic data and baseline characteristics are summarized in the primary analysis (Day 57) CSR (Section 5.4).

5.5 Medical History

Medical history data are summarized in the primary analysis (Day 57) CSR (Section 5.5). After the database lock for the primary analysis (Day 57) CSR, 4 participants had additional medical history reported: vitamin B complex deficiency in 1 participant (placebo group), hypertonic bladder and Raynaud's phenomenon in 1 participant (mRNA-1273 100 µg group); benign prostatic hyperplasia in 1 participant (placebo group), and gastroesophageal reflux disease in 1 participant (mRNA-1273 100 µg group). Overall, there was no change in the most commonly reported medical history conditions.

5.6 COVID-19 Impact

COVID-19 impacted protocol-specified procedures for 12 participants: 3 in the mRNA-1273 50 µg group, 1 in the mRNA-1273 100 µg group, and 8 in the placebo group (Listing 16.2.2.3). Of the 21 impacts for these 12 participants, the most common COVID-19 impact category was “missed assessment,” and the most common relationship of the impact to COVID-19 was “exposure to COVID-19.”

5.7 Prior and Concomitant Medications

Prior and concomitant medications are summarized in the primary analysis (Day 57) CSR (Section 5.4).

5.8 Exposure and Compliance

Exposure and compliance data are summarized in the primary analysis (Day 57) CSR (Section 5.8).

6 Efficacy Results

Not applicable.

7 Safety Results

This CSR Addendum 1 includes safety results presented up to the Participant Decision Clinic Visit (database lock date of 10 Jun 2021). The median follow-up time from randomization to the Participant Decision Clinic Visit was approximately 8 months.

7.1 Solicited Adverse Reactions

Solicited ARs reported after each injection are presented in the primary analysis (Day 57) CSR (Section 7.1).

7.2 Unsolicited Adverse Events

Unsolicited AEs included in this CSR addendum are as follows:

- Summary of unsolicited TEAEs from Day 1 to End of Part A
- SAEs, MAAEs (including clinically significant physical examination findings), and AEs leading to study discontinuation
- AEs of interest

7.2.1 Overview of Unsolicited Adverse Events

The incidence of unsolicited TEAEs during Part A was similar between the mRNA-1273 overall group (181/400 [45.3%]) participants and placebo group (94/200 [47.0%] participants; Table 14.3.1.7.2). Treatment-related TEAEs were more commonly reported by participants who received mRNA-1273 (47/400 [11.8%] participants) than by those who received placebo (13/200 [6.5%] participants). The number of participants who experienced unsolicited TEAEs regardless of causality was 105/200 (52.5%) participants in the mRNA-1273 50 µg group and 76/200 (38.0%) participants in the mRNA-1273 100 µg group. The number of participants who experienced unsolicited TEAEs related to the study vaccine was 19/200 (9.5%) participants in the mRNA-1273 50 µg and 28/200 (14%) participants in the mRNA-1273 100 µg group.

Serious AEs were reported in 7/400 (1.8%) participants in the mRNA-1273 overall group; none were related to the study vaccine. No SAEs were reported in the placebo group during Part A.

No participants died during Part A of the study.

The incidence of MAAEs during Part A was similar between the mRNA-1273 overall group (112/400 [28.0%] participants) and the placebo group (64/200 [32.0%] participants). The incidence of treatment-related MAAEs remained low during Part A (8/400 [2.0%] participants in

the mRNA-1273 overall group and 2/200 [1.0%] participants in the placebo group). Of note, the incidence of MAAEs regardless of causality increased during the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (from 39 to 112 participants in the mRNA-1273 overall group and from 17 to 64 participants in the placebo group), which was likely due to the longer duration of follow-up. The incidence of treatment-related MAAEs was similar in the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (8 and 6 participants in the mRNA-1273 group, respectively, and 2 and 1 participants in the placebo group, respectively).

One participant each in the mRNA-1273 50 µg and placebo groups discontinued the vaccine due to TEAEs (pneumonia in the participant randomized to the mRNA-1273 50 µg group and COVID-19 in the participant randomized to the placebo group). The details are provided in the primary analysis (Day 57) CSR (Section 7.3.3.1).

No unsolicited TEAE led to study discontinuation in any group.

The incidence of unsolicited severe TEAEs regardless of relationship to the study vaccine in Part A was low in each group (18/400 [4.5%]) in the mRNA-1273 overall group and 5/200 [2.5%] in the placebo group. The incidence of unsolicited severe TEAEs related to the study vaccine was similar to what was reported in the primary analysis (Day 57) CSR (6/400 [1.5%] participants in the mRNA-1273 overall group and 2/200 [1.0%] in the placebo group).

Age Cohorts

The overall incidence of unsolicited TEAEs was similar between Cohort 1 (≥ 18 to <55 years) and Cohort 2 (≥55 years; Table 14.3.1.7.2). There was no notable difference between Cohort 1 and Cohort 2 for unsolicited TEAEs in the mRNA-1273 overall group. The incidence of MAAEs within the mRNA-1273 50 µg was numerically higher in Cohort 1 (44/100 [44%] participants) than in Cohort 2 (30/100 [30%] participants). 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 (9/100 [9.0%]) and the placebo group (7/100 [7.0%]).

7.2.2 Most Common Unsolicited Adverse Events

The most common unsolicited TEAEs by system organ class (SOC) (incidence > 5%) in the mRNA-1273 overall or placebo groups were infection and infestations (48/400 [12.0%] and 45/200 [22.5%], respectively); nervous system disorders (40/400 [10.0%] and 11/200 [5.5%],

respectively); respiratory, thoracic and mediastinal disorders (20/400 [5.0%] and 11/200 [5.5%], respectively); gastrointestinal disorders (31/400 [7.8%] and 10/200 [5.0%], respectively); musculoskeletal and connective tissue disorders (39/400 [9.8%] and 11/200 [5.5%], respectively); general disorders and administration site conditions (43/400 [10.8%] and 12/200 [6.0%], respectively); and injury, poisoning, and procedural complications (23/400 [5.8%] and 7/200 [3.5%], respectively; Table 5). Within the mRNA-1273 overall group, the incidences of the most common unsolicited TEAEs by SOCs were generally higher in the mRNA-1273 50 µg group than in the mRNA-1273 100 µg group except for the SOCs of general disorders and administration site conditions and injury, poisoning, and procedural complications where rates were similar.

The incidence of the most common unsolicited TEAEs was similar between the mRNA-1273 overall and placebo groups except for the AE of COVID-19, where the incidence was notably higher in the placebo group. The most common unsolicited TEAEs (incidence ≥ 2%) in the mRNA-1273 overall or placebo groups were COVID-19 (5/400 [1.3%] and 26/200 [13.0%], respectively), headache (25/400 [6.3%] and 8/200 [4.0%], respectively), fatigue (21/400 [5.3%] and 7/200 [3.5%], respectively), arthralgia (11/400 [2.8%] and 4/200 [2.0%], respectively), oropharyngeal pain (8/400 [2.0%] and 4/200 [2.0%], respectively), myalgia (8/400 [2.0%] and 3/200 [1.5%], respectively), upper respiratory tract infection (6/400 [1.5%] and 4/200 [2.0%], respectively), and dermatitis contact (8/400 [2.0%] and 3/200 [1.5%], respectively). Within the mRNA-1273 overall group, the incidence of headache and fatigue appeared higher in the mRNA-1273 50 µg group (16/200 [8.0%] and 16/200 [8.0%], respectively) than in the mRNA-1273 100 µg group (9/200 [4.5%] and 5/200 [2.5%], respectively).

Age Cohorts

Within the placebo group, the incidence of COVID-19 was higher in Cohort 1 (≥ 18 to <55 years; 18/100 [18.0%] participants) than in Cohort 2 (≥ 55 years; 8/100 [8.0%] participants). No notable differences in other most common unsolicited TEAEs were observed between Cohort 1 and Cohort 2 across groups (Table 14.3.1.8.2).

Table 5: Participant Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A (≥2% in Any Vaccination Group Based on Preferred Term) (Safety Set)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)				Overall			
		mRNA-1273				mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects reporting unsolicited adverse events	47 (47.0)	56 (56.0)	35 (35.0)	91 (45.5)	47 (47.0)	49 (49.0)	41 (41.0)	90 (45.0)	94 (47.0)	105 (52.5)	76 (38.0)	181 (45.3)
Number of unsolicited adverse events	94	139	77	216	69	105	76	181	163	244	153	397
Infections and infestations	27 (27.0)	20 (20.0)	8 (8.0)	28 (14.0)	18 (18.0)	12 (12.0)	8 (8.0)	20 (10.0)	45 (22.5)	32 (16.0)	16 (8.0)	48 (12.0)
Upper respiratory tract infection	3 (3.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	4 (2.0)	4 (2.0)	2 (1.0)	6 (1.5)
COVID-19	18 (18.0)	2 (2.0)	1 (1.0)	3 (1.5)	8 (8.0)	1 (1.0)	1 (1.0)	2 (1.0)	26 (13.0)	3 (1.5)	2 (1.0)	5 (1.3)
Urinary tract infection	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	1 (1.0)	0	1 (0.5)	3 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)
Sinusitis	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Viral infection	0	3 (3.0)	1 (1.0)	4 (2.0)	0	0	0	0	0	3 (1.5)	1 (0.5)	4 (1.0)
Viral upper respiratory tract infection	0	3 (3.0)	0	3 (1.5)	1 (1.0)	0	0	0	1 (0.5)	3 (1.5)	0	3 (0.8)
Suspected COVID-19	2 (2.0)	0	0	0	0	2 (2.0)	0	2 (1.0)	2 (1.0)	2 (1.0)	0	2 (0.5)
Immune system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Seasonal allergy	0	1 (1.0)	0	1 (0.5)	0	0	2 (2.0)	2 (1.0)	0	1 (0.5)	2 (1.0)	3 (0.8)
Psychiatric disorders	2 (2.0)	4 (4.0)	5 (5.0)	9 (4.5)	2 (2.0)	5 (5.0)	0	5 (2.5)	4 (2.0)	9 (4.5)	5 (2.5)	14 (3.5)
Anxiety	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Depression	1 (1.0)	1 (1.0)	4 (4.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)	2 (1.0)	3 (1.5)	4 (2.0)	7 (1.8)
Insomnia	0	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)	0	3 (1.5)	0	3 (0.8)
Nervous system disorders	8 (8.0)	16 (16.0)	6 (6.0)	22 (11.0)	3 (3.0)	9 (9.0)	9 (9.0)	18 (9.0)	11 (5.5)	25 (12.5)	15 (7.5)	40 (10.0)
Headache	6 (6.0)	10 (10.0)	4 (4.0)	14 (7.0)	2 (2.0)	6 (6.0)	5 (5.0)	11 (5.5)	8 (4.0)	16 (8.0)	9 (4.5)	25 (6.3)
Tension headache	0	2 (2.0)	0	2 (1.0)	0	0	0	0	0	2 (1.0)	0	2 (0.5)
Lethargy	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0	2 (1.0)	1 (0.5)	0	1 (0.3)

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)				Overall			
		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=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Vascular disorders	0	3 (3.0)	1 (1.0)	4 (2.0)	0	2 (2.0)	1 (1.0)	3 (1.5)	0	5 (2.5)	2 (1.0)	7 (1.8)
Hypertension	0	3 (3.0)	0	3 (1.5)	0	2 (2.0)	1 (1.0)	3 (1.5)	0	5 (2.5)	1 (0.5)	6 (1.5)
Respiratory, thoracic and mediastinal disorders	6 (6.0)	11 (11.0)	3 (3.0)	14 (7.0)	5 (5.0)	4 (4.0)	2 (2.0)	6 (3.0)	11 (5.5)	15 (7.5)	5 (2.5)	20 (5.0)
Oropharyngeal pain	2 (2.0)	4 (4.0)	0	4 (2.0)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	4 (2.0)	7 (3.5)	1 (0.5)	8 (2.0)
Rhinorrhoea	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	0	1 (1.0)	1 (0.5)	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
Cough	3 (3.0)	3 (3.0)	0	3 (1.5)	0	0	0	0	3 (1.5)	3 (1.5)	0	3 (0.8)
Nasal congestion	1 (1.0)	3 (3.0)	0	3 (1.5)	0	0	0	0	1 (0.5)	3 (1.5)	0	3 (0.8)
Gastrointestinal disorders	5 (5.0)	9 (9.0)	6 (6.0)	15 (7.5)	5 (5.0)	10 (10.0)	6 (6.0)	16 (8.0)	10 (5.0)	19 (9.5)	12 (6.0)	31 (7.8)
Nausea	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	2 (2.0)	3 (1.5)	0	3 (1.5)	4 (2.0)	7 (1.8)
Diarrhoea	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)	1 (0.5)	4 (2.0)	1 (0.5)	5 (1.3)
Gastrooesophageal reflux disease	0	0	0	0	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)
Abdominal discomfort	0	0	2 (2.0)	2 (1.0)	0	0	0	0	0	0	2 (1.0)	2 (0.5)
Gastritis	0	2 (2.0)	0	2 (1.0)	0	0	0	0	0	2 (1.0)	0	2 (0.5)
Skin and subcutaneous tissue disorders	6 (6.0)	6 (6.0)	4 (4.0)	10 (5.0)	4 (4.0)	7 (7.0)	3 (3.0)	10 (5.0)	10 (5.0)	13 (6.5)	7 (3.5)	20 (5.0)
Dermatitis contact	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	3 (1.5)	5 (2.5)	3 (1.5)	8 (2.0)
Rash	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	2 (1.0)	4 (2.0)	0	4 (1.0)
Acne	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Musculoskeletal and connective tissue disorders	3 (3.0)	11 (11.0)	7 (7.0)	18 (9.0)	8 (8.0)	13 (13.0)	8 (8.0)	21 (10.5)	11 (5.5)	24 (12.0)	15 (7.5)	39 (9.8)
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	4 (4.0)	2 (2.0)	6 (3.0)	4 (2.0)	7 (3.5)	4 (2.0)	11 (2.8)
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Back pain	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Muscle spasms	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0	0	1 (0.5)	2 (1.0)	3 (0.8)
Musculoskeletal pain	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
General disorders and administration site conditions	8 (8.0)	13 (13.0)	13 (13.0)	26 (13.0)	4 (4.0)	10 (10.0)	7 (7.0)	17 (8.5)	12 (6.0)	23 (11.5)	20 (10.0)	43 (10.8)

System Organ Class Preferred Term	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)				Overall			
		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=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Fatigue	6 (6.0)	8 (8.0)	4 (4.0)	12 (6.0)	1 (1.0)	8 (8.0)	1 (1.0)	9 (4.5)	7 (3.5)	16 (8.0)	5 (2.5)	21 (5.3)
Injection site pain	1 (1.0)	2 (2.0)	3 (3.0)	5 (2.5)	0	1 (1.0)	0	1 (0.5)	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	2 (2.0)	2 (1.0)	0	1 (0.5)	4 (2.0)	5 (1.3)
Injection site erythema	0	1 (1.0)	2 (2.0)	3 (1.5)	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (0.5)	1 (0.5)	3 (1.5)	4 (1.0)
Injection site swelling	1 (1.0)	0	3 (3.0)	3 (1.5)	0	0	1 (1.0)	1 (0.5)	1 (0.5)	0	4 (2.0)	4 (1.0)
Axillary pain	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0	0	1 (0.5)	2 (1.0)	3 (0.8)
Chest discomfort	0	3 (3.0)	0	3 (1.5)	0	0	0	0	0	3 (1.5)	0	3 (0.8)
Pain	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	1 (1.0)	1 (0.5)	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Pyrexia	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)	1 (0.5)	0	3 (1.5)	3 (0.8)
Investigations	2 (2.0)	2 (2.0)	0	2 (1.0)	7 (7.0)	4 (4.0)	5 (5.0)	9 (4.5)	9 (4.5)	6 (3.0)	5 (2.5)	11 (2.8)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	2 (2.0)	2 (1.0)	2 (1.0)	1 (0.5)	2 (1.0)	3 (0.8)
Injury, poisoning and procedural complications	4 (4.0)	8 (8.0)	4 (4.0)	12 (6.0)	3 (3.0)	4 (4.0)	7 (7.0)	11 (5.5)	7 (3.5)	12 (6.0)	11 (5.5)	23 (5.8)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Skin laceration	2 (2.0)	0	0	0	0	0	0	0	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 14.3.1.8.2.

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

7.3.1 Deaths

No participants died during Part A of the study (Table 14.3.1.7.2).

7.3.2 Other Serious Adverse Events

A total of 7 participants (1.8%) reported SAEs during Part A; 5 participants (2.5%) in the 50 µg mRNA-1273 group reported 5 events and 2 participants (1.0%) in the 100 µg mRNA-1273 group reported 3 events (Table 6). No individual preferred term (PT) was reported in more than 1 participant. All SAEs resolved during Part A (Listing 16.2.7.8) and none were considered related to the vaccine (Table 14.3.1.14.2). No SAEs were reported in the placebo group. The case narratives for these participants are provided in Section 15.

By Age Cohort

Of the 7 participants who reported SAEs during Part A, 2/200 participants (1.0%) were in Cohort 1 (≥ 18 to < 55 years) and 5/200 participants (2.5%) were in Cohort 2 (≥ 55 years; Table 14.3.1.13.2).

Table 6: Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A (Safety Set)

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects reporting unsolicited adverse events	0	5 (2.5)	2 (1.0)	7 (1.8)
Number of unsolicited adverse events	0	6	3	9
Infections and infestations	0	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	0	1 (0.5)	0	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Cardiac disorders	0	2 (1.0)	1 (0.5)	3 (0.8)
Acute myocardial infarction	0	1 (0.5)	0	1 (0.3)
Arrhythmia	0	0	1 (0.5)	1 (0.3)
Bradycardia	0	1 (0.5)	0	1 (0.3)
Musculoskeletal and connective tissue disorders	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Pregnancy, puerperium and perinatal conditions	0	1 (0.5)	1 (0.5)	2 (0.5)
Abortion missed	0	0	1 (0.5)	1 (0.3)
Abortion spontaneous	0	1 (0.5)	0	1 (0.3)
Injury, poisoning and procedural complications	0	0	1 (0.5)	1 (0.3)
Struck by lightning	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

Source: Table 14.3.1.13.2.

7.3.2.1 Serious Adverse Events Related to the Study Treatment

There were no treatment-related SAEs reported during Part A (Table 14.3.1.14.2).

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

Unsolicited AEs leading to discontinuation from the IP are described in the primary (Day 57) CSR (Section 7.3.3.1). No participants reported unsolicited TEAEs leading to discontinuation from the study during Part A (Table 14.3.1.15.2).

7.3.3.2 Medically Attended Adverse Events

The incidence of MAAEs from Day 1 to the End of Part A was similar in the mRNA-1273 overall group (112/400 [28.0%]) and the placebo group (64/200 [32.0%]; Table 7). The MAAEs with incidence > 1.0% in the mRNA-1273 overall group or the placebo group (by decreasing incidence in the mRNA-1273 overall group) were anxiety, depression, COVID-19, headache, hypertension, dermatitis contact, fatigue, sinusitis, and urinary tract infection.

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 14.3.1.18.2).

Table 7: Subject Incidence of Unsolicited Medically Attended TEAEs by System Organ Class and Preferred Term from Day 1 to End of Part A (≥ 1% in Any Vaccination Group in Overall Group Based on Preferred Term) (Safety Set)

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of subjects reporting unsolicited adverse events	64 (32.0)	74 (37.0)	38 (19.0)	112 (28.0)
Number of unsolicited adverse events	93	130	67	197
Infections and infestations	39 (19.5)	27 (13.5)	11 (5.5)	38 (9.5)
COVID-19	24 (12.0)	3 (1.5)	2 (1.0)	5 (1.3)
Sinusitis	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Bronchitis	0	2 (1.0)	1 (0.5)	3 (0.8)
Upper respiratory tract infection	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Urinary tract infection	3 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)
Viral infection	0	3 (1.5)	0	3 (0.8)
Viral upper respiratory tract infection	1 (0.5)	3 (1.5)	0	3 (0.8)
Otitis media	1 (0.5)	0	2 (1.0)	2 (0.5)
Gastroenteritis	2 (1.0)	0	1 (0.5)	1 (0.3)
Suspected COVID-19	2 (1.0)	0	0	0
Psychiatric disorders	4 (2.0)	9 (4.5)	4 (2.0)	13 (3.3)
Anxiety	3 (1.5)	5 (2.5)	1 (0.5)	6 (1.5)
Depression	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Insomnia	0	3 (1.5)	0	3 (0.8)
Nervous system disorders	0	11 (5.5)	3 (1.5)	14 (3.5)
Headache	0	4 (2.0)	1 (0.5)	5 (1.3)

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	**Placebo (N=200) n (%)**	**50 µg (N=200) n (%)**	**100 µg (N=200) n (%)**	**Total (N=400) n (%)**
Dizziness	0	2 (1.0)	1 (0.5)	3 (0.8)
Vascular disorders	0	4 (2.0)	1 (0.5)	5 (1.3)
Hypertension	0	4 (2.0)	1 (0.5)	5 (1.3)
Respiratory, thoracic and mediastinal disorders	2 (1.0)	6 (3.0)	1 (0.5)	7 (1.8)
Nasal congestion	0	2 (1.0)	0	2 (0.5)
Oropharyngeal pain	1 (0.5)	2 (1.0)	0	2 (0.5)
Gastrointestinal disorders	7 (3.5)	8 (4.0)	8 (4.0)	16 (4.0)
Gastrooesophageal reflux disease	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Nausea	0	1 (0.5)	2 (1.0)	3 (0.8)
Gastritis	0	2 (1.0)	0	2 (0.5)
Skin and subcutaneous tissue disorders	5 (2.5)	8 (4.0)	3 (1.5)	11 (2.8)
Dermatitis contact	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
Rash	0	3 (1.5)	0	3 (0.8)
Musculoskeletal and connective tissue disorders	4 (2.0)	6 (3.0)	5 (2.5)	11 (2.8)
Arthralgia	0	0	2 (1.0)	2 (0.5)
Bursitis	2 (1.0)	0	0	0
General disorders and administration site conditions	3 (1.5)	5 (2.5)	5 (2.5)	10 (2.5)
Fatigue	2 (1.0)	4 (2.0)	1 (0.5)	5 (1.3)
Axillary pain	0	0	2 (1.0)	2 (0.5)

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	**Placebo (N=200) n (%)**	**50 µg (N=200) n (%)**	**100 µg (N=200) n (%)**	**Total (N=400) n (%)**
Injury, poisoning and procedural complications	3 (1.5)	10 (5.0)	9 (4.5)	19 (4.8)
Meniscus injury	0	1 (0.5)	2 (1.0)	3 (0.8)
Muscle strain	0	1 (0.5)	2 (1.0)	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 14.3.1.18.2.

7.3.3.3 Adverse Events of Interest

Analyses for AEs of interest were performed by searching the database using SMQs. The SMQs for this study included vasculitis, hypersensitivity, arthritis, angioedema, peripheral neuropathy, demyelinating disease of central nervous system, and convulsions; the SMQs are provided in Appendix 16.1.13.

No participants had AEs of interest in the SMQs of vasculitis (Table 14.3.1.22.1), demyelination (Table 14.3.1.22.6), or convulsions (Table 14.3.1.22.7).

The incidence of hypersensitivity was similar between the mRNA-1273 overall group (14/400 [3.5%]) and placebo group (6/200 [3.0%]; Table 14.3.1.22.2). More participants in the mRNA-1273 50 µg group (10/200 [5.0%]) reported hypersensitivity TEAEs than in the mRNA-1273 100 µg (4/200 [2.0%]). There were no anaphylactic reactions. The following hypersensitivity TEAEs were reported:

- Angioedema: 1/200 (0.5%) participant in the placebo group (also captured as an AE of interest of angioedema; Table 14.3.1.22.4)
- Allergic conjunctivitis: 1/200 (0.5%) in the mRNA-1273 100 µg group
- Dermatitis: 1/200 (0.5%) participant in the mRNA-1273 50 µg group
- Contact dermatitis: 5/200 (2.5%) participants in the mRNA-1273 50 µg group, 3/200 (1.5%) participants in the mRNA-1273 100 µg group, and 3/100 (1.5%) participants in the placebo group
- Rash: 4/200 (2.0%) participants in the mRNA-1273 50 µg group and 2/200 (1.0%) participants in the placebo group
- Allergic rhinitis: 1/200 (0.5%) participants in the mRNA-1273 50 µg group and 1/200 (0.5%) participants in the mRNA-1273 100 µg group.

Two participants reported an AE that was captured in the arthritis SMQ. Specifically, 1/200 (0.5%) participant in the mRNA-1273 50 µg group had a TEAE of periarthritis and 1/200 (0.5%) participant in the mRNA-1273 100 µg group had a TEAE of gout (Table 14.3.1.22.3).

One participant (0.5%) in the placebo group had a TEAE in the peripheral neuropathy SMQ (PT of neuralgia) (Table 14.3.1.22.5).

7.3.3.4 SARS-CoV-2 Exposure and Symptoms

A detailed listing of SARs-CoV-2 exposure by age cohort, vaccination group, visit, and length and reason for exposure for each participant is provided in Listing 16.2.6.5.1. A listing of SARs-CoV-2 or COVID-19 symptoms is provided in Listing 16.2.6.5.2.

7.3.3.5 Unsolicited Adverse Events for Participants Detected With SARS-CoV-2 or COVID-19

SARS-CoV-2 infection or COVID-19 was detected in 27 participants in the placebo group (18 in Cohort 1 and 9 in Cohort 2), 4 participants in the 50 µg group (3 in Cohort 1 and 1 in Cohort 2), and 2 participants in the 100 µg group (1 in Cohort 1 and 1 in Cohort 2) (Table 14.3.1.23.1).

In the mRNA-1273 50 µg group, the TEAEs reported within SOC of Infections and Infestations included COVID-19 and viral infection. Migraine was the only TEAE reported outside of the Infections and Infestations SOC (Table 14.3.1.23.1). The migraine was not temporally associated with COVID-19 infection (migraine resolved 23 Nov 2020; COVID-19 onset 15 Dec 2020) (Listing 16.2.7.12).

In the mRNA-1273 100 µg group, no other TEAEs were reported by the 2 participants who had COVID-19 infection (Table 14.3.1.23.1).

In the placebo group, the TEAEs reported within SOC of Infections and Infestations included COVID-19, asymptomatic COVID-19, gingivitis, otitis externa, pneumonia, and upper respiratory tract infection. The TEAEs reported outside of the Infections and Infestations SOC included hyperestrogenism, depression, oral disorder, rash papular, fatigue, and vitamin D decreased (1 participant each; Table 14.3.1.23.1).

7.4 Clinical Laboratory Evaluation

Clinical safety laboratory evaluations were performed at screening and at Day 29 and Day 57 only for Cohort 2 (≥ 55 years old). The results are presented in the primary analysis (Day 57) CSR (Section 7.4).

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 through Day 209 were comparable to those observed at baseline, with no notable trends or differences across groups (Table 14.3.3.1).

Overall results for shifts from baseline to vital signs toxicity of grade 3 to Day 57 are described in the primary (Day 57) CSR (Section 7.5.1). The following vital signs shifts from baseline to grade 3 at Day 209 were observed:

- In the mRNA-1273 100 µg group, grade 3 systolic hypertension was observed for 2/200 (1.0%) participants at Day 209. One participant was in Cohort 1 (≥ 18 to < 55 years) and the other was in Cohort 2 (≥ 55 years) (Table 14.3.3.2).
- In the placebo group, grade 3 bradycardia was observed for 1/200 (0.5%) participant at Day 209.

7.5.2 Vital Signs Reported as Adverse Events

Vital signs reported as TEAEs up to End of Part A included the following (Table 14.3.1.8.2):

- **mRNA-1273 50 µg group**
    - Diastolic dysfunction: 1/200 (0.5%) participant
    - Hypertension: 5/200 (2.5%) participants
    - Increased blood pressure: 1/200 (0.5%) participant

All the events in the mRNA-1273 50 µg group were reported as MAAEs except 1 event of hypertension.

- **mRNA-1273 100 µg group**
    - Hypertension: 1/200 (0.5%) participant
    - Diastolic hypertension: 1/200 (0.5%) participant
    - Increased blood pressure: 2/200 (1.0%) participants
    - Increased blood pressure diastolic: 1/200 (0.5%) participant

The event of hypertension and 1 event of increased blood pressure were reported as MAAEs in the mRNA-1273 100 µg group.

- **Placebo**
    - Increased blood pressure: 2/200 (1.0%) participants
    - Cardiac murmur: 1/200 (0.5%) participant
    - Decreased heart rate: 2/200 (1.0%) participants

None of the events in the placebo group were reported as MAAEs.

There was no difference between the groups for increased blood pressure.

7.6 Pregnancies

As of the date of the database lock for this CSR addendum, no participants had positive results for urine pregnancy tests performed at the site during Part A (Listing 16.2.8.5).

According to the safety database, 2 pregnancies were reported (1 participant in the mRNA-1273 50 µg group and 1 participant in the mRNA-1273 100 µg group). Both pregnancies resulted in spontaneous abortion and were reported as SAEs. Neither of the spontaneous abortions were considered related to the vaccine. The case narratives for these participants are provided in Section 15.

7.7 Safety Conclusions

In this End of Part A 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) and Cohort 2 (≥ 55 years old). No new safety findings since the primary analysis (Day 57) CSR were identified in this End of Part A analysis.

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

- The incidence of unsolicited TEAEs during Part A was similar between the mRNA-1273 overall group (45.3%) and the placebo group (47.0%). The number of participants who experienced unsolicited TEAEs regardless of causality was 105/200 (52.5%) participants in the mRNA-1273 50 µg group and 76/200 (38.0%) participants in the mRNA-1273 100 µg group. The number of participants who experienced unsolicited TEAEs related to

the study vaccine was 19/200 (9.5%) participants in the mRNA-1273 50 µg and 28/200 (14%) participants in the mRNA-1273 100 µg group.

- The incidence of the most common unsolicited TEAEs was similar between the mRNA-1273 overall and placebo groups except for the AE of COVID-19, where the incidence was notably higher in the placebo group.
- The most common unsolicited TEAEs (incidence ≥ 2%) in the mRNA-1273 overall or placebo groups were COVID-19 (5/400 [1.3%] and 26/200 [13.0%], respectively), headache (25/400 [6.3%] and 8/200 [4.0%], respectively), fatigue (21/400 [5.3%] and 7/200 [3.5%], respectively), arthralgia (11/400 [2.8%] and 4/200 [2.0%], respectively), oropharyngeal pain (8/400 [2.0%] and 4/200 [2.0%], respectively), myalgia (8/400 [2.0%] and 3/200 [1.5%], respectively), upper respiratory tract infection (6/400 [1.5%] and 4/200 [2.0%], respectively), and dermatitis contact (8/400 [2.0%] and 3/200 [1.5%], respectively).
- Of the 6 participants in the overall mRNA-1273 group with confirmed SARS-CoV-2 infection (4 participants in the 50 µg group and 2 participants in the mRNA-1273 100 µg group), only 1 TEAE was reported outside of the Infections and Infestations SOC (migraine in 1 participant that was not temporally associated with COVID-19 infection). In the placebo group, the TEAEs reported outside of the Infections and Infestations SOC included hyperestrogenism, depression, oral disorder, rash papular, fatigue, and vitamin D decreased (1 participant each). No meaningful conclusion can be drawn for these participants due to the limited number of cases.
- No deaths occurred during Part A of the study. A total of 7 participants (1.8%) reported SAEs (5 participants [2.5%] in the 50 µg mRNA-1273 group and 2 participants [1.0%] in the 100 µg mRNA-1273 group). No individual PT was reported in more than 1 participant. No SAEs were reported in the placebo group.
- No participants reported unsolicited TEAEs leading to discontinuation from the study during Part A.
- The incidence of MAAEs from Day 1 to End of Part A was similar in the mRNA-1273 overall group (28.0%) and the placebo group (32.0%). The incidence of MAAEs regardless of causality increased during the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (from 39 to 112 participants in the mRNA-1273 overall group and from 17 to 64 participants in the placebo group), which was likely due to the longer duration of follow-up. The incidence of treatment-related MAAEs was similar in the overall Part A period compared with that observed in the up to 28-day follow-up after any vaccination (8 and 6 participants in the mRNA-1273 group, respectively, and 2 and 1 participants in the placebo group, respectively).

- As identified from analyses of AEs of interest based on an SMQ search of the database, the incidence of hypersensitivity was similar between the mRNA-1273 overall group (3.5%) and placebo group (3.0%). No participants had AEs of interest in the SMQs of vasculitis, demyelination, or convulsions. Two participants in the mRNA-1273 overall group had AEs of interest in the arthritis SMQ (gout in 1 participant and periarthritis in 1 participant). One participant in the placebo group had a TEAE in the peripheral neuropathy SMQ (PT of neuralgia).
- Mean vital sign measurements (diastolic blood pressure, pulse rate, respiratory rate, systolic blood pressure, and temperature) observed through Day 209 were comparable to those observed at baseline, with no notable trends or differences across groups.

8 Immunogenicity Results

The results for the primary and secondary immunogenicity endpoints are presented through Day 209. The number of participants in the Full Analysis Set and PP Sets did not differ by > 10%; thus, supportive analyses of immunogenicity results based on the Full Analysis Set were not required, as specified in the protocol.

8.1 SARS-CoV-2–Specific bAb and Seroresponse

The primary (Day 57) CSR provides the results of SARS-CoV-2 S-2P-specific bAb, which was detected using a qualified assay (VAC58). Subsequently, all samples were re-run using a validated assay, VAC65 (Section 3.3.2). This CSR addendum provides the results of SARS-CoV-2 S-2P-specific bAb that were detected using VAC65.

In both doses, mRNA-1273 induced increases in geometric mean (GM) levels of VAC65 IgG antibodies, as measured by ELISA specific to the SARS-CoV-2 spike protein, by Day 29 (28 days after the first injection). Levels of anti-SARS-CoV-2-spike IgG bAb declined from the peak at Day 43 (14 days after the second injection) to Day 209. The Day 209 GM levels remained higher than the levels observed at Day 29 (before the second injection) for both mRNA-1273 100 µg and mRNA-1273 50 µg dose groups. The mRNA-1273 100 µg dose group had numerically greater responses than the mRNA-1273 50 µg dose group at all post-dose visits with non-overlapping 95% CIs on Days 29, 57, and 209 and an overlapping 95% CI on Day 43 (Table 8 and Figure 3). No formal comparison between 50 µg and 100 µg were performed. Levels of anti-SARS-CoV-2-spike IgG bAb in the placebo group remained low from baseline to Day 209.

The geometric mean fold-rises (GMFRs) trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at all postbaseline visits. However, GMFR results showed a robust response in both treatment groups, with seroresponse criteria (defined as a change of bAb level from below the LLOQ to equal to or above the LLOQ, or at least a 4.6-fold rise if baseline was equal to or above the LLOQ) being met in over 97% of participants at each postbaseline visit. At Day 43 and Day 57, seroresponse criteria were met for 100% of participants in both mRNA-1273 dose groups (Table 8).

Similar trends were observed in both Cohort 1 and Cohort 2, and GM levels and GMFRs were generally higher in Cohort 1 than Cohort 2 at each postbaseline visit. In both cohorts, seroresponse criteria were met in over 97% of participants at each postbaseline visit, with 100% of participants in Cohort 1 and Cohort 2 meeting seroresponse criteria at Day 43 and Day 57. (Table 9 and Figure 4).

Analysis of VAC65 SARS-CoV-2 spike IgG antibodies using the analysis of covariance (ANCOVA) model showed results of GM levels, GMFRs, and corresponding CIs consistent with those presented above (Table 14.2.1.2.12.1).

Table 8: Summary of Binding Antibody Levels (Per-Protocol Set for SARS-CoV-2-Specific bAb)

Timepoint Data Category Statistic	Overall Placebo (N=186)	Overall mRNA-1273 50 µg (N=185)	Overall mRNA-1273 100 µg (N=189)	Overall mRNA-1273 Total (N=374)
Antibody: VAC65 spike IgG antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)				
Baseline				
n[a]	186	185	189	374
GM level	0.67	0.70	0.67	0.68
95% CI[b]	0.61, 0.73	0.63, 0.78	0.60, 0.73	0.63, 0.73
Median	0.50	0.50	0.50	0.50
Min, Max	0.5, 20.4	0.5, 72.0	0.5, 135.5	0.5, 135.5
Day 29				
n[c]	182	183	189	372
GM level	0.68	59.42	81.51	69.77
95% CI[b]	0.61, 0.76	52.05, 67.82	70.19, 94.67	63.08, 77.18
Median	0.50	66.30	88.20	75.75
Min, Max	0.5, 144.4	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM fold-rise	1.03	85.84	122.40	102.79
95% CI[b]	0.93, 1.15	72.93, 101.03	103.88, 144.23	91.49, 115.50
Seroresponse[d]				
n[e] (%)	11 (6.0)	181 (98.9)	185 (97.9)	366 (98.4)
95% CI[f]	3.1, 10.6	96.1, 99.9	94.7, 99.4	96.5, 99.4
Seroresponse (>=4 fold rise)[g]				
n[e] (%)	2 (1.1)	181 (98.9)	185 (97.9)	366 (98.4)
95% CI [f]	0.1, 3.9	96.1, 99.9	94.7, 99.4	96.5, 99.4
Day 43				
n[c]	180	176	180	356
GM level	0.65	720.85	834.66	776.31
95% CI[b]	0.59, 0.71	660.30, 786.96	765.28, 910.33	729.73, 825.86
Median	0.50	765.25	896.20	810.00
Min, Max	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0

	Overall			
		mRNA-1273		
Timepoint **Data Category** **Statistic**	**Placebo** **(N=186)**	**50 µg** **(N=185)**	**100 µg** **(N=189)**	**Total** **(N=374)**
GM fold-rise	0.97	1020.31	1240.91	1126.46
95% CI[b]	0.90, 1.05	887.47, 1173.04	1088.53, 1414.63	1023.64, 1239.59
Seroresponse[d]				
n[e] (%)	3 (1.7)	176 (100)	180 (100)	356 (100)
95% CI[f]	0.3, 4.8	97.9, 100.0	98.0, 100.0	99.0, 100.0
Seroresponse (>=4 fold rise)[g]				
n[e] (%)	1 (0.6)	176 (100)	180 (100)	356 (100)
95% CI[f]	0.0, 3.1	97.9, 100.0	98.0, 100.0	99.0, 100.0
Day 57				
n[c]	174	176	174	350
GM level	0.67	519.48	647.22	579.48
95% CI[b]	0.60, 0.75	474.00, 569.33	588.98, 711.21	542.24, 619.27
Median	0.50	577.80	709.15	632.50
Min, Max	0.5, 67.8	112.3, 2052.0	86.0, 2052.0	86.0, 2052.0
GM fold-rise	1.01	732.00	974.31	843.82
95% CI[b]	0.92, 1.11	636.03, 842.45	849.28, 1117.74	764.34, 931.56
Seroresponse[d]				
n[e] (%)	9 (5.2)	176 (100)	174 (100)	350 (100)
95% CI[f]	2.4, 9.6	97.9, 100.0	97.9, 100.0	99.0, 100.0
Seroresponse (>=4 fold rise)[g]				
n[e] (%)	2 (1.1)	176 (100)	174 (100)	350 (100)
95% CI[f]	0.1, 4.1	97.9, 100.0	97.9, 100.0	99.0, 100.0
Day 209				
n[c]	154	170	174	344
GM level	0.91	97.02	128.00	111.62
95% CI[b]	0.73, 1.14	87.58, 107.47	114.44, 143.18	103.35, 120.55
Median	0.50	94.80	128.15	114.65
Min, Max	0.5, 467.3	13.5, 854.2	19.5, 1362.4	13.5, 1362.4

Timepoint Data Category Statistic	Overall Placebo (N=186)	mRNA-1273 50 µg (N=185)	mRNA-1273 100 µg (N=189)	mRNA-1273 Total (N=374)
GM fold-rise	1.38	136.84	200.28	165.92
95% CI[b]	1.13, 1.69	117.91, 158.82	173.93, 230.63	149.53, 184.10
Seroresponse[d]				
n[e] (%)	16 (10.4)	169 (99.4)	173 (99.4)	342 (99.4)
95% CI[f]	6.1, 16.3	96.8, 100.0	96.8, 100.0	97.9, 99.9
Seroresponse (>=4 fold rise)[g]				
n[e] (%)	14 (9.1)	169 (99.4)	174 (100)	343 (99.7)
95% CI[f]	5.1, 14.8	96.8, 100.0	97.9, 100.0	98.4, 100.0

Abbreviations: bAb = binding antibody; GM = geometric mean; Max = maximum; Min = minimum; CI = confidence intervals; ELISA = enzyme-linked immunosorbent assay; LLOQ = lower limit of quantification; ULOQ = upper limit of quantification.

Antibody values reported as below the LLOQ are replaced by 0.5 x LLOQ. Values that are greater than the ULOQ are converted to the ULOQ if actual values are not available.

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 bAb from the First Lot at the corresponding visit (n[c]).

[a] Number of subjects with non-missing 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.

[d] Seroresponse specific to SARS-CoV-2 spike protein measured by ELISA at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.

[e] Number of subjects in the corresponding category at the corresponding time point.

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

[g] Seroresponse (>=4-fold rise) specific to SARS-CoV-2 spike protein measured by ELISA at a subject level is defined as a >= 4 x LLOQ for participants with baseline antibody level below the LLOQ, or a 4-times or higher ratio in participants with pre-existing bAb levels.

Source: Table 14.2.1.1.12.1.

Table 9: Summary of Binding Antibody Levels by Dose Group and Age Cohort (Per-Protocol Set for SARS-CoV-2-Specific bAb)

Timepoint / Data / Statistic	Category	Cohort 1 (Age >= 18 and age < 55) Placebo (N=92)	Cohort 1 mRNA-1273 50 µg (N=90)	Cohort 1 mRNA-1273 100 µg (N=95)	Cohort 1 mRNA-1273 Total (N=185)	Cohort 2 (Age >= 55) Placebo (N=94)	Cohort 2 mRNA-1273 50 µg (N=95)	Cohort 2 mRNA-1273 100 µg (N=94)	Cohort 2 mRNA-1273 Total (N=189)
Antibody: VAC65 spike IgG antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)									
Baseline									
n[a]		92	90	95	185	94	95	94	189
GM level		0.69	0.71	0.59	0.65	0.65	0.68	0.75	0.71
95% CI [b]		0.61, 0.79	0.60, 0.85	0.55, 0.64	0.59, 0.71	0.58, 0.73	0.59, 0.78	0.63, 0.89	0.64, 0.80
Median		0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Min, Max		0.5, 11.1	0.5, 72.0	0.5, 3.4	0.5, 72.0	0.5, 20.4	0.5, 14.9	0.5, 135.5	0.5, 135.5
Day 29									
n[c]		88	88	95	183	94	95	94	189
GM level		0.69	80.82	114.53	96.85	0.67	44.69	57.80	50.79
95% CI [b]		0.59, 0.82	69.20, 94.39	94.82, 138.34	85.50, 109.71	0.57, 0.79	36.73, 54.36	46.67, 71.60	43.94, 58.71
Median		0.50	80.65	134.90	107.10	0.50	46.70	63.15	56.80
Min, Max		0.5, 144.4	15.1, 338.7	0.5, 1666.1	0.5, 1666.1	0.5, 135.8	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM fold-rise		1.03	114.89	193.24	150.49	1.04	65.52	77.15	71.07
95% CI[b]		0.87, 1.22	90.98, 145.10	158.77, 235.20	128.89, 175.72	0.91, 1.18	52.71, 81.44	61.22, 97.23	60.70, 83.21
Seroresponse[d]									
n[e] (%)		6 (6.8)	87 (98.9)	94 (98.9)	181 (98.9)	5 (5.3)	94 (98.9)	91 (96.8)	185 (97.9)
95% CI [f]		2.5, 14.3	93.8, 100.0	94.3, 100.0	96.1, 99.9	1.7, 12.0	94.3, 100.0	91.0, 99.3	94.7, 99.4
Seroresponse (>=4-fold rise)[g]									
n[e] (%)		1 (1.1)	87 (98.9)	94 (98.9)	181 (98.9)	1 (1.1)	94 (98.9)	91 (96.8)	185 (97.9)
95% CI [f]		0.0, 6.2	93.8, 100.0	94.3, 100.0	96.1, 99.9	0.0, 5.8	94.3, 100.0	91.0, 99.3	94.7, 99.4
Day 43									
n[c]		87	84	93	177	93	92	87	179
GM level		0.62	760.95	937.29	849.02	0.67	686.09	737.34	710.54

Timepoint / Data / Statistic	Category	Cohort 1 (Age >= 18 and age < 55) Placebo (N=92)	mRNA-1273 50 µg (N=90)	mRNA-1273 100 µg (N=95)	mRNA-1273 Total (N=185)	Cohort 2 (Age >= 55) Placebo (N=94)	mRNA-1273 50 µg (N=95)	mRNA-1273 100 µg (N=94)	mRNA-1273 Total (N=189)
95% CI [b]		0.55, 0.70	678.54, 853.38	852.64, 1030.34	787.99, 914.78	0.58, 0.79	600.95, 783.28	637.24, 853.16	644.53, 783.30
Median		0.50	759.80	961.00	849.40	0.50	767.30	823.70	778.10
Min, Max		0.5, 8.5	164.3, 2052.0	199.5, 2052.0	164.3, 2052.0	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0
GM fold-rise		0.91	1047.83	1575.67	1298.33	1.04	995.82	961.30	978.89
95% CI [b]		0.82, 1.00	843.27, 1302.02	1396.86, 1777.37	1147.51, 1468.96	0.92, 1.16	829.77, 1195.09	764.28, 1209.12	847.40, 1130.79
Seroresponse[d]									
n[e] (%)		0	84 (100)	93 (100)	177 (100)	3 (3.2)	92 (100)	87 (100)	179 (100)
95% CI [f]		0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.7, 9.1	96.1, 100.0	95.8, 100.0	98.0, 100.0
Seroresponse (>=4-fold rise)[g]									
n[e] (%)		0	84 (100)	93 (100)	177 (100)	1 (1.1)	92 (100)	87 (100)	179 (100)
95% CI [f]		0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	96.1, 100.0	95.8, 100.0	98.0, 100.0
Day 57									
n[c]		83	84	85	169	91	92	89	181
GM level		0.68	566.56	772.04	661.97	0.66	479.93	546.89	511.76
95% CI [b]		0.57, 0.80	502.80, 638.40	694.74, 857.93	609.71, 718.70	0.57, 0.77	418.32, 550.60	471.66, 634.13	462.90, 565.78
Median		0.50	586.20	827.50	667.20	0.50	549.55	653.10	577.00
Min, Max		0.5, 67.8	165.7, 2052.0	135.3, 2052.0	135.3, 2052.0	0.5, 56.4	112.3, 2052.0	86.0, 1927.8	86.0, 2052.0
GM fold-rise		0.98	772.86	1319.00	1011.25	1.03	696.58	729.56	712.61
95% CI [b]		0.84, 1.14	619.81, 963.70	1165.49, 1492.72	886.84, 1153.11	0.92, 1.16	581.00, 835.16	580.97, 916.14	617.22, 822.73
Seroresponse[d]									
n[e] (%)		5 (6.0)	84 (100)	85 (100)	169 (100)	4 (4.4)	92 (100)	89 (100)	181 (100)
95% CI [f]		2.0, 13.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	1.2, 10.9	96.1, 100.0	95.9, 100.0	98.0, 100.0
Seroresponse (>=4-fold)[g]									
n[e] (%)		1 (1.2)	84 (100)	85 (100)	169 (100)	1 (1.1)	92 (100)	89 (100)	181 (100)
95% CI [f]		0.0, 6.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	0.0, 6.0	96.1, 100.0	95.9, 100.0	98.0, 100.0

Timepoint / Data Statistic	Category	Cohort 1 (Age >= 18 and age < 55) Placebo (N=92)	Cohort 1 mRNA-1273 50 µg (N=90)	Cohort 1 mRNA-1273 100 µg (N=95)	Cohort 1 mRNA-1273 Total (N=185)	Cohort 2 (Age >= 55) Placebo (N=94)	Cohort 2 mRNA-1273 50 µg (N=95)	Cohort 2 mRNA-1273 100 µg (N=94)	Cohort 2 mRNA-1273 Total (N=189)
Day 209									
n[c]		74	80	90	170	80	90	84	174
GM level		0.96	104.13	132.94	118.50	0.86	91.11	122.92	105.28
95% CI [b]		0.69, 1.35	89.86, 120.66	113.31, 155.97	106.18, 132.26	0.63, 1.17	78.93, 105.16	104.78, 144.19	94.48, 117.32
Median		0.50	94.80	131.90	116.85	0.50	96.00	126.75	107.50
Min, Max		0.5, 467.3	29.0, 854.2	19.5, 1006.2	19.5, 1006.2	0.5, 446.9	13.5, 419.6	20.4, 1362.4	13.5, 1362.4
GM fold-rise		1.43	142.13	223.91	180.79	1.33	132.31	177.72	152.57
95% CI[b]		1.07, 1.91	111.65, 180.91	188.45, 266.05	155.89, 209.68	1.00, 1.79	109.82, 159.41	141.58, 223.10	131.80, 176.60
Seroresponse[d]									
n[e] (%)		8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	8 (10.0)	90 (100)	83 (98.8)	173 (99.4)
95% CI [f]		4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	4.4, 18.8	96.0, 100.0	93.5, 100.0	96.8, 100.0
Seroresponse (>=4-fold rise)[g]									
n[e] (%)		8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	6 (7.5)	90 (100)	84 (100)	174 (100)
95% CI[f]		4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	2.8, 15.6	96.0, 100.0	95.7, 100.0	97.9, 100.0

Abbreviations: bAb = binding antibody; GM = geometric mean; Max = maximum; Min = minimum; CI = confidence intervals; ELISA = enzyme-linked immunosorbent assay; LLOQ = lower limit of quantification; ULOQ = upper limit of quantification.

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 if actual values are not available.

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 bAb from the First Lot at the corresponding visit (n[c]).

[a] Number of subjects with non-missing 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.

[d] Seroresponse specific to SARS-CoV-2 spike protein measured by ELISA at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.

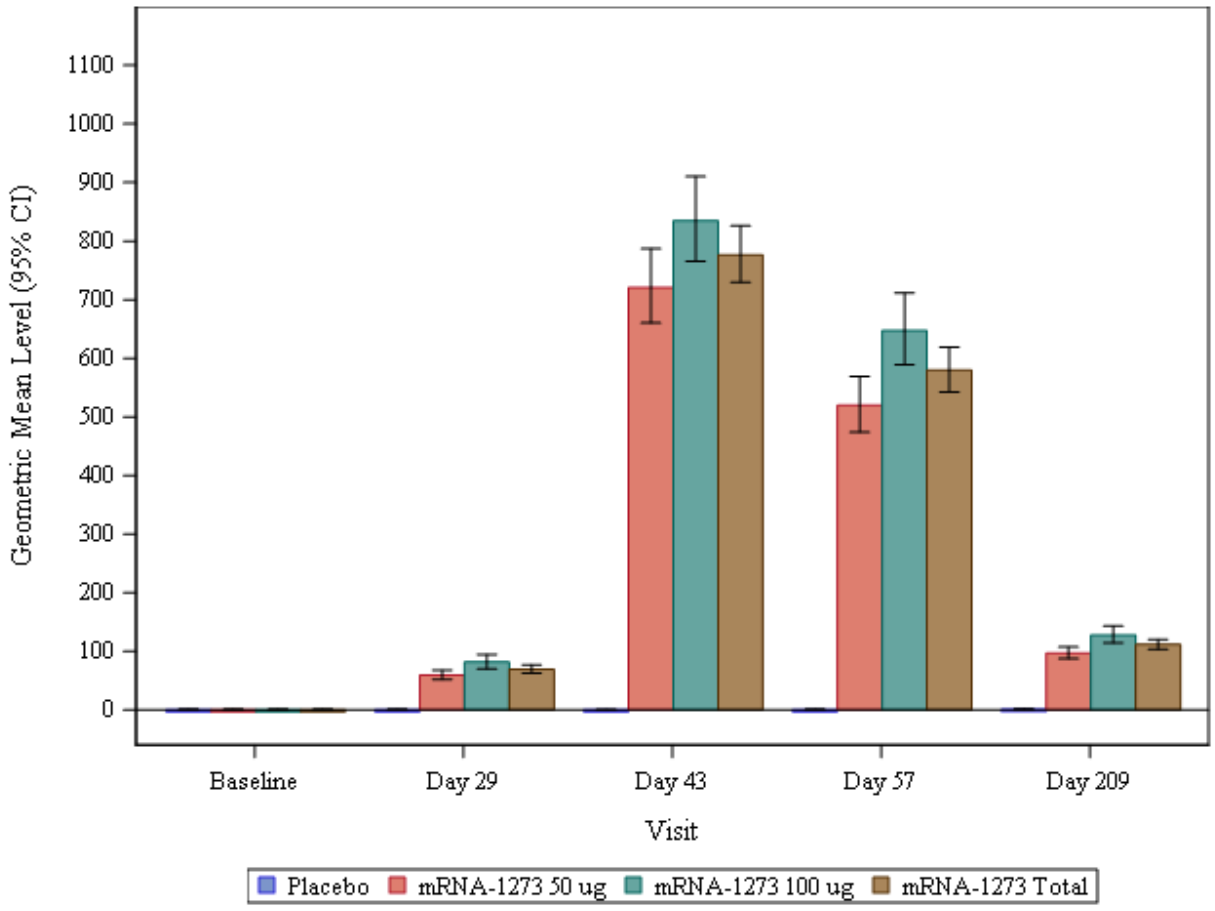
[e] Number of subjects in the corresponding category at the corresponding time point.

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

[g] Seroresponse (>=4-fold rise) specific to SARS-CoV-2 spike protein measured by ELISA at a subject level is defined as a >= 4 x LLOQ for participants with baseline antibody level below the LLOQ, or a 4-times or higher ratio in participants with pre-existing bAb levels.

Source: Table 14.2.1.1.12.1.

Figure 3: Geometric Mean Levels of Binding Antibody Immunogenicity Results by ELISA (Per-Protocol Set for SARS-CoV-2-specific bAb)



Abbreviations: bAb = binding antibody; ELISA = enzyme-linked immunosorbent; 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 x LLOQ. Values that are greater than the ULOQ are converted to the ULOQ if actual values are not available.

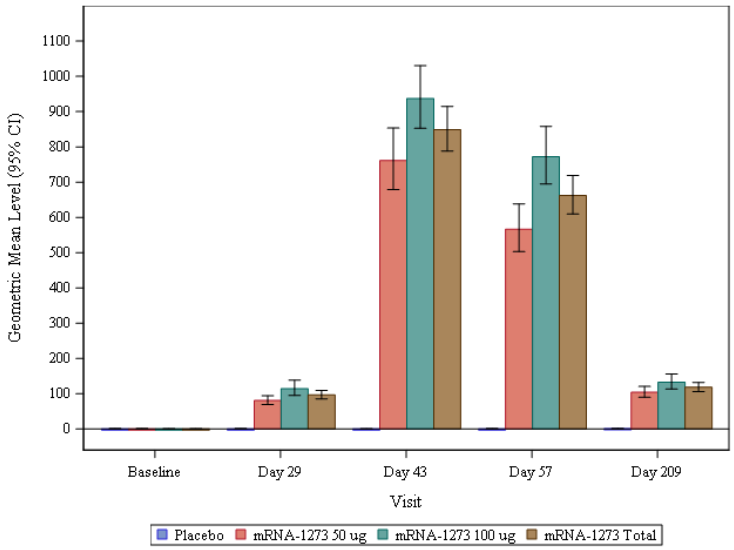
Confidence intervals are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

Source: Figure 14.2.1.11.1.

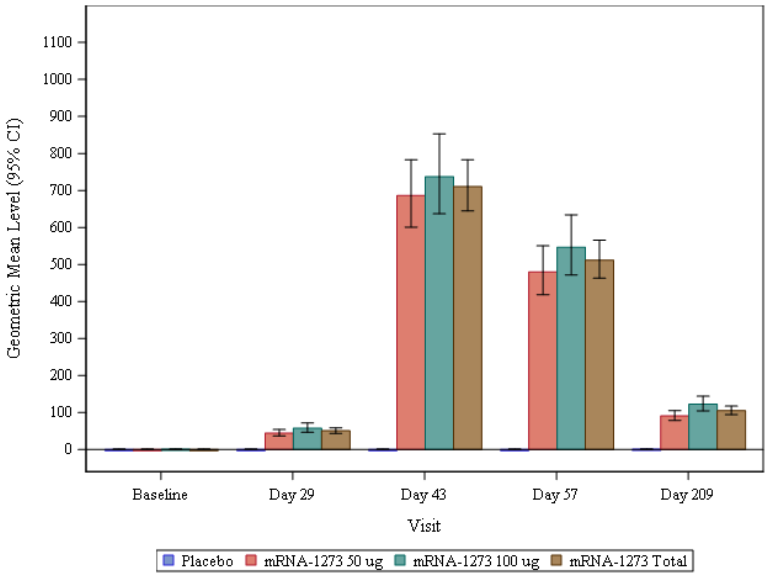
Figure 4: Geometric Mean Levels of Binding Antibody Immunogenicity Results by ELISA by Age (Per-Protocol Set for SARS-CoV-2-specific bAb)

VAC65 Spike IgG Antibody (AU/mL) (LLOQ: 1, ULOQ: 2052)

Cohort 1 (≥ 18 and < 55 Years)



Cohort 2 (≥ 55 Years)



Abbreviations: bAb = binding antibody; ELISA = enzyme-linked immunosorbent; 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 x LLOQ. Values that are greater than the ULOQ are converted to the ULOQ if actual values are not available.

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

Source: Figure 14.2.1.11.1.

8.2 SARS-CoV-2–Specific Microneutralization Antibody

A vast majority samples at baseline, Day 29, Day 43, and Day 57 were tested using the first viral lot; all samples at Day 209 were tested using the new viral lot. SARS-CoV-2-specific nAb results for the PP Set for SARS-CoV-2-specific nAb from the First Lot is provided in Table 14.2.2.1.1.1, Table 14.2.2.2.1.1, Figure 14.2.4.1.1, and Figure 14.2.6.1.1.

At the time of primary analysis, the laboratory was not able to provide results of 30 participants because of required additional re-testing and, therefore, results were missing for these 30 samples in the primary analysis (Day 57) CSR. Data from these 30 samples are included in this CSR addendum.

In both doses, mRNA-1273 induced increases in MN and MN_{50} endpoint titers from baseline by Day 29 (28 days after the first injection). The MN_{50} and MN endpoint titers declined from the peak at Day 43 (14 days after the second injection) to Day 209. The Day 209 geometric mean titers (GMTs) remained higher than the values observed at Day 29 (before the second injection) for both 100 µg and 50 µg dose groups (Table 10 and Figure 5). GMTs were numerically higher in the 100 µg dose group at each postbaseline time point. No formal comparison between 50 µg and 100 µg were performed. The MN_{50} and MN endpoint titers in the placebo group remained low from baseline to Day 209.

Within the mRNA-1273 100 µg group, the GMT of MN_{50} and MN endpoint titers were numerically higher in Cohort 1 than in Cohort 2 at each postbaseline visit (Table 11 and Figure 6).

Analysis of MN_{50} antibody titer and MN endpoint titer using an ANCOVA model showed results of GMTs and corresponding CIs consistent with those presented above (Table 14.2.2.2.1.2).

Table 10: Summary of Neutralizing Antibody Titers (Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Antibody: MN endpoint titer				
Baseline				
n[a]	186	185	189	374
GMT	20.8	20.6	20.6	20.6
95% CI[b]	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
Day 29				
n[c]	184	184	187	371
GMT	21.9	112.2	149.6	129.7
95% CI[b]	20.5, 23.5	94.9, 132.7	127.3, 175.9	115.4, 145.8
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
Day 43				
n[c]	180	174	181	355
GMT	21.2	1145.4	1185.8	1165.8
95% CI[b]	20.1, 22.4	1101.3, 1191.1	1142.9, 1230.3	1135.0, 1197.5
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
Day 57				
n[c]	175	176	177	353
GMT	21.8	1090.6	1095.5	1093.1
95% CI[b]	20.4, 23.4	1038.9, 1144.9	1041.5, 1152.2	1055.6, 1131.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280

Timepoint Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 209				
n[c]	153	171	174	345
GMT	85.3	254.4	354.8	300.9
95% CI[b]	80.6, 90.2	219.4, 294.9	309.2, 407.2	271.7, 333.2
Median	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280
Antibody: MN50				
Baseline				
n[a]	186	185	189	374
GMT	47.109	46.500	46.684	46.593
95% CI[b]	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
Day 29				
n[c]	184	184	187	371
GMT	49.231	173.750	227.433	199.004
95% CI[b]	46.355, 52.285	148.550, 203.225	194.207, 266.343	177.992, 222.496
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
Day 43				
n[c]	180	174	181	355
GMT	48.059	1761.660	1813.480	1787.893
95% CI[b]	45.820, 50.408	1690.216, 1836.124	1741.280, 1888.673	1736.969, 1840.310
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

Timepoint Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[c]	175	176	177	353
GMT	49.141	1632.442	1656.064	1644.244
95% CI[b]	46.267, 52.194	1550.245, 1718.998	1570.464, 1746.330	1584.736, 1705.987
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
Day 209				
n[c]	153	171	174	345
GMT	167.002	401.508	538.798	465.710
95% CI[b]	159.249, 175.133	350.667, 459.720	472.772, 614.045	423.548, 512.069
Median	159.230	339.411	678.823	495.361
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

Abbreviations: 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 x LLOQ. Values that are greater than the 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. Vast majority samples at Baseline, Day 29, Day 43 and Day 57 were tested using the first viral lot; all samples at Day 209 were tested using the new viral lot.

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 non-missing baseline.

[b] 95% CI is calculated based on the t-distribution of the log-transformed values for GMT, then back transformed to the original scale for presentation.

[c] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

Source: Table 14.2.2.1.1.2.

Table 11: Summary of Neutralizing Antibody Titers by Dose Group and Age Cohort (Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Antibody: MN endpoint titer								
Baseline								
n[a]	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 [b]	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
Day 29								
n[c]	90	89	94	183	94	95	93	188
GMT	20.9	126.4	183.4	153.0	22.9	100.4	121.8	110.4
95% CI [b]	19.2, 22.7	100.8, 158.5	147.1, 228.7	130.6, 179.4	20.6, 25.5	78.3, 128.6	96.5, 153.8	93.2, 130.9
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
Day 43								
n[c]	87	83	94	177	93	91	87	178
GMT	20.0	1127.7	1232.7	1182.3	22.5	1161.7	1137.2	1149.7
95% CI [b]	NE, NE	1055.8, 1204.5	1201.8, 1264.3	1142.8, 1223.2	20.3, 24.9	1109.6, 1216.2	1058.9, 1221.4	1102.7, 1198.6
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
Day 57								
n[c]	84	84	87	171	91	92	90	182
GMT	21.5	1066.9	1135.2	1101.1	22.1	1112.8	1058.5	1085.6
95% CI [b]	19.4, 23.9	988.5, 1151.5	1072.4, 1201.6	1050.4, 1154.2	20.1, 24.3	1045.4, 1184.5	973.9, 1150.3	1031.1, 1143.0
Median	20.0	1280.0	1280.0	1280.0	20.0	1280.0	1280.0	1280.0

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	**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)**
Min, Max	20, 640	240, 1280	320, 1280	240, 1280	20, 640	320, 1280	200, 1280	200, 1280
Day 209								
n[c]	74	81	90	171	79	90	84	174
GMT	85.6	273.2	375.3	322.9	85.0	238.6	334.1	280.7
95% CI [b]	78.7, 93.0	221.6, 336.8	313.1, 449.9	281.2, 370.8	78.8, 91.7	193.0, 294.8	270.3, 413.0	241.5, 326.3
Median	80.0	240.0	400.0	320.0	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280	80, 960	80, 1280	80, 1280	80, 1280
Antibody: MN50								
Baseline								
n[a]	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 [b]	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
Day 29								
n[c]	90	89	94	183	94	95	93	188
GMT	47.301	184.278	272.772	225.405	51.152	164.433	189.259	176.278
95% CI [b]	43.885, 50.982	147.555, 230.140	220.239, 337.837	192.975, 263.285	46.555, 56.203	131.409, 205.756	150.303, 238.312	150.281, 206.773
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	164.468
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
Day 43								
n[c]	87	83	94	177	93	91	87	178
GMT	45.550	1727.866	1902.388	1818.457	50.532	1793.060	1722.081	1758.010
95% CI [b]	NE, NE	1610.014, 1854.343	1844.760, 1961.817	1751.994, 1887.442	46.091, 55.400	1710.583, 1879.514	1594.239, 1860.175	1681.683, 1837.802
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	1917.830

Timepoint Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
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
Day 57								
n[c]	84	84	87	171	91	92	90	182
GMT	48.508	1584.249	1704.173	1644.169	49.733	1677.724	1610.851	1644.315
95% CI [b]	44.389, 53.009	1459.163, 1720.058	1602.726, 1812.040	1562.671, 1729.917	45.745, 54.069	1571.714, 1790.885	1477.046, 1756.777	1558.391, 1734.977
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
Day 209								
n[c]	74	81	90	171	79	90	84	174
GMT	167.803	435.677	558.848	496.678	166.255	373.053	518.114	437.158
95% CI [b]	155.864, 180.658	359.609, 527.836	468.470, 666.661	436.142, 565.615	156.199, 176.960	307.612, 452.415	425.305, 631.174	380.508, 502.241
Median	159.230	452.548	678.823	565.685	159.230	339.411	622.254	452.548
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

Abbreviations: nAb = neutralizing antibody; GMT = geometric mean titer; Max = maximum; Min = minimum; CI = confidence intervals; LLOQ = lower limit of quantification; ULOQ = upper limit of quantification.

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. Vast majority samples at Baseline, Day 29, Day 43 and Day 57 were tested using the first viral lot; all samples at Day 209 were tested using the new viral lot.

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.

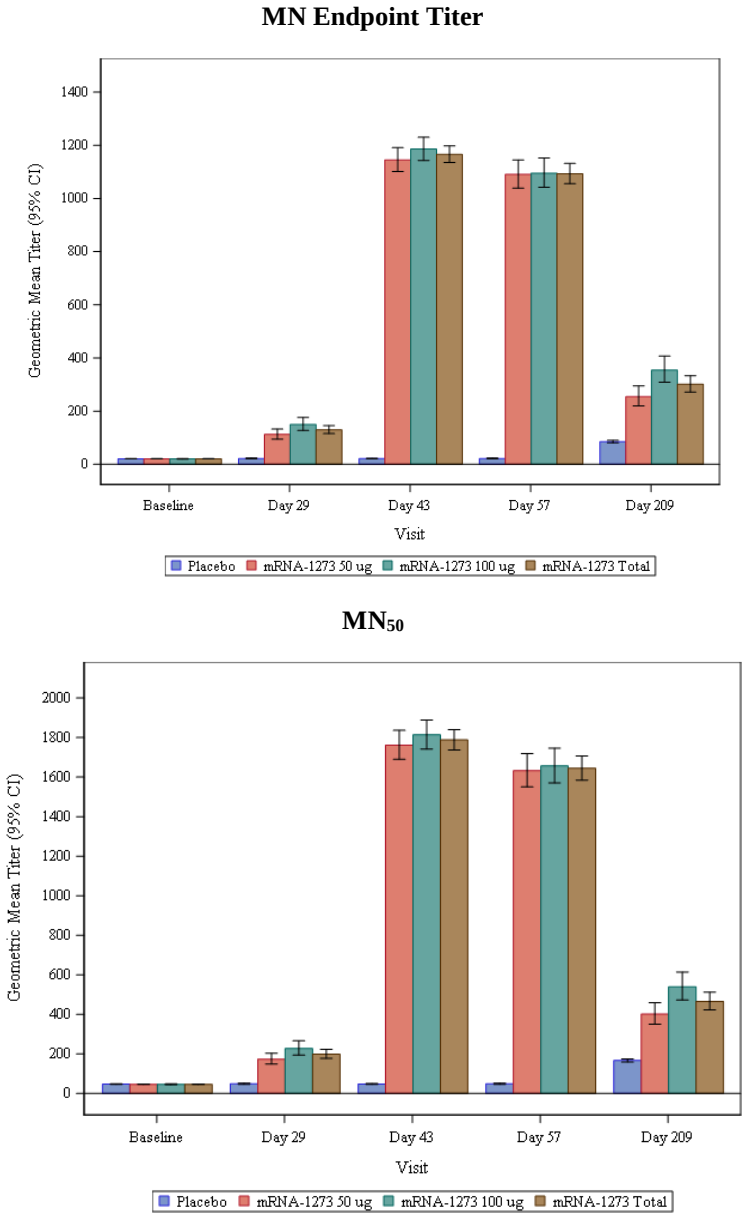
[a] Number of subjects with non-missing baseline.

[b] 95% CI is calculated based on the t-distribution of the log-transformed values for GMT, then back transformed to the original scale for presentation.

[c] Number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots at the corresponding visit.

Source: Table 14.2.2.1.1.2

Figure 5: Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results (Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots)



Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantification; Max = maximum; Min = minimum; MN = microneutralization; 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 LLOQ are replaced by 0.5 x LLOQ. Values that are greater than the ULOQ are converted to the ULOQ.

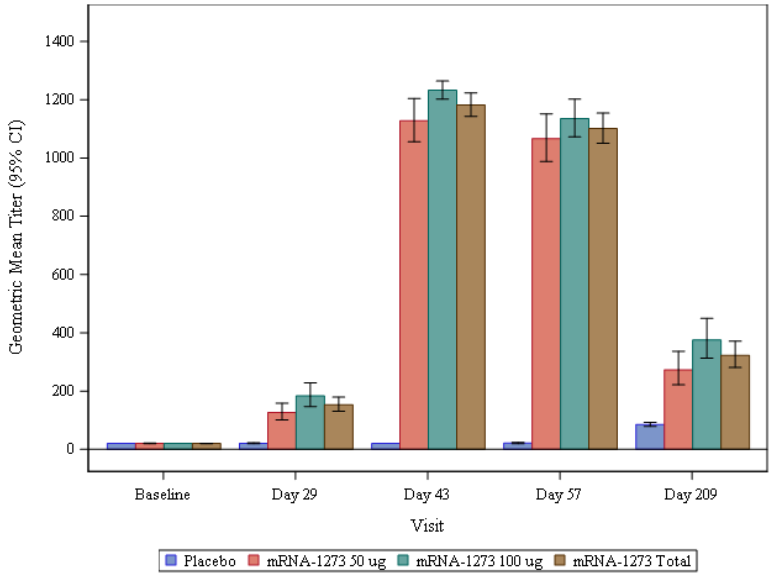
For MN Endpoint Titer (the First Lot): LLOQ=40 and ULOQ=1280. For MN50 (the First Lot): LLOQ=91.10 and ULOQ=2031.87. For MN Endpoint Titer (the new Lot): LLOQ=160 and ULOQ=1280. For MN50 (the new Lot): LLOQ=318.46 and ULOQ=1917.83.

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

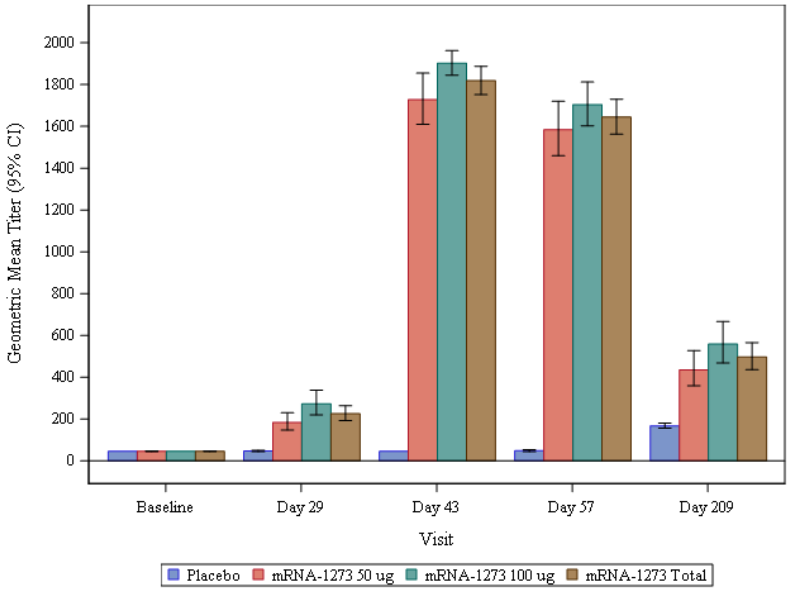
Source: Figure 14.2.4.1.2.

Figure 6: Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results by Age (Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots)

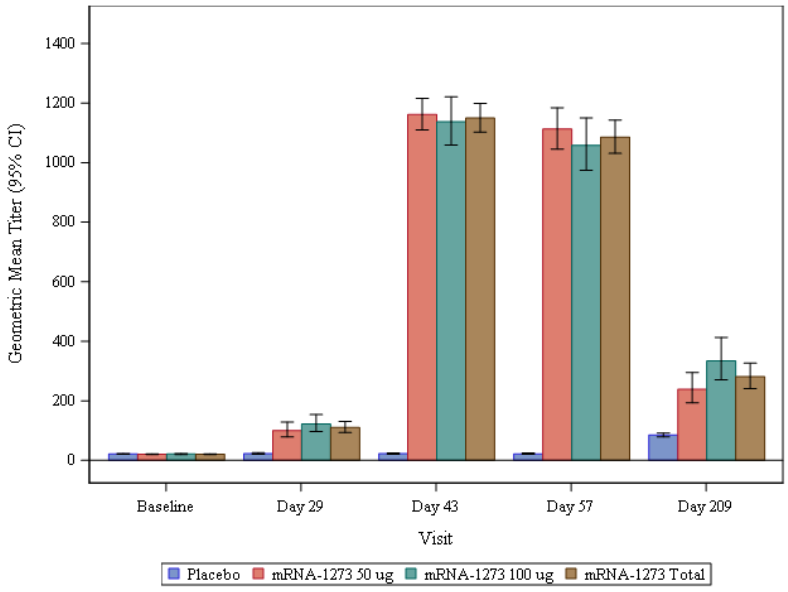
Cohort 1 (≥ 18 and < 55 Years) MN Endpoint Titer



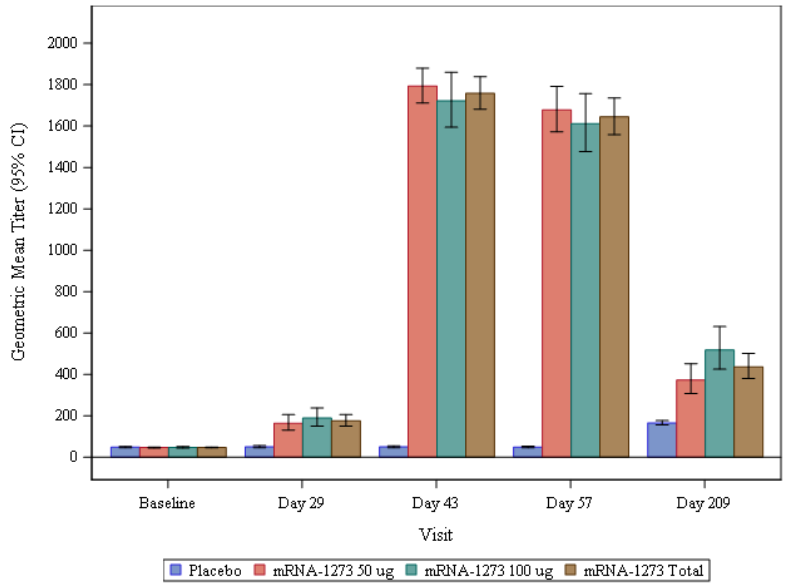
Cohort 1 (≥ 18 and < 55 Years) MN_{50}



Cohort 2 (≥ 55 Years) MN Endpoint Titer



Cohort 2 (≥ 55 Years) MN_{50}



Abbreviations: GMT = geometric mean titer; LLOQ = lower limit of quantification; Max = maximum; Min = minimum; MN = microneutralization; 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 LLOQ are replaced by 0.5 x LLOQ. Values that are greater than the 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 are calculated using t-distribution of log-transformed values then back transformed to the original scale for presentation.

Source: Figure 14.2.4.1.2.

8.3 Immunogenicity Results in Participants with SARS-CoV-2 Infection for COVID-19

A total of 30 participants (24 participants in the placebo group, 4 participants in the mRNA-1273 50 µg group, and 2 participants in the mRNA-1273 100 µg group) had SARS-CoV-2 infection confirmed by a positive RT-PCR test result (Table 12 and Listing 16.2.6.3) or a positive COVID-19 local diagnostic test result (Listing 16.2.6.6). The timing of the first positive tests in mRNA-1273 participants was as follows: Days 10, 57, 195, and 196 in 4 participants, respectively, in the mRNA-1273 50 µg group and Days 185 and 217 in 2 participants in the mRNA-1273 100 µg group. Three additional participants in the placebo group did not have a positive RT-PCR test but had an AE reported as SARS-CoV-2 infection or COVID-19.

The levels of bAb to SARS-CoV-2 spike and nAb for the 33 participants with confirmed SARS-CoV-2 infection are presented graphically in Figure 14.2.7.1 and Figure 14.2.7.2.2. Overall, antibody responses elicited by mRNA-1273 vaccination were not impaired in participants with SARS-CoV-2 infection or COVID-19.

Table 12: Summary of SARS-CoV-2 Test by RT-PCR (Safety Set)

	Overall			
		mRNA-1273		
	Placebo (N=200) n (%)	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	23 (11.5)	3 (1.5)	2 (1.0)	5 (1.3)
Not detected	177 (88.5)	197 (98.5)	198 (99.0)	395 (98.8)
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)
Day 71 or beyond				
n [b]	47 (23.5)	59 (29.5)	39 (19.5)	98 (24.5)
Detected	19 (9.5)	2 (1.0)	2 (1.0)	4 (1.0)
Not detected	28 (14.0)	57 (28.5)	37 (18.5)	94 (23.5)

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 the SARS-CoV-2 test performed by Viracor laboratory. 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 who provided an RT-PCR sample.

Source: Table 14.2.3.1.

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

Data in this End of Part A analysis provided evidence of the robust immunogenicity of both 100 µg and 50 µg dose levels of mRNA-1273 when administered as 2 doses separated by 28 days.

- The time course of bAb response to vaccination was similar in both dose groups: mRNA-1273 induced increases in GM levels from baseline by Day 29 (28 days after the first injection), and declined from the peak at Day 43 (14 days after the second injection) to Day 209. At Day 209, GM levels remained higher than the levels observed at Day 29 (before the second injection) for both mRNA-1273 100 µg and mRNA-1273 50 µg dose groups.
- The GMFRs of bAb response trended higher in the mRNA-1273 100 µg group than in the mRNA-1273 50 µg group at all postbaseline visits. GMFR results showed a robust response in both dose groups, with seroresponse criteria being met in 100% of participants at Day 43 and Day 57.
- Similar trends in bAb response were observed in Cohort 1 (age ≥ 18 and < 55 years) and Cohort 2 (age ≥ 55 years), and GM levels and GMFRs were generally higher in Cohort 1 than Cohort 2 at each postbaseline visit. In both cohorts, seroresponse criteria were met in 100% of participants at Day 43 and Day 57.
- The time course of nAb response to vaccination was similar in both dose groups: mRNA-1273 induced increases in MN_{50} and MN endpoint titer values from baseline by Day 29 (28 days after the first injection) and declined from the peak at Day 43 (14 days after the second injection) to Day 209. The titers at Day 209 remained higher than the values observed at Day 29 (before the second injection) for both 100 µg and 50 µg dose groups.

- Within the mRNA-1273 100 µg group, nAb responses were numerically higher in Cohort 1 than in Cohort 2 at each postbaseline visit.

Overall, the magnitude and kinetics of immune response for both bAb and nAb was consistent across dose groups and age cohorts. Study 201 provided evidence of persistence of immune response through Day 209 (6 months after the second injection of mRNA-1273), which was lower than the peak observed at Day 43 but was higher than that at Day 29 (before the second injection).

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 2 age cohorts: Cohort 1 (≥ 18 to < 55 years old) as well as Cohort 2 (≥ 55 years old).
- Vaccination with mRNA-1273 resulted in robust immune responses to SARS-CoV-2 in participants 18 years and older at both dose levels, and persistence of immune response was observed up to 6 months after the second injection. The titers are numerically higher in participants who received 100 µg compared with 50 µg of mRNA-1273 at Day 209. These results confirm the selection of the 100 µg dose that was brought forward in the pivotal Phase 3 (COVE) study.

This End of Part A CSR addendum is based on the blinded safety and immunogenicity results the Participant Decision Clinic Visit (database lock date of 10 Jun 2021). 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 will provide additional longer-term data on the safety and effectiveness of mRNA-1273 vaccine.

13 References

Centers for Disease Control and Prevention (CDC). COVID-19 (Coronavirus Disease). Symptoms of Coronavirus [Internet]. Atlanta (GA): CDC; 2020 [cited 2020 Dec 10]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

14 Tables and Figures

14.1 Demographic, Background, and Disposition Data

14.2 Efficacy Data

Not applicable.

14.3 Safety Data

14.3.1 Displays of Adverse Events

14.3.2 Displays of Deaths, Other Serious and Clinically Meaningful Adverse Events

14.3.3 Displays of Laboratory Values

14.4 Immunogenicity Data

Table 14.1.1.1
Subject Disposition
Randomized Set

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) 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)	1 (0.5)	0	1 (0.3)	2 (0.3)
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)	0	1 (0.5)	1 (0.3)	3 (0.5)

Percentages are based on the number of randomized subjects.
[1] Completed Part A is defined as a subject who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14010101.sas 19JUL2021 20:33 Database Lock Date: 10JUN2021

Table 14.1.1.1
Subject Disposition
Randomized Set

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) n (%)
Completed End of Part A [1]	182 (91.0)	188 (94.0)	185 (92.5)	373 (93.3)	555 (92.5)
Discontinued from Study	18 (9.0)	12 (6.0)	15 (7.5)	27 (6.8)	45 (7.5)
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	7 (3.5)	6 (3.0)	6 (3.0)	12 (3.0)	19 (3.2)
Physician Decision	0	1 (0.5)	2 (1.0)	3 (0.8)	3 (0.5)
Pregnancy	0	0	0	0	0
Protocol Deviation	8 (4.0)	3 (1.5)	3 (1.5)	6 (1.5)	14 (2.3)
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	1 (0.5)	4 (2.0)	5 (1.3)	5 (0.8)
Other	3 (1.5)	0	0	0	3 (0.5)

Percentages are based on the number of randomized subjects.
[1] Completed Part A is defined as a subject who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14010101.sas 19JUL2021 20:33 Database Lock Date: 10JUN2021

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	1 (1.0)	0	1 (0.5)	1 (0.3)
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	0	0	0	0

Percentages are based on the number of randomized subjects.
[1] Completed Part A is defined as a subject who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14010101.sas 19JUL2021 20:33 Database Lock Date: 10JUN2021

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 (%)
Completed End of Part A [1]	89 (89.0)	93 (93.0)	93 (93.0)	186 (93.0)	275 (91.7)	93 (93.0)	95 (95.0)	92 (92.0)	187 (93.5)	280 (93.3)
Discontinued from Study	11 (11.0)	7 (7.0)	7 (7.0)	14 (7.0)	25 (8.3)	7 (7.0)	5 (5.0)	8 (8.0)	13 (6.5)	20 (6.7)
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	7 (7.0)	5 (5.0)	4 (4.0)	9 (4.5)	16 (5.3)	0	1 (1.0)	2 (2.0)	3 (1.5)	3 (1.0)
Physician Decision	0	0	0	0	0	0	1 (1.0)	2 (2.0)	3 (1.5)	3 (1.0)
Pregnancy	0	0	0	0	0	0	0	0	0	0
Protocol Deviation	3 (3.0)	1 (1.0)	1 (1.0)	2 (1.0)	5 (1.7)	5 (5.0)	2 (2.0)	2 (2.0)	4 (2.0)	9 (3.0)
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	2 (2.0)	2 (1.0)	2 (0.7)	0	1 (1.0)	2 (2.0)	3 (1.5)	3 (1.0)
Other	1 (1.0)	0	0	0	1 (0.3)	2 (2.0)	0	0	0	2 (0.7)

Percentages are based on the number of randomized subjects.
[1] Completed Part A is defined as a subject who completed 12 months of follow up after the last injection received in Part A or the initiation of Part B, whichever is earlier.

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Table 14.1.1.4
Major Protocol Deviations
Randomized Set

	Overall				
		mRNA-1273			
Deviation Type	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) n (%)
Concomitant Medication	3 (1.5)	3 (1.5)	3 (1.5)	6 (1.5)	9 (1.5)
Exclusion Criteria	3 (1.5)	2 (1.0)	5 (2.5)	7 (1.8)	10 (1.7)
ICF Process/Timing	4 (2.0)	7 (3.5)	9 (4.5)	16 (4.0)	20 (3.3)
Inclusion Criteria	2 (1.0)	0	0	0	2 (0.3)
Informed Consent	2 (1.0)	1 (0.5)	0	1 (0.3)	3 (0.5)
Inv Record Keeping Source Docs	6 (3.0)	8 (4.0)	6 (3.0)	14 (3.5)	20 (3.3)
Inv Safety Reporting (CRF)	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)	4 (0.7)
Missing Endpoint Assessments	11 (5.5)	11 (5.5)	10 (5.0)	21 (5.3)	32 (5.3)
Study Procedures/Assessments	60 (30.0)	61 (30.5)	52 (26.0)	113 (28.3)	173 (28.8)
Study Treatment Admin/Dispense	4 (2.0)	4 (2.0)	3 (1.5)	7 (1.8)	11 (1.8)
Visit Scheduling	50 (25.0)	68 (34.0)	51 (25.5)	119 (29.8)	169 (28.2)

Table 14.1.1.4
Major Protocol Deviations
Randomized Set

	Cohort 1 (Age >= 18 and age < 55)					Cohort 2 (Age >= 55)				
		mRNA-1273					mRNA-1273			
Deviation Type	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 (%)
Concomitant Medication	1 (1.0)	0	1 (1.0)	1 (0.5)	2 (0.7)	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	7 (2.3)
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	1 (1.0)	4 (4.0)	4 (4.0)	8 (4.0)	9 (3.0)	3 (3.0)	3 (3.0)	5 (5.0)	8 (4.0)	11 (3.7)
Inclusion Criteria	1 (1.0)	0	0	0	1 (0.3)	1 (1.0)	0	0	0	1 (0.3)
Informed Consent	2 (2.0)	1 (1.0)	0	1 (0.5)	3 (1.0)	0	0	0	0	0
Inv Record Keeping Source Docs	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	4 (1.3)	5 (5.0)	6 (6.0)	5 (5.0)	11 (5.5)	16 (5.3)
Inv Safety Reporting (CRF)	1 (1.0)	1 (1.0)	2 (2.0)	3 (1.5)	4 (1.3)	0	0	0	0	0
Missing Endpoint Assessments	9 (9.0)	8 (8.0)	6 (6.0)	14 (7.0)	23 (7.7)	2 (2.0)	3 (3.0)	4 (4.0)	7 (3.5)	9 (3.0)
Study Procedures/Assessments	33 (33.0)	35 (35.0)	32 (32.0)	67 (33.5)	100 (33.3)	27 (27.0)	26 (26.0)	20 (20.0)	46 (23.0)	73 (24.3)
Study Treatment Admin/Dispense	3 (3.0)	2 (2.0)	3 (3.0)	5 (2.5)	8 (2.7)	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (1.0)
Visit Scheduling	27 (27.0)	41 (41.0)	27 (27.0)	68 (34.0)	95 (31.7)	23 (23.0)	27 (27.0)	24 (24.0)	51 (25.5)	74 (24.7)

Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) 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 [1]					
Full Analysis Set for SARS-CoV-2-specific bAb	197 (98.5)	198 (99.0)	197 (98.5)	395 (98.8)	592 (98.7)
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)
Day 209	185 (92.5)	182 (91.0)	185 (92.5)	367 (91.8)	552 (92.0)
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)
Day 209	0	0	0	0	0
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots	197 (98.5)	198 (99.0)	198 (99.0)	396 (99.0)	593 (98.8)
Day 29	194 (97.0)	196 (98.0)	194 (97.0)	390 (97.5)	584 (97.3)
Day 57	196 (98.0)	194 (97.0)	198 (99.0)	392 (98.0)	588 (98.0)
Day 209	186 (93.0)	185 (92.5)	186 (93.0)	371 (92.8)	557 (92.8)

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Table 14.1.2
Number of Subjects in Each Analysis Set
Randomized Set

	Overall				
		mRNA-1273			
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)	Overall (N=600) 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)
Day 209	154 (77.0)	170 (85.0)	174 (87.0)	344 (86.0)	498 (83.0)
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)
Day 209	0	0	0	0	0
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)	184 (92.0)	187 (93.5)	371 (92.8)	555 (92.5)
Day 57	175 (87.5)	176 (88.0)	177 (88.5)	353 (88.3)	528 (88.0)
Day 209	153 (76.5)	171 (85.5)	174 (87.0)	345 (86.3)	498 (83.0)

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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) 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 (%)
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 Safety Set	100 (100)	100 (100)	100 (100)	200 (100)	300 (100)	99 (99.0)	100 (100)	100 (100)	200 (100)	299 (99.7)
Second Injection Solicited Safety Set	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)

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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) 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 (%)
Full Analysis Set [1]										
Full Analysis Set for SARS-CoV-2-specific bAb	97 (97.0)	98 (98.0)	99 (99.0)	197 (98.5)	294 (98.0)	100 (100)	100 (100)	98 (98.0)	198 (99.0)	298 (99.3)
Day 29	94 (94.0)	97 (97.0)	98 (98.0)	195 (97.5)	289 (96.3)	100 (100)	99 (99.0)	97 (97.0)	196 (98.0)	296 (98.7)
Day 57	96 (96.0)	95 (95.0)	99 (99.0)	194 (97.0)	290 (96.7)	100 (100)	99 (99.0)	98 (98.0)	197 (98.5)	297 (99.0)
Day 209	94 (94.0)	87 (87.0)	96 (96.0)	183 (91.5)	277 (92.3)	91 (91.0)	95 (95.0)	89 (89.0)	184 (92.0)	275 (91.7)
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot	96 (96.0)	98 (98.0)	100 (100)	198 (99.0)	294 (98.0)	95 (95.0)	94 (94.0)	95 (95.0)	189 (94.5)	284 (94.7)
Day 29	94 (94.0)	97 (97.0)	98 (98.0)	195 (97.5)	289 (96.3)	94 (94.0)	83 (83.0)	89 (89.0)	172 (86.0)	266 (88.7)
Day 57	96 (96.0)	91 (91.0)	94 (94.0)	185 (92.5)	281 (93.7)	95 (95.0)	76 (76.0)	76 (76.0)	152 (76.0)	247 (82.3)
Day 209	0	0	0	0	0	0	0	0	0	0
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots	97 (97.0)	98 (98.0)	100 (100)	198 (99.0)	295 (98.3)	100 (100)	100 (100)	98 (98.0)	198 (99.0)	298 (99.3)
Day 29	94 (94.0)	97 (97.0)	98 (98.0)	195 (97.5)	289 (96.3)	100 (100)	99 (99.0)	96 (96.0)	195 (97.5)	295 (98.3)
Day 57	96 (96.0)	95 (95.0)	100 (100)	195 (97.5)	291 (97.0)	100 (100)	99 (99.0)	98 (98.0)	197 (98.5)	297 (99.0)
Day 209	94 (94.0)	89 (89.0)	97 (97.0)	186 (93.0)	280 (93.3)	92 (92.0)	96 (96.0)	89 (89.0)	185 (92.5)	277 (92.3)

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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) 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 (%)
Per-Protocol (PP) Set [2]										
PP Set for SARS-CoV-2-specific bAb	92 (92.0)	90 (90.0)	95 (95.0)	185 (92.5)	277 (92.3)	94 (94.0)	95 (95.0)	94 (94.0)	189 (94.5)	283 (94.3)
Day 29	90 (90.0)	89 (89.0)	95 (95.0)	184 (92.0)	274 (91.3)	94 (94.0)	95 (95.0)	94 (94.0)	189 (94.5)	283 (94.3)
Day 57	84 (84.0)	84 (84.0)	87 (87.0)	171 (85.5)	255 (85.0)	91 (91.0)	92 (92.0)	90 (90.0)	182 (91.0)	273 (91.0)
Day 209	74 (74.0)	80 (80.0)	90 (90.0)	170 (85.0)	244 (81.3)	80 (80.0)	90 (90.0)	84 (84.0)	174 (87.0)	254 (84.7)
PP Set for SARS-CoV-2-specific nAb from the First Lot	92 (92.0)	90 (90.0)	95 (95.0)	185 (92.5)	277 (92.3)	89 (89.0)	89 (89.0)	91 (91.0)	180 (90.0)	269 (89.7)
Day 29	90 (90.0)	89 (89.0)	94 (94.0)	183 (91.5)	273 (91.0)	88 (88.0)	79 (79.0)	86 (86.0)	165 (82.5)	253 (84.3)
Day 57	84 (84.0)	80 (80.0)	82 (82.0)	162 (81.0)	246 (82.0)	87 (87.0)	70 (70.0)	70 (70.0)	140 (70.0)	227 (75.7)
Day 209	0	0	0	0	0	0	0	0	0	0
PP Set for SARS-CoV-2-specific nAb from All Lots	92 (92.0)	90 (90.0)	95 (95.0)	185 (92.5)	277 (92.3)	94 (94.0)	95 (95.0)	94 (94.0)	189 (94.5)	283 (94.3)
Day 29	90 (90.0)	89 (89.0)	94 (94.0)	183 (91.5)	273 (91.0)	94 (94.0)	95 (95.0)	93 (93.0)	188 (94.0)	282 (94.0)
Day 57	84 (84.0)	84 (84.0)	87 (87.0)	171 (85.5)	255 (85.0)	91 (91.0)	92 (92.0)	90 (90.0)	182 (91.0)	273 (91.0)
Day 209	74 (74.0)	81 (81.0)	90 (90.0)	171 (85.5)	245 (81.7)	79 (79.0)	90 (90.0)	84 (84.0)	174 (87.0)	253 (84.3)

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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 14.2.1.1.1
Summary of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) by ELISA (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 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

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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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	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

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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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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

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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	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 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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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

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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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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
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 x 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 14.2.1.2.1
Analysis of Binding Antibody Levels
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) by ELISA (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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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) by ELISA (LLOQ: 9, ULOQ: 33000)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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

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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	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]	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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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) by ELISA (LLOQ: 3.9, ULOQ: 487)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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

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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 x 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 14.2.3.1
Summary of SARS-CoV-2 Test by RT-PCR
Safety Set

	Overall			
		mRNA-1273		
	Placebo (N=200) n (%)	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	23 (11.5)	3 (1.5)	2 (1.0)	5 (1.3)
Not Detected	177 (88.5)	197 (98.5)	198 (99.0)	395 (98.8)
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)
Day 71 or Beyond				
n [2]	47 (23.5)	59 (29.5)	39 (19.5)	98 (24.5)
Detected	19 (9.5)	2 (1.0)	2 (1.0)	4 (1.0)
Not Detected	28 (14.0)	57 (28.5)	37 (18.5)	94 (23.5)

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 (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 (%)
Overall [1]								
n [2]	100 (100)	100 (100)	100 (100)	200 (100)	100 (100)	100 (100)	100 (100)	200 (100)
Detected	15 (15.0)	3 (3.0)	1 (1.0)	4 (2.0)	8 (8.0)	0	1 (1.0)	1 (0.5)
Not Detected	85 (85.0)	97 (97.0)	99 (99.0)	196 (98.0)	92 (92.0)	100 (100)	99 (99.0)	199 (99.5)
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)
Day 71 or Beyond								
n [2]	27 (27.0)	38 (38.0)	21 (21.0)	59 (29.5)	20 (20.0)	21 (21.0)	18 (18.0)	39 (19.5)
Detected	12 (12.0)	2 (2.0)	1 (1.0)	3 (1.5)	7 (7.0)	0	1 (1.0)	1 (0.5)
Not Detected	15 (15.0)	36 (36.0)	20 (20.0)	56 (28.0)	13 (13.0)	21 (21.0)	17 (17.0)	38 (19.0)

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 14.3.1.7.2
Summary of Unsolicited TEAE from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Unsolicited TEAEs Regardless of Relationship to Study Vaccination				
All	94 (47.0)	105 (52.5)	76 (38.0)	181 (45.3)
Serious	0	5 (2.5)	2 (1.0)	7 (1.8)
Fatal	0	0	0	0
Medically-Attended	64 (32.0)	74 (37.0)	38 (19.0)	112 (28.0)
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	5 (2.5)	10 (5.0)	8 (4.0)	18 (4.5)
Unsolicited TEAEs Related to Study Vaccination				
All	13 (6.5)	19 (9.5)	28 (14.0)	47 (11.8)
Serious	0	0	0	0
Fatal	0	0	0	0
Medically-Attended	2 (1.0)	3 (1.5)	5 (2.5)	8 (2.0)
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 End of Part A
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	47 (47.0)	56 (56.0)	35 (35.0)	91 (45.5)	47 (47.0)	49 (49.0)	41 (41.0)	90 (45.0)
Serious	0	1 (1.0)	1 (1.0)	2 (1.0)	0	4 (4.0)	1 (1.0)	5 (2.5)
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	35 (35.0)	44 (44.0)	17 (17.0)	61 (30.5)	29 (29.0)	30 (30.0)	21 (21.0)	51 (25.5)
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)	6 (6.0)	4 (4.0)	10 (5.0)	3 (3.0)	4 (4.0)	4 (4.0)	8 (4.0)
Unsolicited TEAEs Related to Study Vaccination								
All	7 (7.0)	9 (9.0)	18 (18.0)	27 (13.5)	6 (6.0)	10 (10.0)	10 (10.0)	20 (10.0)
Serious	0	0	0	0	0	0	0	0
Fatal	0	0	0	0	0	0	0	0
Medically-Attended	1 (1.0)	3 (3.0)	4 (4.0)	7 (3.5)	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 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	94 (47.0)	105 (52.5)	76 (38.0)	181 (45.3)
Number of Unsolicited Adverse Events	163	244	153	397
Infections and infestations	45 (22.5)	32 (16.0)	16 (8.0)	48 (12.0)
Upper respiratory tract infection	4 (2.0)	4 (2.0)	2 (1.0)	6 (1.5)
COVID-19	26 (13.0)	3 (1.5)	2 (1.0)	5 (1.3)
Urinary tract infection	3 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)
Sinusitis	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Viral infection	0	3 (1.5)	1 (0.5)	4 (1.0)
Bronchitis	0	2 (1.0)	1 (0.5)	3 (0.8)
Viral upper respiratory tract infection	1 (0.5)	3 (1.5)	0	3 (0.8)
Acute sinusitis	0	0	2 (1.0)	2 (0.5)
Nasopharyngitis	1 (0.5)	1 (0.5)	1 (0.5)	2 (0.5)
Otitis media	1 (0.5)	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

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Infections and infestations (cont.)				
Pharyngitis	0	1 (0.5)	1 (0.5)	2 (0.5)
Suspected COVID-19	2 (1.0)	2 (1.0)	0	2 (0.5)
Cellulitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Eye infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Fungal skin infection	0	1 (0.5)	0	1 (0.3)
Gastroenteritis	2 (1.0)	0	1 (0.5)	1 (0.3)
Gastroenteritis viral	0	0	1 (0.5)	1 (0.3)
Herpes zoster	0	1 (0.5)	0	1 (0.3)
Infected bite	0	1 (0.5)	0	1 (0.3)
Influenza	0	0	1 (0.5)	1 (0.3)
Oral candidiasis	1 (0.5)	1 (0.5)	0	1 (0.3)
Pneumonia	1 (0.5)	1 (0.5)	0	1 (0.3)
Tinea pedis	0	1 (0.5)	0	1 (0.3)
Tooth abscess	0	1 (0.5)	0	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Urethritis	0	1 (0.5)	0	1 (0.3)
Asymptomatic COVID-19	1 (0.5)	0	0	0
Gingivitis	1 (0.5)	0	0	0
Herpes simplex	1 (0.5)	0	0	0
Hordeolum	1 (0.5)	0	0	0
Localised infection	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

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Infections and infestations (cont.)				
Otitis externa	1 (0.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (0.5)	1 (0.5)	2 (0.5)
Basal cell carcinoma	0	0	1 (0.5)	1 (0.3)
Benign neoplasm of skin	0	1 (0.5)	0	1 (0.3)
Blood and lymphatic system disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Lymphadenopathy	0	1 (0.5)	0	1 (0.3)
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

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\Part A end of Part A\TLF\t1403010802.sas 19JUL2021 20:35 Database Lock Date: 10JUN2021

Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Endocrine disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Hypothyroidism	0	1 (0.5)	0	1 (0.3)
Hyperoestrogenism	1 (0.5)	0	0	0
Metabolism and nutrition disorders	3 (1.5)	3 (1.5)	2 (1.0)	5 (1.3)
Gout	0	0	1 (0.5)	1 (0.3)
Hyperlipidaemia	1 (0.5)	1 (0.5)	0	1 (0.3)
Insulin resistance	0	1 (0.5)	0	1 (0.3)
Vitamin B12 deficiency	0	1 (0.5)	0	1 (0.3)
Vitamin D deficiency	1 (0.5)	0	1 (0.5)	1 (0.3)
Hypercholesterolaemia	1 (0.5)	0	0	0
Psychiatric disorders	4 (2.0)	9 (4.5)	5 (2.5)	14 (3.5)
Anxiety	3 (1.5)	5 (2.5)	2 (1.0)	7 (1.8)
Depression	2 (1.0)	3 (1.5)	4 (2.0)	7 (1.8)
Insomnia	0	3 (1.5)	0	3 (0.8)
Major depression	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	11 (5.5)	25 (12.5)	15 (7.5)	40 (10.0)
Headache	8 (4.0)	16 (8.0)	9 (4.5)	25 (6.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Nervous system disorders (cont.)				
Dizziness	0	2 (1.0)	1 (0.5)	3 (0.8)
Syncope	0	2 (1.0)	1 (0.5)	3 (0.8)
Migraine	0	1 (0.5)	1 (0.5)	2 (0.5)
Paraesthesia	0	1 (0.5)	1 (0.5)	2 (0.5)
Tension headache	0	2 (1.0)	0	2 (0.5)
Ageusia	0	1 (0.5)	0	1 (0.3)
Cerebrovascular accident	0	1 (0.5)	0	1 (0.3)
Dysgeusia	0	0	1 (0.5)	1 (0.3)
Lethargy	2 (1.0)	1 (0.5)	0	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)
Tremor	0	1 (0.5)	0	1 (0.3)
Neuralgia	1 (0.5)	0	0	0
Restless legs syndrome	1 (0.5)	0	0	0
Eye disorders	0	1 (0.5)	2 (1.0)	3 (0.8)
Cataract	0	1 (0.5)	0	1 (0.3)
Conjunctivitis allergic	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Eye disorders (cont.)				
Glaucoma	0	0	1 (0.5)	1 (0.3)
Ear and labyrinth disorders	0	4 (2.0)	1 (0.5)	5 (1.3)
Deafness unilateral	0	1 (0.5)	0	1 (0.3)
Ear pain	0	1 (0.5)	0	1 (0.3)
Excessive cerumen production	0	1 (0.5)	0	1 (0.3)
Tinnitus	0	0	1 (0.5)	1 (0.3)
Vertigo	0	1 (0.5)	0	1 (0.3)
Cardiac disorders	0	2 (1.0)	1 (0.5)	3 (0.8)
Acute myocardial infarction	0	1 (0.5)	0	1 (0.3)
Arrhythmia	0	0	1 (0.5)	1 (0.3)
Bradycardia	0	1 (0.5)	0	1 (0.3)
Diastolic dysfunction	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	5 (2.5)	2 (1.0)	7 (1.8)
Hypertension	0	5 (2.5)	1 (0.5)	6 (1.5)
Diastolic hypertension	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	11 (5.5)	15 (7.5)	5 (2.5)	20 (5.0)
Oropharyngeal pain	4 (2.0)	7 (3.5)	1 (0.5)	8 (2.0)
Rhinorrhoea	2 (1.0)	2 (1.0)	3 (1.5)	5 (1.3)
Cough	3 (1.5)	3 (1.5)	0	3 (0.8)
Nasal congestion	1 (0.5)	3 (1.5)	0	3 (0.8)
Rhinitis allergic	0	1 (0.5)	1 (0.5)	2 (0.5)
Dyspnoea	1 (0.5)	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)
Sneezing	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	10 (5.0)	19 (9.5)	12 (6.0)	31 (7.8)
Nausea	0	3 (1.5)	4 (2.0)	7 (1.8)
Diarrhoea	1 (0.5)	4 (2.0)	1 (0.5)	5 (1.3)
Gastrooesophageal reflux disease	1 (0.5)	3 (1.5)	1 (0.5)	4 (1.0)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders (cont.)				
Vomiting	0	1 (0.5)	2 (1.0)	3 (0.8)
Abdominal discomfort	0	0	2 (1.0)	2 (0.5)
Gastritis	0	2 (1.0)	0	2 (0.5)
Haemorrhoids	0	1 (0.5)	1 (0.5)	2 (0.5)
Toothache	1 (0.5)	2 (1.0)	0	2 (0.5)
Abdominal pain	0	1 (0.5)	0	1 (0.3)
Aphthous ulcer	0	0	1 (0.5)	1 (0.3)
Dental caries	1 (0.5)	1 (0.5)	0	1 (0.3)
Diverticulum	1 (0.5)	0	1 (0.5)	1 (0.3)
Dry mouth	0	0	1 (0.5)	1 (0.3)
Inguinal hernia	0	0	1 (0.5)	1 (0.3)
Intestinal obstruction	0	0	1 (0.5)	1 (0.3)
Irritable bowel syndrome	0	1 (0.5)	0	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Paraesthesia oral	0	0	1 (0.5)	1 (0.3)
Tongue discomfort	0	1 (0.5)	0	1 (0.3)
Abdominal tenderness	1 (0.5)	0	0	0
Duodenitis	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders (cont.)				
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	10 (5.0)	13 (6.5)	7 (3.5)	20 (5.0)
Dermatitis contact	3 (1.5)	5 (2.5)	3 (1.5)	8 (2.0)
Rash	2 (1.0)	4 (2.0)	0	4 (1.0)
Acne	2 (1.0)	1 (0.5)	1 (0.5)	2 (0.5)
Pruritus	0	1 (0.5)	1 (0.5)	2 (0.5)
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
Hirsutism	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	11 (5.5)	24 (12.0)	15 (7.5)	39 (9.8)
Arthralgia	4 (2.0)	7 (3.5)	4 (2.0)	11 (2.8)
Myalgia	3 (1.5)	6 (3.0)	2 (1.0)	8 (2.0)
Neck pain	0	2 (1.0)	2 (1.0)	4 (1.0)
Back pain	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Muscle spasms	0	1 (0.5)	2 (1.0)	3 (0.8)
Musculoskeletal pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Musculoskeletal chest pain	0	1 (0.5)	1 (0.5)	2 (0.5)
Plantar fasciitis	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 stiffness	0	0	1 (0.5)	1 (0.3)
Periarthritis	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)
Tendonitis	0	1 (0.5)	0	1 (0.3)
Bursitis	2 (1.0)	0	0	0
Exostosis	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Renal and urinary disorders	2 (1.0)	2 (1.0)	2 (1.0)	4 (1.0)
Nephrolithiasis	0	1 (0.5)	1 (0.5)	2 (0.5)
Haematuria	1 (0.5)	0	1 (0.5)	1 (0.3)
Hypertonic bladder	1 (0.5)	1 (0.5)	0	1 (0.3)
Pregnancy, puerperium and perinatal conditions	0	1 (0.5)	1 (0.5)	2 (0.5)
Abortion missed	0	0	1 (0.5)	1 (0.3)
Abortion spontaneous	0	1 (0.5)	0	1 (0.3)
Reproductive system and breast disorders	3 (1.5)	0	2 (1.0)	2 (0.5)
Breast pain	0	0	1 (0.5)	1 (0.3)
Prostatomegaly	1 (0.5)	0	1 (0.5)	1 (0.3)
Postmenopausal haemorrhage	1 (0.5)	0	0	0
Testicular cyst	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions	12 (6.0)	23 (11.5)	20 (10.0)	43 (10.8)
Fatigue	7 (3.5)	16 (8.0)	5 (2.5)	21 (5.3)
Injection site pain	1 (0.5)	3 (1.5)	3 (1.5)	6 (1.5)
Injection site induration	0	1 (0.5)	4 (2.0)	5 (1.3)
Injection site erythema	1 (0.5)	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	3 (1.5)	0	3 (0.8)
Chills	0	1 (0.5)	2 (1.0)	3 (0.8)
Pain	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Pyrexia	1 (0.5)	0	3 (1.5)	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)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions (cont.)				
Mass	0	0	1 (0.5)	1 (0.3)
Peripheral swelling	0	1 (0.5)	0	1 (0.3)
Investigations	9 (4.5)	6 (3.0)	5 (2.5)	11 (2.8)
Blood pressure increased	2 (1.0)	1 (0.5)	2 (1.0)	3 (0.8)
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)
Blood cholesterol increased	1 (0.5)	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)
Hormone level abnormal	0	1 (0.5)	0	1 (0.3)
Platelet count decreased	0	1 (0.5)	0	1 (0.3)

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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Investigations (cont.)				
Platelet count increased	0	1 (0.5)	0	1 (0.3)
Staphylococcus test positive	0	1 (0.5)	0	1 (0.3)
White blood cell count decreased	0	0	1 (0.5)	1 (0.3)
Blood testosterone decreased	1 (0.5)	0	0	0
Blood triglycerides increased	1 (0.5)	0	0	0
Cardiac murmur	1 (0.5)	0	0	0
Computerised tomogram coronary artery abnormal	1 (0.5)	0	0	0
Heart rate decreased	2 (1.0)	0	0	0
Vitamin D decreased	1 (0.5)	0	0	0
Injury, poisoning and procedural complications	7 (3.5)	12 (6.0)	11 (5.5)	23 (5.8)
Arthropod bite	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Meniscus injury	0	1 (0.5)	2 (1.0)	3 (0.8)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Muscle strain	1 (0.5)	1 (0.5)	2 (1.0)	3 (0.8)
Concussion	0	1 (0.5)	1 (0.5)	2 (0.5)
Breast injury	0	1 (0.5)	0	1 (0.3)
Chemical burn	0	0	1 (0.5)	1 (0.3)
Corneal abrasion	0	1 (0.5)	0	1 (0.3)
Epicondylitis	0	1 (0.5)	0	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Heat exhaustion	0	1 (0.5)	0	1 (0.3)
Joint injury	0	0	1 (0.5)	1 (0.3)
Limb injury	0	0	1 (0.5)	1 (0.3)
Muscle contusion	0	0	1 (0.5)	1 (0.3)
Muscle rupture	0	1 (0.5)	0	1 (0.3)
Post-traumatic pain	0	1 (0.5)	0	1 (0.3)
Procedural pain	0	1 (0.5)	0	1 (0.3)
Road traffic accident	0	1 (0.5)	0	1 (0.3)
Struck by lightning	0	0	1 (0.5)	1 (0.3)
Tendon rupture	0	0	1 (0.5)	1 (0.3)
Tooth fracture	1 (0.5)	1 (0.5)	0	1 (0.3)
Nail avulsion	1 (0.5)	0	0	0
Skin laceration	2 (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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Tendon injury	1 (0.5)	0	0	0

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Percentages are based on the number of safety subjects.
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Table 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	47 (47.0)	56 (56.0)	35 (35.0)	91 (45.5)	47 (47.0)	49 (49.0)	41 (41.0)	90 (45.0)
Number of Unsolicited Adverse Events	94	139	77	216	69	105	76	181
Infections and infestations	27 (27.0)	20 (20.0)	8 (8.0)	28 (14.0)	18 (18.0)	12 (12.0)	8 (8.0)	20 (10.0)
Upper respiratory tract infection	3 (3.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)
COVID-19	18 (18.0)	2 (2.0)	1 (1.0)	3 (1.5)	8 (8.0)	1 (1.0)	1 (1.0)	2 (1.0)
Urinary tract infection	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	1 (1.0)	0	1 (0.5)
Sinusitis	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Viral infection	0	3 (3.0)	1 (1.0)	4 (2.0)	0	0	0	0
Bronchitis	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Viral upper respiratory tract infection	0	3 (3.0)	0	3 (1.5)	1 (1.0)	0	0	0
Acute sinusitis	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Nasopharyngitis	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	1 (1.0)	1 (0.5)
Otitis media	1 (1.0)	0	1 (1.0)	1 (0.5)	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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Pharyngitis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Suspected COVID-19	2 (2.0)	0	0	0	0	2 (2.0)	0	2 (1.0)
Cellulitis	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Eye infection	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Fungal skin infection	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Gastroenteritis viral	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Herpes zoster	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Infected bite	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Influenza	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Oral candidiasis	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Pneumonia	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Tinea pedis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tooth abscess	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Urethritis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Asymptomatic COVID-19	0	0	0	0	1 (1.0)	0	0	0
Gingivitis	1 (1.0)	0	0	0	0	0	0	0
Herpes simplex	0	0	0	0	1 (1.0)	0	0	0
Hordeolum	1 (1.0)	0	0	0	0	0	0	0
Localised infection	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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Basal cell carcinoma	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 and lymphatic system disorders	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Lymphadenopathy	0	1 (1.0)	0	1 (0.5)	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

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 (%)
Endocrine disorders	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Hypothyroidism	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Hyperoestrogenism	1 (1.0)	0	0	0	0	0	0	0
Metabolism and nutrition disorders	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	2 (2.0)	2 (2.0)	4 (2.0)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hyperlipidaemia	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Insulin resistance	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vitamin B12 deficiency	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Vitamin D deficiency	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Hypercholesterolaemia	0	0	0	0	1 (1.0)	0	0	0
Psychiatric disorders	2 (2.0)	4 (4.0)	5 (5.0)	9 (4.5)	2 (2.0)	5 (5.0)	0	5 (2.5)
Anxiety	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Depression	1 (1.0)	1 (1.0)	4 (4.0)	5 (2.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Insomnia	0	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Major depression	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Nervous system disorders	8 (8.0)	16 (16.0)	6 (6.0)	22 (11.0)	3 (3.0)	9 (9.0)	9 (9.0)	18 (9.0)
Headache	6 (6.0)	10 (10.0)	4 (4.0)	14 (7.0)	2 (2.0)	6 (6.0)	5 (5.0)	11 (5.5)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Dizziness	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Syncope	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Migraine	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Paraesthesia	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Tension headache	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Ageusia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Cerebrovascular accident	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Dysgeusia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Lethargy	2 (2.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
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)
Tremor	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Neuralgia	1 (1.0)	0	0	0	0	0	0	0
Restless legs syndrome	0	0	0	0	1 (1.0)	0	0	0
Eye disorders	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Cataract	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Conjunctivitis allergic	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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Glaucoma	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ear and labyrinth disorders	0	1 (1.0)	0	1 (0.5)	0	3 (3.0)	1 (1.0)	4 (2.0)
Deafness unilateral	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Ear pain	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Excessive cerumen production	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tinnitus	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Vertigo	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Cardiac disorders	0	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
Acute myocardial infarction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Arrhythmia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Bradycardia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diastolic dysfunction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vascular disorders	0	3 (3.0)	1 (1.0)	4 (2.0)	0	2 (2.0)	1 (1.0)	3 (1.5)
Hypertension	0	3 (3.0)	0	3 (1.5)	0	2 (2.0)	1 (1.0)	3 (1.5)
Diastolic hypertension	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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	6 (6.0)	11 (11.0)	3 (3.0)	14 (7.0)	5 (5.0)	4 (4.0)	2 (2.0)	6 (3.0)
Oropharyngeal pain	2 (2.0)	4 (4.0)	0	4 (2.0)	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)
Rhinorrhoea	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)	1 (1.0)	0	1 (1.0)	1 (0.5)
Cough	3 (3.0)	3 (3.0)	0	3 (1.5)	0	0	0	0
Nasal congestion	1 (1.0)	3 (3.0)	0	3 (1.5)	0	0	0	0
Rhinitis allergic	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Dyspnoea	1 (1.0)	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)
Sneezing	0	1 (1.0)	0	1 (0.5)	0	0	0	0
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	5 (5.0)	9 (9.0)	6 (6.0)	15 (7.5)	5 (5.0)	10 (10.0)	6 (6.0)	16 (8.0)
Nausea	0	2 (2.0)	2 (2.0)	4 (2.0)	0	1 (1.0)	2 (2.0)	3 (1.5)
Diarrhoea	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)	0	1 (1.0)	0	1 (0.5)
Gastrooesophageal reflux disease	0	0	0	0	1 (1.0)	3 (3.0)	1 (1.0)	4 (2.0)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Vomiting	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Abdominal discomfort	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Gastritis	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Haemorrhoids	0	0	1 (1.0)	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 pain	0	1 (1.0)	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	1 (1.0)	1 (1.0)	0	1 (0.5)
Diverticulum	1 (1.0)	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
Inguinal hernia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Intestinal obstruction	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Irritable bowel syndrome	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)
Paraesthesia oral	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Tongue discomfort	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Abdominal tenderness	0	0	0	0	1 (1.0)	0	0	0
Duodenitis	0	0	0	0	1 (1.0)	0	0	0

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Gastrointestinal disorders (cont.)								
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	6 (6.0)	6 (6.0)	4 (4.0)	10 (5.0)	4 (4.0)	7 (7.0)	3 (3.0)	10 (5.0)
Dermatitis contact	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	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)	2 (2.0)	0	2 (1.0)
Acne	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Pruritus	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
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
Hirsutism	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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Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	3 (3.0)	11 (11.0)	7 (7.0)	18 (9.0)	8 (8.0)	13 (13.0)	8 (8.0)	21 (10.5)
Arthralgia	1 (1.0)	3 (3.0)	2 (2.0)	5 (2.5)	3 (3.0)	4 (4.0)	2 (2.0)	6 (3.0)
Myalgia	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Neck pain	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Back pain	0	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	1 (1.0)	2 (1.0)
Muscle spasms	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Musculoskeletal pain	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Musculoskeletal chest pain	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Plantar fasciitis	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 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)
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)
Tendonitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Bursitis	1 (1.0)	0	0	0	1 (1.0)	0	0	0
Exostosis	0	0	0	0	1 (1.0)	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 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	1 (1.0)	0	0	0	1 (1.0)	2 (2.0)	2 (2.0)	4 (2.0)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Haematuria	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Hypertonic bladder	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Pregnancy, puerperium and perinatal conditions	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Abortion missed	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Abortion spontaneous	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Reproductive system and breast disorders	1 (1.0)	0	0	0	2 (2.0)	0	2 (2.0)	2 (1.0)
Breast pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Prostatomegaly	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Postmenopausal haemorrhage	0	0	0	0	1 (1.0)	0	0	0
Testicular cyst	1 (1.0)	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 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	8 (8.0)	13 (13.0)	13 (13.0)	26 (13.0)	4 (4.0)	10 (10.0)	7 (7.0)	17 (8.5)
Fatigue	6 (6.0)	8 (8.0)	4 (4.0)	12 (6.0)	1 (1.0)	8 (8.0)	1 (1.0)	9 (4.5)
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 induration	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	2 (2.0)	2 (1.0)
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 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	3 (3.0)	0	3 (1.5)	0	0	0	0
Chills	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Pain	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Pyrexia	0	0	1 (1.0)	1 (0.5)	1 (1.0)	0	2 (2.0)	2 (1.0)
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)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Mass	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)
Investigations	2 (2.0)	2 (2.0)	0	2 (1.0)	7 (7.0)	4 (4.0)	5 (5.0)	9 (4.5)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	2 (2.0)	0	2 (2.0)	2 (1.0)
Blood alkaline phosphatase increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Blood cholesterol increased	0	0	0	0	1 (1.0)	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)
Hormone level abnormal	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 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Staphylococcus test positive	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)
Blood testosterone decreased	1 (1.0)	0	0	0	0	0	0	0
Blood triglycerides increased	0	0	0	0	1 (1.0)	0	0	0
Cardiac murmur	0	0	0	0	1 (1.0)	0	0	0
Computerised tomogram coronary artery abnormal	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
Vitamin D decreased	1 (1.0)	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	4 (4.0)	8 (8.0)	4 (4.0)	12 (6.0)	3 (3.0)	4 (4.0)	7 (7.0)	11 (5.5)
Arthropod bite	0	0	1 (1.0)	1 (0.5)	1 (1.0)	2 (2.0)	0	2 (1.0)
Meniscus injury	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.
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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 strain	1 (1.0)	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Concussion	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Breast injury	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Chemical burn	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Corneal abrasion	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Epicondylitis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Heat exhaustion	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)
Limb injury	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle contusion	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle rupture	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Post-traumatic pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Procedural pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Road traffic accident	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Struck by lightning	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tendon rupture	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth fracture	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Nail avulsion	0	0	0	0	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 14.3.1.8.2
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Tendon injury	1 (1.0)	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 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	0	5 (2.5)	2 (1.0)	7 (1.8)
Number of Unsolicited Adverse Events	0	6	3	9
Infections and infestations	0	1 (0.5)	0	1 (0.3)
Pneumonia	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	0	1 (0.5)	0	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Cardiac disorders	0	2 (1.0)	1 (0.5)	3 (0.8)
Acute myocardial infarction	0	1 (0.5)	0	1 (0.3)
Arrhythmia	0	0	1 (0.5)	1 (0.3)
Bradycardia	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

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Table 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Pregnancy, puerperium and perinatal conditions	0	1 (0.5)	1 (0.5)	2 (0.5)
Abortion missed	0	0	1 (0.5)	1 (0.3)
Abortion spontaneous	0	1 (0.5)	0	1 (0.3)
Injury, poisoning and procedural complications	0	0	1 (0.5)	1 (0.3)
Struck by lightning	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 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	0	1 (1.0)	1 (1.0)	2 (1.0)	0	4 (4.0)	1 (1.0)	5 (2.5)
Number of Unsolicited Adverse Events	0	1	1	2	0	5	2	7
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)
Nervous system disorders	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)
Cardiac disorders	0	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
Acute myocardial infarction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Arrhythmia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Bradycardia	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

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Table 14.3.1.13.2
Subject Incidence of Serious TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	0	0	0	0	1 (1.0)	0	1 (0.5)
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pregnancy, puerperium and perinatal conditions	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Abortion missed	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Abortion spontaneous	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Injury, poisoning and procedural complications	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Struck by lightning	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

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Table 14.3.1.14.2
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) 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

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Table 14.3.1.14.2
Subject Incidence of Serious Treatment-Related TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 (%)

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

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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 End of Part A

Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) 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

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 (%)

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\Part A end of Part A\TLF\t1403011502.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.18.2

Subject Incidence of Unsolicited Medically-Attended TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A

Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	64 (32.0)	74 (37.0)	38 (19.0)	112 (28.0)
Number of Unsolicited Adverse Events	93	130	67	197
Infections and infestations	39 (19.5)	27 (13.5)	11 (5.5)	38 (9.5)
COVID-19	24 (12.0)	3 (1.5)	2 (1.0)	5 (1.3)
Sinusitis	3 (1.5)	3 (1.5)	1 (0.5)	4 (1.0)
Bronchitis	0	2 (1.0)	1 (0.5)	3 (0.8)
Upper respiratory tract infection	2 (1.0)	2 (1.0)	1 (0.5)	3 (0.8)
Urinary tract infection	3 (1.5)	2 (1.0)	1 (0.5)	3 (0.8)
Viral infection	0	3 (1.5)	0	3 (0.8)
Viral upper respiratory tract infection	1 (0.5)	3 (1.5)	0	3 (0.8)
Otitis media	1 (0.5)	0	2 (1.0)	2 (0.5)
Acute sinusitis	0	0	1 (0.5)	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Infections and infestations (cont.)				
Cellulitis	1 (0.5)	1 (0.5)	0	1 (0.3)
Eye infection	1 (0.5)	1 (0.5)	0	1 (0.3)
Fungal skin infection	0	1 (0.5)	0	1 (0.3)
Gastroenteritis	2 (1.0)	0	1 (0.5)	1 (0.3)
Herpes zoster	0	1 (0.5)	0	1 (0.3)
Infected bite	0	1 (0.5)	0	1 (0.3)
Influenza	0	0	1 (0.5)	1 (0.3)
Nasopharyngitis	0	0	1 (0.5)	1 (0.3)
Oral candidiasis	1 (0.5)	1 (0.5)	0	1 (0.3)
Pneumonia	1 (0.5)	1 (0.5)	0	1 (0.3)
Tinea pedis	0	1 (0.5)	0	1 (0.3)
Tooth abscess	0	1 (0.5)	0	1 (0.3)
Tooth infection	0	0	1 (0.5)	1 (0.3)
Urethritis	0	1 (0.5)	0	1 (0.3)
Asymptomatic COVID-19	1 (0.5)	0	0	0
Gingivitis	1 (0.5)	0	0	0
Herpes simplex	1 (0.5)	0	0	0
Localised infection	1 (0.5)	0	0	0
Otitis externa	1 (0.5)	0	0	0
Suspected COVID-19	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Blood and lymphatic system disorders	0	1 (0.5)	0	1 (0.3)
Lymphadenopathy	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
Endocrine disorders	1 (0.5)	1 (0.5)	0	1 (0.3)
Hypothyroidism	0	1 (0.5)	0	1 (0.3)
Hyperoestrogenism	1 (0.5)	0	0	0
Metabolism and nutrition disorders	3 (1.5)	2 (1.0)	2 (1.0)	4 (1.0)
Gout	0	0	1 (0.5)	1 (0.3)
Insulin resistance	0	1 (0.5)	0	1 (0.3)
Vitamin B12 deficiency	0	1 (0.5)	0	1 (0.3)
Vitamin D deficiency	1 (0.5)	0	1 (0.5)	1 (0.3)
Hypercholesterolaemia	1 (0.5)	0	0	0
Hyperlipidaemia	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 End of Part A

Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Psychiatric disorders	4 (2.0)	9 (4.5)	4 (2.0)	13 (3.3)
Anxiety	3 (1.5)	5 (2.5)	1 (0.5)	6 (1.5)
Depression	2 (1.0)	3 (1.5)	3 (1.5)	6 (1.5)
Insomnia	0	3 (1.5)	0	3 (0.8)
Major depression	0	1 (0.5)	0	1 (0.3)
Nervous system disorders	0	11 (5.5)	3 (1.5)	14 (3.5)
Headache	0	4 (2.0)	1 (0.5)	5 (1.3)
Dizziness	0	2 (1.0)	1 (0.5)	3 (0.8)
Migraine	0	1 (0.5)	1 (0.5)	2 (0.5)
Ageusia	0	1 (0.5)	0	1 (0.3)
Cerebrovascular accident	0	1 (0.5)	0	1 (0.3)
Nervous system cyst	0	1 (0.5)	0	1 (0.3)
Paraesthesia	0	1 (0.5)	0	1 (0.3)
Tension headache	0	1 (0.5)	0	1 (0.3)
Tremor	0	1 (0.5)	0	1 (0.3)
Eye disorders	0	1 (0.5)	2 (1.0)	3 (0.8)
Cataract	0	1 (0.5)	0	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Eye disorders (cont.)				
Conjunctivitis allergic	0	0	1 (0.5)	1 (0.3)
Glaucoma	0	0	1 (0.5)	1 (0.3)
Ear and labyrinth disorders	0	1 (0.5)	1 (0.5)	2 (0.5)
Excessive cerumen production	0	1 (0.5)	0	1 (0.3)
Tinnitus	0	0	1 (0.5)	1 (0.3)
Cardiac disorders	0	2 (1.0)	1 (0.5)	3 (0.8)
Acute myocardial infarction	0	1 (0.5)	0	1 (0.3)
Arrhythmia	0	0	1 (0.5)	1 (0.3)
Bradycardia	0	1 (0.5)	0	1 (0.3)
Diastolic dysfunction	0	1 (0.5)	0	1 (0.3)
Vascular disorders	0	4 (2.0)	1 (0.5)	5 (1.3)
Hypertension	0	4 (2.0)	1 (0.5)	5 (1.3)

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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 End of Part A

Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Respiratory, thoracic and mediastinal disorders	2 (1.0)	6 (3.0)	1 (0.5)	7 (1.8)
Nasal congestion	0	2 (1.0)	0	2 (0.5)
Oropharyngeal pain	1 (0.5)	2 (1.0)	0	2 (0.5)
Rhinitis allergic	0	1 (0.5)	1 (0.5)	2 (0.5)
Cough	1 (0.5)	1 (0.5)	0	1 (0.3)
Dyspnoea	1 (0.5)	1 (0.5)	0	1 (0.3)
Rhinorrhoea	1 (0.5)	1 (0.5)	0	1 (0.3)
Sneezing	0	1 (0.5)	0	1 (0.3)
Dry throat	1 (0.5)	0	0	0
Gastrointestinal disorders	7 (3.5)	8 (4.0)	8 (4.0)	16 (4.0)
Gastrooesophageal reflux disease	1 (0.5)	2 (1.0)	1 (0.5)	3 (0.8)
Nausea	0	1 (0.5)	2 (1.0)	3 (0.8)
Diarrhoea	0	1 (0.5)	1 (0.5)	2 (0.5)
Gastritis	0	2 (1.0)	0	2 (0.5)
Abdominal discomfort	0	0	1 (0.5)	1 (0.3)
Abdominal pain	0	1 (0.5)	0	1 (0.3)
Dental caries	1 (0.5)	1 (0.5)	0	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Gastrointestinal disorders (cont.)				
Diverticulum	1 (0.5)	0	1 (0.5)	1 (0.3)
Haemorrhoids	0	0	1 (0.5)	1 (0.3)
Inguinal hernia	0	0	1 (0.5)	1 (0.3)
Intestinal obstruction	0	0	1 (0.5)	1 (0.3)
Oesophageal food impaction	0	1 (0.5)	0	1 (0.3)
Tongue discomfort	0	1 (0.5)	0	1 (0.3)
Vomiting	0	0	1 (0.5)	1 (0.3)
Duodenitis	1 (0.5)	0	0	0
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	5 (2.5)	8 (4.0)	3 (1.5)	11 (2.8)
Dermatitis contact	1 (0.5)	3 (1.5)	2 (1.0)	5 (1.3)
Rash	0	3 (1.5)	0	3 (0.8)
Acne	1 (0.5)	1 (0.5)	0	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Skin and subcutaneous tissue disorders (cont.)				
Erythema	0	0	1 (0.5)	1 (0.3)
Angioedema	1 (0.5)	0	0	0
Hirsutism	1 (0.5)	0	0	0
Rash papular	1 (0.5)	0	0	0
Musculoskeletal and connective tissue disorders	4 (2.0)	6 (3.0)	5 (2.5)	11 (2.8)
Arthralgia	0	0	2 (1.0)	2 (0.5)
Back pain	1 (0.5)	1 (0.5)	0	1 (0.3)
Muscle spasms	0	0	1 (0.5)	1 (0.3)
Musculoskeletal pain	0	1 (0.5)	0	1 (0.3)
Myalgia	0	1 (0.5)	0	1 (0.3)
Neck pain	0	0	1 (0.5)	1 (0.3)
Plantar fasciitis	1 (0.5)	0	1 (0.5)	1 (0.3)
Rotator cuff syndrome	0	1 (0.5)	0	1 (0.3)
Spondylolisthesis	0	1 (0.5)	0	1 (0.3)
Tendonitis	0	1 (0.5)	0	1 (0.3)
Bursitis	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 End of Part A

Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Musculoskeletal and connective tissue disorders (cont.)				
Exostosis	1 (0.5)	0	0	0
Renal and urinary disorders	0	2 (1.0)	2 (1.0)	4 (1.0)
Nephrolithiasis	0	1 (0.5)	1 (0.5)	2 (0.5)
Haematuria	0	0	1 (0.5)	1 (0.3)
Hypertonic bladder	0	1 (0.5)	0	1 (0.3)
Pregnancy, puerperium and perinatal conditions	0	1 (0.5)	1 (0.5)	2 (0.5)
Abortion missed	0	0	1 (0.5)	1 (0.3)
Abortion spontaneous	0	1 (0.5)	0	1 (0.3)
Reproductive system and breast disorders	2 (1.0)	0	2 (1.0)	2 (0.5)
Breast pain	0	0	1 (0.5)	1 (0.3)
Prostatomegaly	1 (0.5)	0	1 (0.5)	1 (0.3)
Testicular cyst	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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
General disorders and administration site conditions	3 (1.5)	5 (2.5)	5 (2.5)	10 (2.5)
Fatigue	2 (1.0)	4 (2.0)	1 (0.5)	5 (1.3)
Axillary pain	0	0	2 (1.0)	2 (0.5)
Chills	0	1 (0.5)	1 (0.5)	2 (0.5)
Chest pain	0	1 (0.5)	0	1 (0.3)
Malaise	0	0	1 (0.5)	1 (0.3)
Pain	1 (0.5)	1 (0.5)	0	1 (0.3)
Pyrexia	0	0	1 (0.5)	1 (0.3)
Investigations	4 (2.0)	5 (2.5)	1 (0.5)	6 (1.5)
Blood pressure increased	0	1 (0.5)	1 (0.5)	2 (0.5)
Blood alkaline phosphatase increased	0	1 (0.5)	0	1 (0.3)
Blood cholesterol increased	1 (0.5)	1 (0.5)	0	1 (0.3)
Hormone level abnormal	0	1 (0.5)	0	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Investigations (cont.)				
Platelet count increased	0	1 (0.5)	0	1 (0.3)
Staphylococcus test positive	0	1 (0.5)	0	1 (0.3)
Blood testosterone decreased	1 (0.5)	0	0	0
Blood triglycerides increased	1 (0.5)	0	0	0
Computerised tomogram coronary artery abnormal	1 (0.5)	0	0	0
Vitamin D decreased	1 (0.5)	0	0	0
Injury, poisoning and procedural complications	3 (1.5)	10 (5.0)	9 (4.5)	19 (4.8)
Meniscus injury	0	1 (0.5)	2 (1.0)	3 (0.8)
Muscle strain	0	1 (0.5)	2 (1.0)	3 (0.8)
Concussion	0	1 (0.5)	1 (0.5)	2 (0.5)
Arthropod bite	0	1 (0.5)	0	1 (0.3)
Breast injury	0	1 (0.5)	0	1 (0.3)

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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 End of Part A
Safety Set

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Injury, poisoning and procedural complications (cont.)				
Chemical burn	0	0	1 (0.5)	1 (0.3)
Corneal abrasion	0	1 (0.5)	0	1 (0.3)
Epicondylitis	0	1 (0.5)	0	1 (0.3)
Foreign body in eye	0	1 (0.5)	0	1 (0.3)
Limb injury	0	0	1 (0.5)	1 (0.3)
Muscle rupture	0	1 (0.5)	0	1 (0.3)
Post-traumatic pain	0	1 (0.5)	0	1 (0.3)
Procedural pain	0	1 (0.5)	0	1 (0.3)
Road traffic accident	0	1 (0.5)	0	1 (0.3)
Struck by lightning	0	0	1 (0.5)	1 (0.3)
Tendon rupture	0	0	1 (0.5)	1 (0.3)
Tooth fracture	0	1 (0.5)	0	1 (0.3)
Skin laceration	2 (1.0)	0	0	0
Tendon injury	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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	35 (35.0)	44 (44.0)	17 (17.0)	61 (30.5)	29 (29.0)	30 (30.0)	21 (21.0)	51 (25.5)
Number of Unsolicited Adverse Events	58	81	34	115	35	49	33	82
Infections and infestations	24 (24.0)	18 (18.0)	5 (5.0)	23 (11.5)	15 (15.0)	9 (9.0)	6 (6.0)	15 (7.5)
COVID-19	17 (17.0)	2 (2.0)	1 (1.0)	3 (1.5)	7 (7.0)	1 (1.0)	1 (1.0)	2 (1.0)
Sinusitis	2 (2.0)	1 (1.0)	0	1 (0.5)	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Bronchitis	0	1 (1.0)	1 (1.0)	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Upper respiratory tract infection	2 (2.0)	2 (2.0)	0	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Urinary tract infection	2 (2.0)	2 (2.0)	1 (1.0)	3 (1.5)	1 (1.0)	0	0	0
Viral infection	0	3 (3.0)	0	3 (1.5)	0	0	0	0
Viral upper respiratory tract infection	0	3 (3.0)	0	3 (1.5)	1 (1.0)	0	0	0
Otitis media	1 (1.0)	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Acute sinusitis	0	0	0	0	0	0	1 (1.0)	1 (0.5)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Cellulitis	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Eye infection	0	1 (1.0)	0	1 (0.5)	1 (1.0)	0	0	0
Fungal skin infection	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Gastroenteritis	1 (1.0)	0	1 (1.0)	1 (0.5)	1 (1.0)	0	0	0
Herpes zoster	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Infected bite	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Influenza	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Nasopharyngitis	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Oral candidiasis	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Pneumonia	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Tinea pedis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tooth abscess	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tooth infection	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Urethritis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Asymptomatic COVID-19	0	0	0	0	1 (1.0)	0	0	0
Gingivitis	1 (1.0)	0	0	0	0	0	0	0
Herpes simplex	0	0	0	0	1 (1.0)	0	0	0
Localised infection	1 (1.0)	0	0	0	0	0	0	0
Otitis externa	1 (1.0)	0	0	0	0	0	0	0
Suspected COVID-19	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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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 and lymphatic system disorders	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Lymphadenopathy	0	1 (1.0)	0	1 (0.5)	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
Endocrine disorders	1 (1.0)	0	0	0	0	1 (1.0)	0	1 (0.5)
Hypothyroidism	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Hyperoestrogenism	1 (1.0)	0	0	0	0	0	0	0
Metabolism and nutrition disorders	1 (1.0)	1 (1.0)	0	1 (0.5)	2 (2.0)	1 (1.0)	2 (2.0)	3 (1.5)
Gout	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Insulin resistance	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vitamin B12 deficiency	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Vitamin D deficiency	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Hypercholesterolaemia	0	0	0	0	1 (1.0)	0	0	0
Hyperlipidaemia	0	0	0	0	1 (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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	2 (2.0)	4 (4.0)	4 (4.0)	8 (4.0)	2 (2.0)	5 (5.0)	0	5 (2.5)
Anxiety	2 (2.0)	3 (3.0)	1 (1.0)	4 (2.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Depression	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	1 (1.0)	2 (2.0)	0	2 (1.0)
Insomnia	0	2 (2.0)	0	2 (1.0)	0	1 (1.0)	0	1 (0.5)
Major depression	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Nervous system disorders	0	8 (8.0)	2 (2.0)	10 (5.0)	0	3 (3.0)	1 (1.0)	4 (2.0)
Headache	0	4 (4.0)	1 (1.0)	5 (2.5)	0	0	0	0
Dizziness	0	1 (1.0)	0	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Migraine	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Ageusia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Cerebrovascular accident	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)
Paraesthesia	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tension headache	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Tremor	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Eye disorders	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Cataract	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Conjunctivitis allergic	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Glaucoma	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Ear and labyrinth disorders	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Excessive cerumen production	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tinnitus	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Cardiac disorders	0	0	0	0	0	2 (2.0)	1 (1.0)	3 (1.5)
Acute myocardial infarction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Arrhythmia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Bradycardia	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Diastolic dysfunction	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vascular disorders	0	3 (3.0)	0	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Hypertension	0	3 (3.0)	0	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)

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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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	2 (2.0)	5 (5.0)	1 (1.0)	6 (3.0)	0	1 (1.0)	0	1 (0.5)
Nasal congestion	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Oropharyngeal pain	1 (1.0)	2 (2.0)	0	2 (1.0)	0	0	0	0
Rhinitis allergic	0	0	1 (1.0)	1 (0.5)	0	1 (1.0)	0	1 (0.5)
Cough	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Dyspnoea	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Rhinorrhoea	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Sneezing	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Dry throat	1 (1.0)	0	0	0	0	0	0	0
Gastrointestinal disorders	3 (3.0)	4 (4.0)	5 (5.0)	9 (4.5)	4 (4.0)	4 (4.0)	3 (3.0)	7 (3.5)
Gastrooesophageal reflux disease	0	0	0	0	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)
Nausea	0	1 (1.0)	2 (2.0)	3 (1.5)	0	0	0	0
Diarrhoea	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Gastritis	0	2 (2.0)	0	2 (1.0)	0	0	0	0
Abdominal discomfort	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Abdominal pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Dental caries	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)

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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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Diverticulum	1 (1.0)	0	0	0	0	0	1 (1.0)	1 (0.5)
Haemorrhoids	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Inguinal hernia	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Intestinal obstruction	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)
Tongue discomfort	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Vomiting	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Duodenitis	0	0	0	0	1 (1.0)	0	0	0
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	3 (3.0)	4 (4.0)	1 (1.0)	5 (2.5)	2 (2.0)	4 (4.0)	2 (2.0)	6 (3.0)
Dermatitis contact	1 (1.0)	2 (2.0)	1 (1.0)	3 (1.5)	0	1 (1.0)	1 (1.0)	2 (1.0)
Rash	0	1 (1.0)	0	1 (0.5)	0	2 (2.0)	0	2 (1.0)
Acne	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Dermatitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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)
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Hirsutism	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	1 (1.0)	1 (1.0)	3 (3.0)	4 (2.0)	3 (3.0)	5 (5.0)	2 (2.0)	7 (3.5)
Arthralgia	0	0	1 (1.0)	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Back pain	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Muscle spasms	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Musculoskeletal 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
Neck pain	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Plantar fasciitis	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)
Spondylolisthesis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Tendonitis	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Bursitis	1 (1.0)	0	0	0	1 (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 End of Part A
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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
Renal and urinary disorders	0	0	0	0	0	2 (2.0)	2 (2.0)	4 (2.0)
Nephrolithiasis	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Haematuria	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Hypertonic bladder	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Pregnancy, puerperium and perinatal conditions	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Abortion missed	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Abortion spontaneous	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Reproductive system and breast disorders	1 (1.0)	0	0	0	1 (1.0)	0	2 (2.0)	2 (1.0)
Breast pain	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Prostatomegaly	0	0	0	0	1 (1.0)	0	1 (1.0)	1 (0.5)
Testicular cyst	1 (1.0)	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 End of Part A

Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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	3 (3.0)	4 (4.0)	4 (4.0)	8 (4.0)	0	1 (1.0)	1 (1.0)	2 (1.0)
Fatigue	2 (2.0)	4 (4.0)	1 (1.0)	5 (2.5)	0	0	0	0
Axillary pain	0	0	2 (2.0)	2 (1.0)	0	0	0	0
Chills	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	0	0
Chest pain	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	1 (1.0)	1 (1.0)	0	1 (0.5)	0	0	0	0
Pyrexia	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Investigations	1 (1.0)	2 (2.0)	0	2 (1.0)	3 (3.0)	3 (3.0)	1 (1.0)	4 (2.0)
Blood pressure increased	0	1 (1.0)	0	1 (0.5)	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 cholesterol increased	0	0	0	0	1 (1.0)	1 (1.0)	0	1 (0.5)
Hormone level abnormal	0	0	0	0	0	1 (1.0)	0	1 (0.5)

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Safety Set

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		mRNA-1273				mRNA-1273		
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Investigations (cont.)								
Platelet count increased	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Staphylococcus test positive	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Blood testosterone decreased	1 (1.0)	0	0	0	0	0	0	0
Blood triglycerides increased	0	0	0	0	1 (1.0)	0	0	0
Computerised tomogram coronary artery abnormal	0	0	0	0	1 (1.0)	0	0	0
Vitamin D decreased	1 (1.0)	0	0	0	0	0	0	0
Injury, poisoning and procedural complications	3 (3.0)	8 (8.0)	3 (3.0)	11 (5.5)	0	2 (2.0)	6 (6.0)	8 (4.0)
Meniscus injury	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Muscle strain	0	1 (1.0)	1 (1.0)	2 (1.0)	0	0	1 (1.0)	1 (0.5)
Concussion	0	1 (1.0)	0	1 (0.5)	0	0	1 (1.0)	1 (0.5)
Arthropod bite	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Breast injury	0	1 (1.0)	0	1 (0.5)	0	0	0	0

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	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	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.)								
Chemical burn	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Corneal abrasion	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Epicondylitis	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Foreign body in eye	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Limb injury	0	0	1 (1.0)	1 (0.5)	0	0	0	0
Muscle rupture	0	0	0	0	0	1 (1.0)	0	1 (0.5)
Post-traumatic pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Procedural pain	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Road traffic accident	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Struck by lightning	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tendon rupture	0	0	0	0	0	0	1 (1.0)	1 (0.5)
Tooth fracture	0	1 (1.0)	0	1 (0.5)	0	0	0	0
Skin laceration	2 (2.0)	0	0	0	0	0	0	0
Tendon injury	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\Part A end of Part A\TLF\t1403011802.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.1
Subject Incidence of Unsolicited Adverse Event of Special Interest - Vasculitis by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012201.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.1
Subject Incidence of Unsolicited Adverse Event of Special Interest - Vasculitis by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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 (%)

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\Part A end of Part A\TLF\t1403012201.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.2
Subject Incidence of Unsolicited Adverse Event of Special Interest - Hypersensitivity by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Hypersensitivity [1]	6 (3.0)	10 (5.0)	4 (2.0)	14 (3.5)
Number of Hypersensitivity [1]	6	11	5	16
Angioedema	1 (0.5)	0	0	0
Conjunctivitis allergic	0	0	1 (0.5)	1 (0.3)
Dermatitis	0	1 (0.5)	0	1 (0.3)
Dermatitis contact	3 (1.5)	5 (2.5)	3 (1.5)	8 (2.0)
Rash	2 (1.0)	4 (2.0)	0	4 (1.0)
Rhinitis allergic	0	1 (0.5)	1 (0.5)	2 (0.5)

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Hypersensitivity is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012202.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.2
Subject Incidence of Unsolicited Adverse Event of Special Interest - Hypersensitivity by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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)	3 (3.0)	8 (4.0)	3 (3.0)	5 (5.0)	1 (1.0)	6 (3.0)
Number of Hypersensitivity [1]	3	5	4	9	3	6	1	7
Angioedema	0	0	0	0	1 (1.0)	0	0	0
Conjunctivitis allergic	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)
Dermatitis contact	2 (2.0)	3 (3.0)	2 (2.0)	5 (2.5)	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)	2 (2.0)	0	2 (1.0)
Rhinitis allergic	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
[1] Hypersensitivity is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012202.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.3
Subject Incidence of Unsolicited Adverse Event of Special Interest - Arthritis by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Arthritis [1]	0	1 (0.5)	1 (0.5)	2 (0.5)
Number of Arthritis [1]	0	1	1	2
Gout	0	0	1 (0.5)	1 (0.3)
Periarthritis	0	1 (0.5)	0	1 (0.3)

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Arthritis is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012203.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.3
Subject Incidence of Unsolicited Adverse Event of Special Interest - Arthritis by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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 Arthritis [1]	0	0	0	0	0	1 (1.0)	1 (1.0)	2 (1.0)
Number of Arthritis [1]	0	0	0	0	0	1	1	2
Gout	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)

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Arthritis is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012203.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.4
Subject Incidence of Unsolicited Adverse Event of Special Interest - Angioedema by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	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\Part A end of Part A\TLF\t1403012204.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.4
Subject Incidence of Unsolicited Adverse Event of Special Interest - Angioedema by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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 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\Part A end of Part A\TLF\t1403012204.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.5
Subject Incidence of Unsolicited Adverse Event of Special Interest - Peripheral Neuropathy by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	50 µg (N=200) n (%)	100 µg (N=200) n (%)	Total (N=400) n (%)
Number of Subjects Reporting Peripheral Neuropathy [1]	1 (0.5)	0	0	0
Number of Peripheral Neuropathy [1]	1	0	0	0
Neuralgia	1 (0.5)	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Peripheral Neuropathy is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012205.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

Table 14.3.1.22.5
Subject Incidence of Unsolicited Adverse Event of Special Interest - Peripheral Neuropathy by SMQ
Safety Set

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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 Peripheral Neuropathy [1]	1 (1.0)	0	0	0	0	0	0	0
Number of Peripheral Neuropathy [1]	1	0	0	0	0	0	0	0
Neuralgia	1 (1.0)	0	0	0	0	0	0	0

Percentages are based on the number of safety subjects.
MedDRA version 23.0
[1] Peripheral Neuropathy is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012205.sas 19JUL2021 20:36 Database Lock Date: 10JUN2021

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

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	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] Demyelinating Disease of Central Nervous System is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012206.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Preferred Term	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 (%)

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\Part A end of Part A\TLF\t1403012206.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.22.7
Subject Incidence of Unsolicited Adverse Event of Special Interest - Convulsions by SMQ
Safety Set

	Overall			
		mRNA-1273		
Preferred Term	Placebo (N=200) n (%)	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] Convulsions is identified through selected SMQ.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012207.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

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		
Preferred Term	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 (%)

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\Part A end of Part A\TLF\t1403012207.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=27) n (%)	50 µg (N=4) n (%)	100 µg (N=2) n (%)	Total (N=6) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	27 (100)	4 (100)	2 (100)	6 (100)
Number of Unsolicited Adverse Events	45	5	2	7
Infections and infestations	27 (100)	4 (100)	2 (100)	6 (100)
COVID-19	26 (96.3)	3 (75.0)	2 (100)	5 (83.3)
Viral infection	0	1 (25.0)	0	1 (16.7)
Asymptomatic COVID-19	1 (3.7)	0	0	0
Gingivitis	1 (3.7)	0	0	0
Otitis externa	1 (3.7)	0	0	0
Pneumonia	1 (3.7)	0	0	0
Upper respiratory tract infection	1 (3.7)	0	0	0
Endocrine disorders	1 (3.7)	0	0	0
Hyperoestrogenism	1 (3.7)	0	0	0
Psychiatric disorders	1 (3.7)	0	0	0
Depression	1 (3.7)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=27) n (%)	50 µg (N=4) n (%)	100 µg (N=2) n (%)	Total (N=6) n (%)
Nervous system disorders	2 (7.4)	1 (25.0)	0	1 (16.7)
Migraine	0	1 (25.0)	0	1 (16.7)
Headache	1 (3.7)	0	0	0
Sinus headache	1 (3.7)	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (3.7)	0	0	0
Cough	1 (3.7)	0	0	0
Gastrointestinal disorders	1 (3.7)	0	0	0
Oral disorder	1 (3.7)	0	0	0
Skin and subcutaneous tissue disorders	2 (7.4)	0	0	0
Rash	1 (3.7)	0	0	0
Rash papular	1 (3.7)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Overall			
		mRNA-1273		
System Organ Class Preferred Term	Placebo (N=27) n (%)	50 µg (N=4) n (%)	100 µg (N=2) n (%)	Total (N=6) n (%)
Reproductive system and breast disorders	1 (3.7)	0	0	0
Postmenopausal haemorrhage	1 (3.7)	0	0	0
General disorders and administration site conditions	2 (7.4)	0	0	0
Fatigue	2 (7.4)	0	0	0
Investigations	2 (7.4)	0	0	0
Blood testosterone decreased	1 (3.7)	0	0	0
Heart rate decreased	1 (3.7)	0	0	0
Vitamin D decreased	1 (3.7)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1
Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	Placebo (N=18) n (%)	50 µg (N=3) n (%)	100 µg (N=1) n (%)	Total (N=4) n (%)	Placebo (N=9) n (%)	50 µg (N=1) n (%)	100 µg (N=1) n (%)	Total (N=2) n (%)
Number of Subjects Reporting Unsolicited Adverse Events	18 (100)	3 (100)	1 (100)	4 (100)	9 (100)	1 (100)	1 (100)	2 (100)
Number of Unsolicited Adverse Events	32	4	1	5	13	1	1	2
Infections and infestations	18 (100)	3 (100)	1 (100)	4 (100)	9 (100)	1 (100)	1 (100)	2 (100)
COVID-19	18 (100)	2 (66.7)	1 (100)	3 (75.0)	8 (88.9)	1 (100)	1 (100)	2 (100)
Viral infection	0	1 (33.3)	0	1 (25.0)	0	0	0	0
Asymptomatic COVID-19	0	0	0	0	1 (11.1)	0	0	0
Gingivitis	1 (5.6)	0	0	0	0	0	0	0
Otitis externa	1 (5.6)	0	0	0	0	0	0	0
Pneumonia	0	0	0	0	1 (11.1)	0	0	0
Upper respiratory tract infection	1 (5.6)	0	0	0	0	0	0	0
Endocrine disorders	1 (5.6)	0	0	0	0	0	0	0
Hyperoestrogenism	1 (5.6)	0	0	0	0	0	0	0
Psychiatric disorders	0	0	0	0	1 (11.1)	0	0	0
Depression	0	0	0	0	1 (11.1)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	Placebo (N=18) n (%)	50 µg (N=3) n (%)	100 µg (N=1) n (%)	Total (N=4) n (%)	Placebo (N=9) n (%)	50 µg (N=1) n (%)	100 µg (N=1) n (%)	Total (N=2) n (%)
Nervous system disorders	2 (11.1)	1 (33.3)	0	1 (25.0)	0	0	0	0
Migraine	0	1 (33.3)	0	1 (25.0)	0	0	0	0
Headache	1 (5.6)	0	0	0	0	0	0	0
Sinus headache	1 (5.6)	0	0	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	1 (5.6)	0	0	0	0	0	0	0
Cough	1 (5.6)	0	0	0	0	0	0	0
Gastrointestinal disorders	1 (5.6)	0	0	0	0	0	0	0
Oral disorder	1 (5.6)	0	0	0	0	0	0	0
Skin and subcutaneous tissue disorders	2 (11.1)	0	0	0	0	0	0	0
Rash	1 (5.6)	0	0	0	0	0	0	0
Rash papular	1 (5.6)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.1.23.1

Subject Incidence of Unsolicited TEAE by System Organ Class and Preferred Term from Day 1 to End of Part A
Safety Set - Subjects with SARS-CoV-2 Infection or COVID-19

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
System Organ Class Preferred Term	Placebo (N=18) n (%)	50 µg (N=3) n (%)	100 µg (N=1) n (%)	Total (N=4) n (%)	Placebo (N=9) n (%)	50 µg (N=1) n (%)	100 µg (N=1) n (%)	Total (N=2) n (%)
Reproductive system and breast disorders	0	0	0	0	1 (11.1)	0	0	0
Postmenopausal haemorrhage	0	0	0	0	1 (11.1)	0	0	0
General disorders and administration site conditions	2 (11.1)	0	0	0	0	0	0	0
Fatigue	2 (11.1)	0	0	0	0	0	0	0
Investigations	1 (5.6)	0	0	0	1 (11.1)	0	0	0
Blood testosterone decreased	1 (5.6)	0	0	0	0	0	0	0
Heart rate decreased	0	0	0	0	1 (11.1)	0	0	0
Vitamin D decreased	1 (5.6)	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 who had SARS-CoV-2 infection or COVID-19.
MedDRA version 23.0

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t1403012301.sas 19JUL2021 20:37 Database Lock Date: 10JUN2021

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Diastolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 209				
Absolute Result				
n	186	187	187	374
Mean (SD)	78.8 (7.95)	78.1 (8.39)	78.4 (7.66)	78.2 (8.02)
Median	79.0	79.0	78.0	78.0
Min, Max	58, 98	50, 99	60, 99	50, 99
Change from Baseline				
n	186	187	187	374
Mean (SD)	3.0 (9.68)	2.5 (9.38)	2.4 (9.72)	2.5 (9.54)
Median	2.0	2.0	3.0	3.0
Min, Max	-20, 41	-31, 33	-32, 27	-32, 33

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)			
		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)
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

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)			
		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)	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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 209								
Absolute Result								
n	94	91	97	188	92	96	90	186
Mean (SD)	79.1 (8.12)	78.3 (8.38)	78.1 (6.79)	78.2 (7.58)	78.5 (7.79)	78.0 (8.44)	78.7 (8.51)	78.3 (8.46)
Median	80.0	79.0	78.0	78.0	79.0	80.0	78.0	78.5
Min, Max	62, 98	61, 99	60, 94	60, 99	58, 97	50, 95	60, 99	50, 99
Change from Baseline								
n	94	91	97	188	92	96	90	186
Mean (SD)	4.2 (9.09)	3.4 (9.47)	2.8 (8.58)	3.1 (9.00)	1.8 (10.16)	1.7 (9.27)	1.9 (10.84)	1.8 (10.03)
Median	4.0	2.0	3.0	3.0	1.0	2.5	3.0	3.0
Min, Max	-15, 26	-17, 33	-20, 25	-20, 33	-20, 41	-31, 21	-32, 27	-32, 27

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Pulse Rate (beats/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 209				
Absolute Result				
n	186	187	187	374
Mean (SD)	71.4 (11.25)	71.9 (10.20)	71.8 (10.06)	71.8 (10.12)
Median	70.0	72.0	72.0	72.0
Min, Max	41, 98	51, 101	45, 101	45, 101
Change from Baseline				
n	186	187	187	374
Mean (SD)	1.8 (10.81)	0.1 (11.04)	1.2 (10.77)	0.6 (10.90)
Median	1.0	-1.0	0.0	0.0
Min, Max	-32, 39	-34, 30	-29, 33	-34, 33

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)			
		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)
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

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)			
		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	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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 209								
Absolute Result								
n	94	91	97	188	92	96	90	186
Mean (SD)	71.6 (11.46)	73.3 (11.34)	72.3 (10.39)	72.8 (10.84)	71.1 (11.08)	70.5 (8.83)	71.2 (9.71)	70.8 (9.25)
Median	70.5	73.0	72.0	72.0	70.0	70.0	71.5	70.0
Min, Max	41, 97	51, 101	45, 101	45, 101	51, 98	53, 96	50, 92	50, 96
Change from Baseline								
n	94	91	97	188	92	96	90	186
Mean (SD)	2.8 (10.92)	0.8 (12.49)	1.3 (10.63)	1.1 (11.54)	0.8 (10.67)	-0.6 (9.48)	1.1 (10.98)	0.2 (10.24)
Median	2.0	0.0	0.0	0.0	0.0	-1.0	-1.0	-1.0
Min, Max	-32, 39	-34, 30	-29, 33	-34, 33	-24, 30	-27, 26	-21, 30	-27, 30

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Respiratory Rate (breaths/min)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 209				
Absolute Result				
n	186	187	187	374
Mean (SD)	15.0 (1.81)	14.6 (1.78)	14.9 (1.68)	14.8 (1.73)
Median	15.0	15.0	15.0	15.0
Min, Max	12, 22	12, 18	12, 18	12, 18
Change from Baseline				
n	186	187	187	374
Mean (SD)	-0.1 (1.90)	-0.3 (1.91)	-0.1 (1.97)	-0.2 (1.94)
Median	0.0	0.0	0.0	0.0
Min, Max	-6, 6	-6, 6	-6, 4	-6, 6

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)			
		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)
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

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)			
		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	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

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)			
		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 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

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)			
		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 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

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)			
		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 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)			
		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 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

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)			
		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 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

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)			
		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 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

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)			
		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 209								
Absolute								
Result								
n	94	91	97	188	92	96	90	186
Mean (SD)	14.9 (1.76)	14.4 (1.82)	15.0 (1.65)	14.7 (1.75)	15.0 (1.88)	14.8 (1.73)	14.9 (1.71)	14.8 (1.72)
Median	15.0	14.0	16.0	15.0	15.5	15.0	15.0	15.0
Min, Max	12, 18	12, 18	12, 18	12, 18	12, 22	12, 18	12, 18	12, 18
Change from								
Baseline								
n	94	91	97	188	92	96	90	186
Mean (SD)	0.1 (1.92)	-0.4 (1.93)	-0.1 (2.04)	-0.3 (1.99)	-0.3 (1.87)	-0.2 (1.90)	-0.1 (1.90)	-0.2 (1.90)
Median	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Min, Max	-4, 4	-4, 6	-6, 4	-6, 6	-6, 6	-6, 4	-5, 4	-6, 4

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Systolic Blood Pressure (mmHg)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 209				
Absolute Result				
n	186	187	187	374
Mean (SD)	123.5 (10.90)	124.0 (12.78)	123.8 (11.64)	123.9 (12.21)
Median	123.0	124.0	124.0	124.0
Min, Max	99, 154	91, 155	96, 157	91, 157
Change from Baseline				
n	186	187	187	374
Mean (SD)	2.0 (12.56)	3.1 (13.45)	2.0 (13.08)	2.6 (13.26)
Median	2.0	3.0	2.0	2.0
Min, Max	-28, 38	-31, 37	-42, 42	-42, 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)			
		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)
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

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)			
		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)	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

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)			
		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 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)			
		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 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

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)			
		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 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)			
		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 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)			
		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 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

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)			
		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 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

Systolic Blood Pressure (mmHg)

	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 209								
Absolute								
Result								
n	94	91	97	188	92	96	90	186
Mean (SD)	121.7 (10.25)	121.5 (13.04)	121.4 (11.32)	121.4 (12.15)	125.5 (11.27)	126.4 (12.12)	126.5 (11.45)	126.4 (11.77)
Median	121.0	122.0	122.0	122.0	126.5	127.0	127.0	127.0
Min, Max	99, 144	91, 146	96, 157	91, 157	102, 154	98, 155	99, 157	98, 157
Change from								
Baseline								
n	94	91	97	188	92	96	90	186
Mean (SD)	2.9 (12.62)	3.3 (13.72)	2.0 (11.43)	2.6 (12.57)	1.0 (12.50)	2.9 (13.25)	2.1 (14.71)	2.5 (13.95)
Median	3.0	3.0	2.0	2.0	1.5	2.0	2.0	2.0
Min, Max	-28, 38	-31, 37	-23, 37	-31, 37	-24, 31	-30, 37	-42, 42	-42, 42

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	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

Table 14.3.3.1
Summary of Vital Signs and Change from Baseline by Visit
Safety Set

Temperature (C)

	Overall			
		mRNA-1273		
	Placebo (N=200)	50 µg (N=200)	100 µg (N=200)	Total (N=400)
Day 209				
Absolute Result				
n	185	187	187	374
Mean (SD)	36.75 (0.275)	36.75 (0.320)	36.73 (0.360)	36.74 (0.340)
Median	36.80	36.70	36.80	36.75
Min, Max	35.7, 37.6	35.7, 37.6	35.1, 38.4	35.1, 38.4
Change from Baseline				
n	185	187	187	374
Mean (SD)	-0.03 (0.350)	-0.02 (0.374)	-0.05 (0.446)	-0.04 (0.411)
Median	0.00	0.00	0.00	0.00
Min, Max	-1.4, 1.2	-1.2, 1.3	-2.5, 1.6	-2.5, 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)			
		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)
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

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

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 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

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 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

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 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

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 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

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 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)			
		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 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

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 209								
Absolute Result								
n	94	91	97	188	91	96	90	186
Mean (SD)	36.76 (0.243)	36.76 (0.300)	36.74 (0.375)	36.75 (0.340)	36.73 (0.305)	36.74 (0.339)	36.72 (0.346)	36.73 (0.341)
Median	36.80	36.70	36.80	36.80	36.80	36.70	36.80	36.70
Min, Max	35.9, 37.3	35.7, 37.5	35.1, 38.4	35.1, 38.4	35.7, 37.6	35.8, 37.6	35.6, 37.6	35.6, 37.6
Change from Baseline								
n	94	91	97	188	91	96	90	186
Mean (SD)	-0.07 (0.350)	-0.02 (0.372)	-0.08 (0.446)	-0.05 (0.412)	0.01 (0.347)	-0.03 (0.378)	-0.01 (0.445)	-0.02 (0.411)
Median	-0.10	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Min, Max	-1.0, 1.2	-0.8, 1.3	-2.5, 1.4	-2.5, 1.4	-1.4, 0.7	-1.2, 0.9	-1.3, 1.6	-1.3, 1.6

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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	1 (0.5)	0	0	0	14 (7.0)
Grade 0	0	171 (85.5)	5 (2.5)	0	0	0	176 (88.0)
Grade 1	0	5 (2.5)	0	1 (0.5)	0	0	6 (3.0)
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	193 (96.5)	6 (3.0)	1 (0.5)	0	0	200 (100)
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

	Baseline											
Timepoint	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		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

	Baseline											
Timepoint	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

	Baseline											
Timepoint Post-Baseline Grade	UNK n	(%)	Grade 0 n	(%)	Grade 1 n	(%)	Grade 2 n	(%)	Grade 3 n	(%)	Grade 4 n	(%)	Total 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

	Baseline											
Timepoint	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)	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

	Baseline											
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Day 209														
UNK	0		14	(7.0)	0		0		0		0		14	(7.0)
Grade 0	0		171	(85.5)	4	(2.0)	0		1	(0.5)	0		176	(88.0)
Grade 1	0		5	(2.5)	1	(0.5)	1	(0.5)	0		0		7	(3.5)
Grade 2	0		1	(0.5)	0		1	(0.5)	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		192	(96.0)	5	(2.5)	2	(1.0)	1	(0.5)	0		200	(100)
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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14030302.sas 19JUL2021 20:38 Database Lock Date: 10JUN2021

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

	Baseline						
Timepoint Post-Baseline Grade	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	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)
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)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14030302.sas 19JUL2021 20:38 Database Lock Date: 10JUN2021

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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14030302.sas 19JUL2021 20:38 Database Lock Date: 10JUN2021

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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	184 (92.0)	0	0	0	0	184 (92.0)
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)
Worst Post-Baseline							
UNK	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

	Baseline						
Timepoint Post-Baseline Grade	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	163 (81.5)	10 (5.0)	0	0	0	173 (86.5)
Grade 1	0	6 (3.0)	21 (10.5)	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)
Day 8							
UNK	0	4 (2.0)	0	0	0	0	4 (2.0)
Grade 0	0	159 (79.5)	25 (12.5)	0	0	0	184 (92.0)
Grade 1	0	6 (3.0)	6 (3.0)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (5.0)	4 (2.0)	0	0	0	14 (7.0)
Grade 0	0	148 (74.0)	12 (6.0)	0	0	0	160 (80.0)
Grade 1	0	10 (5.0)	15 (7.5)	0	0	0	25 (12.5)
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	169 (84.5)	31 (15.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	185 (92.5)	1 (0.5)	0	0	0	186 (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	199 (99.5)	1 (0.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	1 (0.5)	0	0	0	14 (7.0)
Grade 0	0	170 (85.0)	7 (3.5)	0	0	0	177 (88.5)
Grade 1	0	7 (3.5)	0	0	0	0	7 (3.5)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	15 (7.5)	0	0	0	0	15 (7.5)
Grade 0	0	185 (92.5)	0	0	0	0	185 (92.5)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	191 (95.5)	0	0	0	0	191 (95.5)
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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	179 (89.5)	0	0	0	0	179 (89.5)
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	200 (100)	0	0	0	0	200 (100)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	173 (86.5)	0	0	0	0	173 (86.5)
Grade 1	0	22 (11.0)	0	0	0	0	22 (11.0)
Grade 2	0	5 (2.5)	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	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) - Bradycardia

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	179 (89.5)	2 (1.0)	1 (0.5)	0	0	182 (91.0)
Grade 1	0	4 (2.0)	1 (0.5)	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)
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

	Baseline							
Timepoint Post-Baseline Grade	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	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	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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43							
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)
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: mRNA-1273 50 µg (N=200)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	186 (93.0)	0	0	0	0	186 (93.0)
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)
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

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	174 (87.0)	11 (5.5)	0	0	0	185 (92.5)
Grade 1	0	3 (1.5)	6 (3.0)	1 (0.5)	0	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	1 (0.5)	0	0	0	13 (6.5)
Grade 0	0	158 (79.0)	10 (5.0)	1 (0.5)	0	0	169 (84.5)
Grade 1	0	12 (6.0)	6 (3.0)	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	182 (91.0)	17 (8.5)	1 (0.5)	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	185 (92.5)	2 (1.0)	0	0	0	187 (93.5)
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)
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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14030302.sas 19JUL2021 20:38 Database Lock Date: 10JUN2021

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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Day 209														
UNK	0		12	(6.0)	0		0		1	(0.5)	0		13	(6.5)
Grade 0	0		168	(84.0)	7	(3.5)	1	(0.5)	0		0		176	(88.0)
Grade 1	0		9	(4.5)	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		191	(95.5)	7	(3.5)	1	(0.5)	1	(0.5)	0		200	(100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43							
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)
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 Overall; Vaccination Group: mRNA-1273 50 µg (N=200)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	187 (93.5)	0	0	0	0	187 (93.5)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline											
Timepoint	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		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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline													
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Day 209														
UNK	0		13	(6.5)	0		0		0		0		13	(6.5)
Grade 0	0		173	(86.5)	4	(2.0)	1	(0.5)	0		0		178	(89.0)
Grade 1	0		6	(3.0)	0		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		195	(97.5)	4	(2.0)	1	(0.5)	0		0		200	(100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	169 (84.5)	10 (5.0)	0	0	0	179 (89.5)
Grade 1	0	6 (3.0)	1 (0.5)	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	189 (94.5)	11 (5.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43							
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)
Day 57							
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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	185 (92.5)	1 (0.5)	0	0	0	186 (93.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 15							
UNK	0	0	0	0	0	0	0
Grade 0	0	161 (80.5)	7 (3.5)	0	0	0	168 (84.0)
Grade 1	0	8 (4.0)	24 (12.0)	0	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	169 (84.5)	31 (15.5)	0	0	0	200 (100)
Day 29 - Predose							
UNK	0	2 (1.0)	0	0	0	0	2 (1.0)
Grade 0	0	158 (79.0)	8 (4.0)	0	0	0	166 (83.0)
Grade 1	0	9 (4.5)	23 (11.5)	0	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	163 (81.5)	18 (9.0)	0	0	0	181 (90.5)
Grade 1	0	3 (1.5)	13 (6.5)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (5.0)	3 (1.5)	0	0	0	13 (6.5)
Grade 0	0	150 (75.0)	15 (7.5)	0	0	0	165 (82.5)
Grade 1	0	9 (4.5)	13 (6.5)	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	169 (84.5)	31 (15.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t14030302.sas 19JUL2021 20:38 Database Lock Date: 10JUN2021

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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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)
Systolic Blood Pressure (mmHg) - Hypotension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	187 (93.5)	0	0	0	0	187 (93.5)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline													
Timepoint	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		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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	1 (0.5)	0	0	0	13 (6.5)
Grade 0	0	169 (84.5)	6 (3.0)	0	0	0	175 (87.5)
Grade 1	0	8 (4.0)	2 (1.0)	0	0	0	10 (5.0)
Grade 2	0	0	0	0	0	0	0
Grade 3	0	2 (1.0)	0	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 15							
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)
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 Overall; Vaccination Group: mRNA-1273 100 µg (N=200)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	13 (6.5)	0	0	0	0	13 (6.5)
Grade 0	0	186 (93.0)	0	0	0	0	186 (93.0)
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)
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

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline													
Timepoint Post-Baseline Grade	UNK n	(%)	Grade 0 n	(%)	Grade 1 n	(%)	Grade 2 n	(%)	Grade 3 n	(%)	Grade 4 n	(%)	Total 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

	Baseline											
Timepoint	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		381	(95.3)	4	(1.0)	1	(0.3)	0	0	386	(96.5)
Grade 1	0		4	(1.0)	0		0		0	0	4	(1.0)
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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	26 (6.5)	0	0	0	0	26 (6.5)
Grade 0	0	352 (88.0)	4 (1.0)	1 (0.3)	0	0	357 (89.3)
Grade 1	0	11 (2.8)	0	0	0	0	11 (2.8)
Grade 2	0	6 (1.5)	0	0	0	0	6 (1.5)
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)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	347 (86.8)	4 (1.0)	1 (0.3)	0	0	352 (88.0)
Grade 1	0	37 (9.3)	0	0	0	0	37 (9.3)
Grade 2	0	10 (2.5)	0	0	0	0	10 (2.5)
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)
Pulse Rate (beats/min) - Bradycardia

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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		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

	Baseline											
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3	Grade 4	Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n (%)	n (%)	n	(%)
Day 209												
UNK	0		26	(6.5)	0		0		0	0	26	(6.5)
Grade 0	0		348	(87.0)	12	(3.0)	1	(0.3)	0	0	361	(90.3)
Grade 1	0		10	(2.5)	2	(0.5)	0		0	0	12	(3.0)
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		385	(96.3)	14	(3.5)	1	(0.3)	0	0	400	(100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	26 (6.5)	0	0	0	0	26 (6.5)
Grade 0	0	371 (92.8)	1 (0.3)	0	0	0	372 (93.0)
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)
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

	Baseline												
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline											
Timepoint Post-Baseline Grade	UNK n	(%)	Grade 0 n	(%)	Grade 1 n	(%)	Grade 2 n	(%)	Grade 3 n	Grade 4 n	Total 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

	Baseline											
Timepoint	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		337	(84.3)	29	(7.3)	0		0	0	366	(91.5)
Grade 1	0		6	(1.5)	19	(4.8)	1	(0.3)	0	0	26	(6.5)
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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	22 (5.5)	4 (1.0)	0	0	0	26 (6.5)
Grade 0	0	308 (77.0)	25 (6.3)	1 (0.3)	0	0	334 (83.5)
Grade 1	0	21 (5.3)	19 (4.8)	0	0	0	40 (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	351 (87.8)	48 (12.0)	1 (0.3)	0	0	400 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	26 (6.5)	0	0	0	0	26 (6.5)
Grade 0	0	372 (93.0)	2 (0.5)	0	0	0	374 (93.5)
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	398 (99.5)	2 (0.5)	0	0	0	400 (100)
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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint Post-Baseline Grade	UNK n	(%)	Grade 0 n	(%)	Grade 1 n	(%)	Grade 2 n	(%)	Grade 3 n	(%)	Grade 4 n	(%)	Total 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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4	Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	n	(%)
Day 209													
UNK	0		24	(6.0)	1	(0.3)	0		1	(0.3)	0	26	(6.5)
Grade 0	0		337	(84.3)	13	(3.3)	1	(0.3)	0		0	351	(87.8)
Grade 1	0		17	(4.3)	2	(0.5)	0		0		0	19	(4.8)
Grade 2	0		2	(0.5)	0		0		0		0	2	(0.5)
Grade 3	0		2	(0.5)	0		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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	26 (6.5)	0	0	0	0	26 (6.5)
Grade 0	0	373 (93.3)	0	0	0	0	373 (93.3)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	5 (5.0)	1 (1.0)	0	0	0	6 (6.0)
Grade 0	0	85 (85.0)	3 (3.0)	0	0	0	88 (88.0)
Grade 1	0	4 (4.0)	0	1 (1.0)	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	95 (95.0)	4 (4.0)	1 (1.0)	0	0	100 (100)
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

	Baseline											
Timepoint	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		83	(83.0)	3	(3.0)	0		0		0	86	(86.0)
Grade 1	0		7	(7.0)	0		1	(1.0)	0		0	8	(8.0)
Grade 2	0		2	(2.0)	1	(1.0)	0		1	(1.0)	0	4	(4.0)
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)
Day 8													
UNK	0		3	(3.0)	0		0		0		0	3	(3.0)
Grade 0	0		86	(86.0)	2	(2.0)	0		0		0	88	(88.0)
Grade 1	0		3	(3.0)	0		2	(2.0)	0		0	5	(5.0)
Grade 2	0		0		2	(2.0)	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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline											
Timepoint	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

	Baseline											
Timepoint Post-Baseline Grade	UNK n	(%)	Grade 0 n	(%)	Grade 1 n	(%)	Grade 2 n	(%)	Grade 3 n	(%)	Grade 4 n	(%)	Total 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

	Baseline											
Timepoint	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		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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	6 (6.0)	0	0	0	0	6 (6.0)
Grade 0	0	85 (85.0)	3 (3.0)	0	1 (1.0)	0	89 (89.0)
Grade 1	0	0	1 (1.0)	1 (1.0)	0	0	2 (2.0)
Grade 2	0	1 (1.0)	0	1 (1.0)	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	93 (93.0)	4 (4.0)	2 (2.0)	1 (1.0)	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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	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)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	6 (6.0)	0	0	0	0	6 (6.0)
Grade 0	0	93 (93.0)	0	0	0	0	93 (93.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	6 (6.0)	0	0	0	0	6 (6.0)
Grade 0	0	79 (79.0)	3 (3.0)	0	0	0	82 (82.0)
Grade 1	0	6 (6.0)	6 (6.0)	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	6 (6.0)	0	0	0	0	6 (6.0)
Grade 0	0	93 (93.0)	1 (1.0)	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	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)
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)	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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	5 (5.0)	1 (1.0)	0	0	0	6 (6.0)
Grade 0	0	89 (89.0)	2 (2.0)	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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	6 (6.0)	0	0	0	0	6 (6.0)
Grade 0	0	94 (94.0)	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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	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)
Diastolic Blood Pressure (mmHg) - Diastolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	87 (87.0)	0	0	0	0	87 (87.0)
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	100 (100)	0	0	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	84 (84.0)	2 (2.0)	1 (1.0)	0	0	87 (87.0)
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	97 (97.0)	2 (2.0)	1 (1.0)	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	90 (90.0)	0	0	0	0	90 (90.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	89 (89.0)	2 (2.0)	0	0	0	91 (91.0)
Grade 1	0	2 (2.0)	3 (3.0)	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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	80 (80.0)	2 (2.0)	0	0	0	82 (82.0)
Grade 1	0	6 (6.0)	3 (3.0)	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	89 (89.0)	2 (2.0)	0	0	0	91 (91.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	87 (87.0)	2 (2.0)	0	0	0	89 (89.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	91 (91.0)	0	0	0	0	91 (91.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)
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	0	0	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)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	89 (89.0)	1 (1.0)	0	0	0	90 (90.0)
Grade 1	0	7 (7.0)	0	0	0	0	7 (7.0)
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 1 (Age >= 18 and age < 55); Vaccination Group: mRNA-1273 100 µg (N=100)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)
Grade 0	0	88 (88.0)	5 (5.0)	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	95 (95.0)	5 (5.0)	0	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)
Grade 0	0	79 (79.0)	7 (7.0)	0	0	0	86 (86.0)
Grade 1	0	6 (6.0)	5 (5.0)	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	0	0	0	0	3 (3.0)
Grade 0	0	93 (93.0)	1 (1.0)	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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	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	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)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	190 (95.0)	1 (0.5)	0	0	0	191 (95.5)
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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	181 (90.5)	1 (0.5)	0	0	0	182 (91.0)
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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	172 (86.0)	7 (3.5)	1 (0.5)	0	0	180 (90.0)
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	192 (96.0)	7 (3.5)	1 (0.5)	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	185 (92.5)	1 (0.5)	0	0	0	186 (93.0)
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	199 (99.5)	1 (0.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	174 (87.0)	10 (5.0)	0	0	0	184 (92.0)
Grade 1	0	3 (1.5)	7 (3.5)	0	0	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	159 (79.5)	9 (4.5)	0	0	0	168 (84.0)
Grade 1	0	12 (6.0)	8 (4.0)	0	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	183 (91.5)	17 (8.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	186 (93.0)	2 (1.0)	0	0	0	188 (94.0)
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)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	195 (97.5)	1 (0.5)	0	0	0	196 (98.0)
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	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) - Systolic Hypertension

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	180 (90.0)	3 (1.5)	0	0	0	183 (91.5)
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	197 (98.5)	3 (1.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	12 (6.0)	0	0	0	0	12 (6.0)
Grade 0	0	187 (93.5)	0	0	0	0	187 (93.5)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	96 (96.0)	2 (2.0)	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	98 (98.0)	2 (2.0)	0	0	0	100 (100)
Day 8							
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 vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	8 (8.0)	0	0	0	0	8 (8.0)
Grade 0	0	86 (86.0)	2 (2.0)	0	0	0	88 (88.0)
Grade 1	0	1 (1.0)	0	0	0	0	1 (1.0)
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	98 (98.0)	2 (2.0)	0	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	86 (86.0)	0	0	0	0	86 (86.0)
Grade 1	0	10 (10.0)	1 (1.0)	0	0	0	11 (11.0)
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)
Day 8							
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	7 (7.0)	1 (1.0)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	8 (8.0)	0	0	0	0	8 (8.0)
Grade 0	0	86 (86.0)	1 (1.0)	0	0	0	87 (87.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	8 (8.0)	0	0	0	0	8 (8.0)
Grade 0	0	91 (91.0)	0	0	0	0	91 (91.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	76 (76.0)	7 (7.0)	0	0	0	83 (83.0)
Grade 1	0	2 (2.0)	15 (15.0)	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	78 (78.0)	22 (22.0)	0	0	0	100 (100)
Day 8							
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 0	0	74 (74.0)	19 (19.0)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	76 (76.0)	13 (13.0)	0	0	0	89 (89.0)
Grade 1	0	2 (2.0)	9 (9.0)	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	78 (78.0)	22 (22.0)	0	0	0	100 (100)
Day 57							
UNK	0	0	0	0	0	0	0
Grade 0	0	77 (77.0)	15 (15.0)	0	0	0	92 (92.0)
Grade 1	0	0	6 (6.0)	0	0	0	6 (6.0)
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)
Respiratory Rate (breaths/min) - Respiratory Rate Increased

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	4 (4.0)	4 (4.0)	0	0	0	8 (8.0)
Grade 0	0	69 (69.0)	9 (9.0)	0	0	0	78 (78.0)
Grade 1	0	4 (4.0)	9 (9.0)	0	0	0	13 (13.0)
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	78 (78.0)	22 (22.0)	0	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	8 (8.0)	0	0	0	0	8 (8.0)
Grade 0	0	92 (92.0)	0	0	0	0	92 (92.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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)
Day 57							
UNK	0	0	0	0	0	0	0
Grade 0	0	90 (90.0)	5 (5.0)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	8 (8.0)	0	0	0	0	8 (8.0)
Grade 0	0	81 (81.0)	5 (5.0)	0	0	0	86 (86.0)
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)	5 (5.0)	0	0	0	100 (100)
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

	Baseline							
Timepoint Post-Baseline Grade	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	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)
Temperature (C) - Fever

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	0	0	0	0	9 (9.0)
Grade 0	0	91 (91.0)	0	0	0	0	91 (91.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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)
Day 8							
UNK	0	0	0	0	0	0	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)
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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	1 (1.0)	0	0	0	4 (4.0)
Grade 0	0	78 (78.0)	8 (8.0)	1 (1.0)	0	0	87 (87.0)
Grade 1	0	6 (6.0)	3 (3.0)	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	87 (87.0)	12 (12.0)	1 (1.0)	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline											
Timepoint	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline											
Timepoint	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		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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	3 (3.0)	0	0	1 (1.0)	0	4 (4.0)
Grade 0	0	81 (81.0)	5 (5.0)	1 (1.0)	0	0	87 (87.0)
Grade 1	0	7 (7.0)	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	93 (93.0)	5 (5.0)	1 (1.0)	1 (1.0)	0	100 (100)
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

	Baseline							
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (10.0)	0	0	0	0	10 (10.0)
Grade 0	0	79 (79.0)	3 (3.0)	1 (1.0)	0	0	83 (83.0)
Grade 1	0	4 (4.0)	0	0	0	0	4 (4.0)
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	96 (96.0)	3 (3.0)	1 (1.0)	0	0	100 (100)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	85 (85.0)	3 (3.0)	1 (1.0)	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	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)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	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	84 (84.0)	5 (5.0)	0	0	0	89 (89.0)
Grade 1	0	9 (9.0)	0	0	0	0	9 (9.0)
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	94 (94.0)	6 (6.0)	0	0	0	100 (100)
Day 8							
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 0	0	92 (92.0)	5 (5.0)	0	0	0	97 (97.0)
Grade 1	0	0	1 (1.0)	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (10.0)	0	0	0	0	10 (10.0)
Grade 0	0	81 (81.0)	5 (5.0)	0	0	0	86 (86.0)
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	94 (94.0)	6 (6.0)	0	0	0	100 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (10.0)	0	0	0	0	10 (10.0)
Grade 0	0	90 (90.0)	0	0	0	0	90 (90.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	80 (80.0)	6 (6.0)	0	0	0	86 (86.0)
Grade 1	0	1 (1.0)	13 (13.0)	0	0	0	14 (14.0)
Grade 2	0	0	0	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 8							
UNK	0	0	1 (1.0)	0	0	0	1 (1.0)
Grade 0	0	78 (78.0)	10 (10.0)	0	0	0	88 (88.0)
Grade 1	0	3 (3.0)	8 (8.0)	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 15							
UNK	0	0	0	0	0	0	0
Grade 0	0	77 (77.0)	2 (2.0)	0	0	0	79 (79.0)
Grade 1	0	4 (4.0)	17 (17.0)	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	81 (81.0)	19 (19.0)	0	0	0	100 (100)
Day 29 - Predose							
UNK	0	2 (2.0)	0	0	0	0	2 (2.0)
Grade 0	0	74 (74.0)	5 (5.0)	0	0	0	79 (79.0)
Grade 1	0	5 (5.0)	14 (14.0)	0	0	0	19 (19.0)
Grade 2	0	0	0	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	78 (78.0)	10 (10.0)	0	0	0	88 (88.0)
Grade 1	0	2 (2.0)	9 (9.0)	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	7 (7.0)	3 (3.0)	0	0	0	10 (10.0)
Grade 0	0	71 (71.0)	8 (8.0)	0	0	0	79 (79.0)
Grade 1	0	3 (3.0)	8 (8.0)	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (10.0)	0	0	0	0	10 (10.0)
Grade 0	0	90 (90.0)	0	0	0	0	90 (90.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43							
UNK	0	4 (4.0)	0	0	0	0	4 (4.0)
Grade 0	0	82 (82.0)	7 (7.0)	0	0	0	89 (89.0)
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	92 (92.0)	8 (8.0)	0	0	0	100 (100)
Day 57							
UNK	0	1 (1.0)	0	0	0	0	1 (1.0)
Grade 0	0	87 (87.0)	7 (7.0)	0	0	0	94 (94.0)
Grade 1	0	4 (4.0)	0	0	0	0	4 (4.0)
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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	9 (9.0)	1 (1.0)	0	0	0	10 (10.0)
Grade 0	0	76 (76.0)	5 (5.0)	0	0	0	81 (81.0)
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	1 (1.0)	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)
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

	Baseline							
Timepoint Post-Baseline Grade	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	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

	Baseline							
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)		Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (10.0)	0	0	0	0	10 (10.0)
Grade 0	0	90 (90.0)	0	0	0	0	90 (90.0)
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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	171 (85.5)	3 (1.5)	1 (0.5)	0	0	175 (87.5)
Grade 1	0	7 (3.5)	0	0	0	0	7 (3.5)
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	196 (98.0)	3 (1.5)	1 (0.5)	0	0	200 (100)
Worst Post-Baseline							
UNK	0	0	0	0	0	0	0
Grade 0	0	174 (87.0)	3 (1.5)	1 (0.5)	0	0	178 (89.0)
Grade 1	0	16 (8.0)	0	0	0	0	16 (8.0)
Grade 2	0	6 (3.0)	0	0	0	0	6 (3.0)
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)
Pulse Rate (beats/min) - Bradycardia

	Baseline						
Timepoint Post-Baseline Grade	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	176 (88.0)	5 (2.5)	0	0	0	181 (90.5)
Grade 1	0	3 (1.5)	2 (1.0)	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	193 (96.5)	7 (3.5)	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 43							
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)
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)
Pulse Rate (beats/min) - Tachycardia

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	186 (93.0)	0	0	0	0	186 (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	200 (100)	0	0	0	0	200 (100)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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	163 (81.5)	19 (9.5)	0	0	0	182 (91.0)
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)

UNK = unknown due to missing vital sign result.
Worst post-baseline result is defined as the highest toxicity grade during vaccination stage.
Percentages are based on the number in the cell on the Total row and 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	10 (5.0)	4 (2.0)	0	0	0	14 (7.0)
Grade 0	0	149 (74.5)	16 (8.0)	1 (0.5)	0	0	166 (83.0)
Grade 1	0	9 (4.5)	11 (5.5)	0	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)
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

	Baseline						
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	186 (93.0)	0	0	0	0	186 (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	200 (100)	0	0	0	0	200 (100)
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

	Baseline											
Timepoint	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		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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	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

	Baseline											
Timepoint	UNK		Grade 0		Grade 1		Grade 2		Grade 3		Grade 4		Total	
Post-Baseline Grade	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Day 209														
UNK	0		12	(6.0)	1	(0.5)	0		1	(0.5)	0		14	(7.0)
Grade 0	0		157	(78.5)	10	(5.0)	1	(0.5)	0		0		168	(84.0)
Grade 1	0		13	(6.5)	2	(1.0)	0		0		0		15	(7.5)
Grade 2	0		2	(1.0)	0		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		185	(92.5)	13	(6.5)	1	(0.5)	1	(0.5)	0		200	(100)
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

	Baseline							
Timepoint Post-Baseline Grade	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	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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total 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

	Baseline						
Timepoint Post-Baseline Grade	UNK n (%)	Grade 0 n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Total n (%)
Day 209							
UNK	0	14 (7.0)	0	0	0	0	14 (7.0)
Grade 0	0	186 (93.0)	0	0	0	0	186 (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	200 (100)	0	0	0	0	200 (100)
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 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Overall			
		mRNA-1273		
Timepoint Data Category Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Baseline				
n[1]	186	185	189	374
GM Level	0.67	0.70	0.67	0.68
95% CI [2]	0.61, 0.73	0.63, 0.78	0.60, 0.73	0.63, 0.73
Median	0.50	0.50	0.50	0.50
Min, Max	0.5, 20.4	0.5, 72.0	0.5, 135.5	0.5, 135.5

Notes are listed on last page.
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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Overall			
		mRNA-1273		
Timepoint Data Category Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 29				
n[3]	182	183	189	372
GM Level	0.68	59.42	81.51	69.77
95% CI [2]	0.61, 0.76	52.05, 67.82	70.19, 94.67	63.08, 77.18
Median	0.50	66.30	88.20	75.75
Min, Max	0.5, 144.4	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM Fold-Rise	1.03	85.84	122.40	102.79
95% CI [2]	0.93, 1.15	72.93, 101.03	103.88, 144.23	91.49, 115.50
Seroconversion [4]				
n[5] (%)	11 (6.0)	181 (98.9)	185 (97.9)	366 (98.4)
95% CI [6]	3.1, 10.6	96.1, 99.9	94.7, 99.4	96.5, 99.4
Seroresponse [7]				
n[5] (%)	11 (6.0)	181 (98.9)	185 (97.9)	366 (98.4)
95% CI [6]	3.1, 10.6	96.1, 99.9	94.7, 99.4	96.5, 99.4
>=2-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	182 (99.5)	187 (98.9)	369 (99.2)
95% CI [6]	0.1, 3.9	97.0, 100.0	96.2, 99.9	97.7, 99.8

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Overall			
		mRNA-1273		
Timepoint Data Category Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
>=3-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	182 (99.5)	186 (98.4)	368 (98.9)
95% CI [6]	0.1, 3.9	97.0, 100.0	95.4, 99.7	97.3, 99.7
>=4-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	181 (98.9)	185 (97.9)	366 (98.4)
95% CI [6]	0.1, 3.9	96.1, 99.9	94.7, 99.4	96.5, 99.4

Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 43				
n[3]	180	176	180	356
GM Level	0.65	720.85	834.66	776.31
95% CI [2]	0.59, 0.71	660.30, 786.96	765.28, 910.33	729.73, 825.86
Median	0.50	765.25	896.20	810.00
Min, Max	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0
GM Fold-Rise	0.97	1020.31	1240.91	1126.46
95% CI [2]	0.90, 1.05	887.47, 1173.04	1088.53, 1414.63	1023.64, 1239.59
Seroconversion [4]				
n[5] (%)	3 (1.7)	176 (100)	180 (100)	356 (100)
95% CI [6]	0.3, 4.8	97.9, 100.0	98.0, 100.0	99.0, 100.0
Seroresponse [7]				
n[5] (%)	3 (1.7)	176 (100)	180 (100)	356 (100)
95% CI [6]	0.3, 4.8	97.9, 100.0	98.0, 100.0	99.0, 100.0
>=2-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	176 (100)	180 (100)	356 (100)
95% CI [6]	0.1, 4.0	97.9, 100.0	98.0, 100.0	99.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
>=3-fold Increase from Baseline [8]				
n[5] (%)	1 (0.6)	176 (100)	180 (100)	356 (100)
95% CI [6]	0.0, 3.1	97.9, 100.0	98.0, 100.0	99.0, 100.0
>=4-fold Increase from Baseline [8]				
n[5] (%)	1 (0.6)	176 (100)	180 (100)	356 (100)
95% CI [6]	0.0, 3.1	97.9, 100.0	98.0, 100.0	99.0, 100.0

Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	174	176	174	350
GM Level	0.67	519.48	647.22	579.48
95% CI [2]	0.60, 0.75	474.00, 569.33	588.98, 711.21	542.24, 619.27
Median	0.50	577.80	709.15	632.50
Min, Max	0.5, 67.8	112.3, 2052.0	86.0, 2052.0	86.0, 2052.0
GM Fold-Rise	1.01	732.00	974.31	843.82
95% CI [2]	0.92, 1.11	636.03, 842.45	849.28, 1117.74	764.34, 931.56
Seroconversion [4]				
n[5] (%)	9 (5.2)	176 (100)	174 (100)	350 (100)
95% CI [6]	2.4, 9.6	97.9, 100.0	97.9, 100.0	99.0, 100.0
Seroresponse [7]				
n[5] (%)	9 (5.2)	176 (100)	174 (100)	350 (100)
95% CI [6]	2.4, 9.6	97.9, 100.0	97.9, 100.0	99.0, 100.0
>=2-fold Increase from Baseline [8]				
n[5] (%)	3 (1.7)	176 (100)	174 (100)	350 (100)
95% CI [6]	0.4, 5.0	97.9, 100.0	97.9, 100.0	99.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Overall			
		mRNA-1273		
Timepoint Data Category Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
>=3-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	176 (100)	174 (100)	350 (100)
95% CI [6]	0.1, 4.1	97.9, 100.0	97.9, 100.0	99.0, 100.0
>=4-fold Increase from Baseline [8]				
n[5] (%)	2 (1.1)	176 (100)	174 (100)	350 (100)
95% CI [6]	0.1, 4.1	97.9, 100.0	97.9, 100.0	99.0, 100.0

Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 209				
n[3]	154	170	174	344
GM Level	0.91	97.02	128.00	111.62
95% CI [2]	0.73, 1.14	87.58, 107.47	114.44, 143.18	103.35, 120.55
Median	0.50	94.80	128.15	114.65
Min, Max	0.5, 467.3	13.5, 854.2	19.5, 1362.4	13.5, 1362.4
GM Fold-Rise	1.38	136.84	200.28	165.92
95% CI [2]	1.13, 1.69	117.91, 158.82	173.93, 230.63	149.53, 184.10
Seroconversion [4]				
n[5] (%)	17 (11.0)	169 (99.4)	174 (100)	343 (99.7)
95% CI [6]	6.6, 17.1	96.8, 100.0	97.9, 100.0	98.4, 100.0
Seroresponse [7]				
n[5] (%)	16 (10.4)	169 (99.4)	173 (99.4)	342 (99.4)
95% CI [6]	6.1, 16.3	96.8, 100.0	96.8, 100.0	97.9, 99.9
>=2-fold Increase from Baseline [8]				
n[5] (%)	14 (9.1)	169 (99.4)	174 (100)	343 (99.7)
95% CI [6]	5.1, 14.8	96.8, 100.0	97.9, 100.0	98.4, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	Overall			
		mRNA-1273		
	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
>=3-fold Increase from Baseline [8]				
n[5] (%)	14 (9.1)	169 (99.4)	174 (100)	343 (99.7)
95% CI [6]	5.1, 14.8	96.8, 100.0	97.9, 100.0	98.4, 100.0
>=4-fold Increase from Baseline [8]				
n[5] (%)	14 (9.1)	169 (99.4)	174 (100)	343 (99.7)
95% CI [6]	5.1, 14.8	96.8, 100.0	97.9, 100.0	98.4, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Data Category Statistic	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)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Level	0.69	0.71	0.59	0.65	0.65	0.68	0.75	0.71
95% CI [2]	0.61, 0.79	0.60, 0.85	0.55, 0.64	0.59, 0.71	0.58, 0.73	0.59, 0.78	0.63, 0.89	0.64, 0.80
Median	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Min, Max	0.5, 11.1	0.5, 72.0	0.5, 3.4	0.5, 72.0	0.5, 20.4	0.5, 14.9	0.5, 135.5	0.5, 135.5

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Data Category Statistic	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)
Day 29								
n[3]	88	88	95	183	94	95	94	189
GM Level	0.69	80.82	114.53	96.85	0.67	44.69	57.80	50.79
95% CI [2]	0.59, 0.82	69.20, 94.39	94.82, 138.34	85.50, 109.71	0.57, 0.79	36.73, 54.36	46.67, 71.60	43.94, 58.71
Median	0.50	80.65	134.90	107.10	0.50	46.70	63.15	56.80
Min, Max	0.5, 144.4	15.1, 338.7	0.5, 1666.1	0.5, 1666.1	0.5, 135.8	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM Fold-Rise	1.03	114.89	193.24	150.49	1.04	65.52	77.15	71.07
95% CI [2]	0.87, 1.22	90.98, 145.10	158.77, 235.20	128.89, 175.72	0.91, 1.18	52.71, 81.44	61.22, 97.23	60.70, 83.21
Seroconversion [4]								
n[5] (%)	6 (6.8)	87 (98.9)	94 (98.9)	181 (98.9)	5 (5.3)	94 (98.9)	91 (96.8)	185 (97.9)
95% CI [6]	2.5, 14.3	93.8, 100.0	94.3, 100.0	96.1, 99.9	1.7, 12.0	94.3, 100.0	91.0, 99.3	94.7, 99.4
Seroresponse [7]								
n[5] (%)	6 (6.8)	87 (98.9)	94 (98.9)	181 (98.9)	5 (5.3)	94 (98.9)	91 (96.8)	185 (97.9)
95% CI [6]	2.5, 14.3	93.8, 100.0	94.3, 100.0	96.1, 99.9	1.7, 12.0	94.3, 100.0	91.0, 99.3	94.7, 99.4
>=2-fold Increase from Baseline [8]								
n[5] (%)	1 (1.1)	87 (98.9)	94 (98.9)	181 (98.9)	1 (1.1)	95 (100)	93 (98.9)	188 (99.5)
95% CI [6]	0.0, 6.2	93.8, 100.0	94.3, 100.0	96.1, 99.9	0.0, 5.8	96.2, 100.0	94.2, 100.0	97.1, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=3-fold Increase from Baseline [8]								
n[5] (%)	1 (1.1)	87 (98.9)	94 (98.9)	181 (98.9)	1 (1.1)	95 (100)	92 (97.9)	187 (98.9)
95% CI [6]	0.0, 6.2	93.8, 100.0	94.3, 100.0	96.1, 99.9	0.0, 5.8	96.2, 100.0	92.5, 99.7	96.2, 99.9
>=4-fold Increase from Baseline [8]								
n[5] (%)	1 (1.1)	87 (98.9)	94 (98.9)	181 (98.9)	1 (1.1)	94 (98.9)	91 (96.8)	185 (97.9)
95% CI [6]	0.0, 6.2	93.8, 100.0	94.3, 100.0	96.1, 99.9	0.0, 5.8	94.3, 100.0	91.0, 99.3	94.7, 99.4

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Data Category Statistic	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)
Day 43								
n[3]	87	84	93	177	93	92	87	179
GM Level	0.62	760.95	937.29	849.02	0.67	686.09	737.34	710.54
95% CI [2]	0.55, 0.70	678.54, 853.38	852.64, 1030.34	787.99, 914.78	0.58, 0.79	600.95, 783.28	637.24, 853.16	644.53, 783.30
Median	0.50	759.80	961.00	849.40	0.50	767.30	823.70	778.10
Min, Max	0.5, 8.5	164.3, 2052.0	199.5, 2052.0	164.3, 2052.0	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0
GM Fold-Rise	0.91	1047.83	1575.67	1298.33	1.04	995.82	961.30	978.89
95% CI [2]	0.82, 1.00	843.27, 1302.02	1396.86, 1777.37	1147.51, 1468.96	0.92, 1.16	829.77, 1195.09	764.28, 1209.12	847.40, 1130.79
Seroconversion [4]								
n[5] (%)	0	84 (100)	93 (100)	177 (100)	3 (3.2)	92 (100)	87 (100)	179 (100)
95% CI [6]	0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.7, 9.1	96.1, 100.0	95.8, 100.0	98.0, 100.0
Seroresponse [7]								
n[5] (%)	0	84 (100)	93 (100)	177 (100)	3 (3.2)	92 (100)	87 (100)	179 (100)
95% CI [6]	0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.7, 9.1	96.1, 100.0	95.8, 100.0	98.0, 100.0
>=2-fold Increase from Baseline [8]								
n[5] (%)	1 (1.1)	84 (100)	93 (100)	177 (100)	1 (1.1)	92 (100)	87 (100)	179 (100)
95% CI [6]	0.0, 6.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	96.1, 100.0	95.8, 100.0	98.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=3-fold Increase from Baseline [8]								
n[5] (%)	0	84 (100)	93 (100)	177 (100)	1 (1.1)	92 (100)	87 (100)	179 (100)
95% CI [6]	0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	96.1, 100.0	95.8, 100.0	98.0, 100.0
>=4-fold Increase from Baseline [8]								
n[5] (%)	0	84 (100)	93 (100)	177 (100)	1 (1.1)	92 (100)	87 (100)	179 (100)
95% CI [6]	0.0, 4.2	95.7, 100.0	96.1, 100.0	97.9, 100.0	0.0, 5.8	96.1, 100.0	95.8, 100.0	98.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 57								
n[3]	83	84	85	169	91	92	89	181
GM Level	0.68	566.56	772.04	661.97	0.66	479.93	546.89	511.76
95% CI [2]	0.57, 0.80	502.80, 638.40	694.74, 857.93	609.71, 718.70	0.57, 0.77	418.32, 550.60	471.66, 634.13	462.90, 565.78
Median	0.50	586.20	827.50	667.20	0.50	549.55	653.10	577.00
Min, Max	0.5, 67.8	165.7, 2052.0	135.3, 2052.0	135.3, 2052.0	0.5, 56.4	112.3, 2052.0	86.0, 1927.8	86.0, 2052.0
GM Fold-Rise	0.98	772.86	1319.00	1011.25	1.03	696.58	729.56	712.61
95% CI [2]	0.84, 1.14	619.81, 963.70	1165.49, 1492.72	886.84, 1153.11	0.92, 1.16	581.00, 835.16	580.97, 916.14	617.22, 822.73
Seroconversion [4]								
n[5] (%)	5 (6.0)	84 (100)	85 (100)	169 (100)	4 (4.4)	92 (100)	89 (100)	181 (100)
95% CI [6]	2.0, 13.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	1.2, 10.9	96.1, 100.0	95.9, 100.0	98.0, 100.0
Seroresponse [7]								
n[5] (%)	5 (6.0)	84 (100)	85 (100)	169 (100)	4 (4.4)	92 (100)	89 (100)	181 (100)
95% CI [6]	2.0, 13.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	1.2, 10.9	96.1, 100.0	95.9, 100.0	98.0, 100.0
>=2-fold Increase from Baseline [8]								
n[5] (%)	2 (2.4)	84 (100)	85 (100)	169 (100)	1 (1.1)	92 (100)	89 (100)	181 (100)
95% CI [6]	0.3, 8.4	95.7, 100.0	95.8, 100.0	97.8, 100.0	0.0, 6.0	96.1, 100.0	95.9, 100.0	98.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
>=3-fold Increase from Baseline [8]								
n[5] (%)	1 (1.2)	84 (100)	85 (100)	169 (100)	1 (1.1)	92 (100)	89 (100)	181 (100)
95% CI [6]	0.0, 6.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	0.0, 6.0	96.1, 100.0	95.9, 100.0	98.0, 100.0
>=4-fold Increase from Baseline [8]								
n[5] (%)	1 (1.2)	84 (100)	85 (100)	169 (100)	1 (1.1)	92 (100)	89 (100)	181 (100)
95% CI [6]	0.0, 6.5	95.7, 100.0	95.8, 100.0	97.8, 100.0	0.0, 6.0	96.1, 100.0	95.9, 100.0	98.0, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

Timepoint Data Category Statistic	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)	Placebo (N=94)	50 µg (N=95)	100 µg (N=94)	Total (N=189)
Day 209								
n[3]	74	80	90	170	80	90	84	174
GM Level	0.96	104.13	132.94	118.50	0.86	91.11	122.92	105.28
95% CI [2]	0.69, 1.35	89.86, 120.66	113.31, 155.97	106.18, 132.26	0.63, 1.17	78.93, 105.16	104.78, 144.19	94.48, 117.32
Median	0.50	94.80	131.90	116.85	0.50	96.00	126.75	107.50
Min, Max	0.5, 467.3	29.0, 854.2	19.5, 1006.2	19.5, 1006.2	0.5, 446.9	13.5, 419.6	20.4, 1362.4	13.5, 1362.4
GM Fold-Rise	1.43	142.13	223.91	180.79	1.33	132.31	177.72	152.57
95% CI [2]	1.07, 1.91	111.65, 180.91	188.45, 266.05	155.89, 209.68	1.00, 1.79	109.82, 159.41	141.58, 223.10	131.80, 176.60
Seroconversion [4]								
n[5] (%)	9 (12.2)	79 (98.8)	90 (100)	169 (99.4)	8 (10.0)	90 (100)	84 (100)	174 (100)
95% CI [6]	5.7, 21.8	93.2, 100.0	96.0, 100.0	96.8, 100.0	4.4, 18.8	96.0, 100.0	95.7, 100.0	97.9, 100.0
Seroresponse [7]								
n[5] (%)	8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	8 (10.0)	90 (100)	83 (98.8)	173 (99.4)
95% CI [6]	4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	4.4, 18.8	96.0, 100.0	93.5, 100.0	96.8, 100.0
>=2-fold Increase from Baseline [8]								
n[5] (%)	8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	6 (7.5)	90 (100)	84 (100)	174 (100)
95% CI [6]	4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	2.8, 15.6	96.0, 100.0	95.7, 100.0	97.9, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Data Category Statistic	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)
>=3-fold Increase from Baseline [8]								
n[5] (%)	8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	6 (7.5)	90 (100)	84 (100)	174 (100)
95% CI [6]	4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	2.8, 15.6	96.0, 100.0	95.7, 100.0	97.9, 100.0
>=4-fold Increase from Baseline [8]								
n[5] (%)	8 (10.8)	79 (98.8)	90 (100)	169 (99.4)	6 (7.5)	90 (100)	84 (100)	174 (100)
95% CI [6]	4.8, 20.2	93.2, 100.0	96.0, 100.0	96.8, 100.0	2.8, 15.6	96.0, 100.0	95.7, 100.0	97.9, 100.0

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Table 14.2.1.1.12.1
Summary of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals. ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.
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 bAb 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 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.
[4] Seroconversion at participant level is defined as a change of bAb level 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 bAb levels.
[5] Number of subjects in the corresponding category at the corresponding time point.
[6] 95% CI is calculated using the Clopper-Pearson method.
[7] Seroresponse specific to SARS-CoV-2 spike protein measured by ELISA at a subject level is defined as a change from below the LLOQ to equal or above the LLOQ, or at least a 4.6-fold rise if baseline is equal to or above the LLOQ.
[8] >=z-fold increase from baseline at participant level is defined as a >= z x LLOQ for participants with baseline antibody level below the LLOQ, or a z-times or higher ratio in participants with pre-existing bAb levels.

Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	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]	0.67	0.70	0.67	0.68
95% CI [2]	0.61, 0.74	0.63, 0.77	0.60, 0.73	0.64, 0.73
Median	0.50	0.50	0.50	0.50
Min, Max	0.5, 20.4	0.5, 72.0	0.5, 135.5	0.5, 135.5
Day 29				
n[3]	182	183	189	372
GM Value [2]	0.69	59.41	81.67	69.84
95% CI [2]	0.61, 0.78	52.36, 67.40	72.14, 92.46	63.87, 76.37
Median	0.50	66.30	88.20	75.75
Min, Max	0.5, 144.4	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM Fold-Rise [2]	1.03	88.32	121.41	103.83
95% CI [2]	0.91, 1.17	77.85, 100.20	107.24, 137.46	94.95, 113.53
Day 43				
n[3]	180	176	180	356
GM Value [2]	0.65	716.56	835.70	774.54
95% CI [2]	0.60, 0.71	655.83, 782.92	765.66, 912.14	727.60, 824.51
Median	0.50	765.25	896.20	810.00
Min, Max	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0
GM Fold-Rise [2]	0.96	1051.79	1226.66	1136.89
95% CI [2]	0.88, 1.04	962.65, 1149.19	1123.86, 1338.87	1068.00, 1210.23

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Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	174	176	174	350
GM Value [2]	0.68	516.73	651.75	579.99
95% CI [2]	0.61, 0.74	469.89, 568.24	592.39, 717.05	541.85, 620.81
Median	0.50	577.80	709.15	632.50
Min, Max	0.5, 67.8	112.3, 2052.0	86.0, 2052.0	86.0, 2052.0
GM Fold-Rise [2]	0.99	760.75	959.52	853.88
95% CI [2]	0.90, 1.09	691.79, 836.58	872.13, 1055.67	797.73, 913.98
Day 209				
n[3]	154	170	174	344
GM Value [2]	0.92	95.68	129.42	111.49
95% CI [2]	0.79, 1.07	82.70, 110.71	112.06, 149.47	100.57, 123.60
Median	0.50	94.80	128.15	114.65
Min, Max	0.5, 467.3	13.5, 854.2	19.5, 1362.4	13.5, 1362.4
GM Fold-Rise [2]	1.37	143.19	193.67	166.84
95% CI [2]	1.18, 1.60	123.76, 165.67	167.69, 223.68	150.50, 184.96

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Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Baseline								
n[1]	92	90	95	185	94	95	94	189
GM Value [2]	0.69	0.71	0.59	0.65	0.65	0.68	0.75	0.71
95% CI [2]	0.61, 0.79	0.63, 0.82	0.52, 0.67	0.59, 0.71	0.56, 0.75	0.59, 0.79	0.65, 0.87	0.65, 0.79
Median	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Min, Max	0.5, 11.1	0.5, 72.0	0.5, 3.4	0.5, 72.0	0.5, 20.4	0.5, 14.9	0.5, 135.5	0.5, 135.5
Day 29								
n[3]	88	88	95	183	94	95	94	189
GM Value [2]	0.69	79.74	116.57	97.07	0.69	44.96	55.85	50.07
95% CI [2]	0.58, 0.82	67.12, 94.74	98.71, 137.65	86.00, 109.58	0.58, 0.83	37.62, 53.73	46.66, 66.84	44.10, 56.84
Median	0.50	80.65	134.90	107.10	0.50	46.70	63.15	56.80
Min, Max	0.5, 144.4	15.1, 338.7	0.5, 1666.1	0.5, 1666.1	0.5, 135.8	5.8, 440.5	0.5, 2052.0	0.5, 2052.0
GM Fold-Rise [2]	1.06	122.06	178.42	148.59	1.00	65.00	80.74	72.38
95% CI [2]	0.89, 1.25	102.74, 145.02	151.10, 210.69	131.63, 167.73	0.84, 1.20	54.38, 77.69	67.46, 96.63	63.76, 82.18

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Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 43								
n[3]	87	84	93	177	93	92	87	179
GM Value [2]	0.62	746.12	960.00	851.52	0.69	688.53	720.30	703.75
95% CI [2]	0.55, 0.69	669.69, 831.27	866.12, 1064.05	789.49, 918.42	0.60, 0.79	599.91, 790.25	624.91, 830.26	637.60, 776.77
Median	0.50	759.80	961.00	849.40	0.50	767.30	823.70	778.10
Min, Max	0.5, 8.5	164.3, 2052.0	199.5, 2052.0	164.3, 2052.0	0.5, 73.3	148.8, 2052.0	82.7, 2052.0	82.7, 2052.0
GM Fold-Rise [2]	0.93	1124.21	1446.47	1283.01	0.98	985.31	1030.77	1007.09
95% CI [2]	0.84, 1.03	1009.05, 1252.50	1305.01, 1603.25	1189.55, 1383.82	0.86, 1.13	858.48, 1130.87	894.26, 1188.12	912.42, 1111.58
Day 57								
n[3]	83	84	85	169	91	92	89	181
GM Value [2]	0.67	554.94	794.05	664.15	0.67	480.34	536.41	507.08
95% CI [2]	0.59, 0.76	488.29, 630.69	698.93, 902.10	605.52, 728.45	0.59, 0.78	418.10, 551.84	465.69, 617.88	459.25, 559.89
Median	0.50	586.20	827.50	667.20	0.50	549.55	653.10	577.00
Min, Max	0.5, 67.8	165.7, 2052.0	135.3, 2052.0	135.3, 2052.0	0.5, 56.4	112.3, 2052.0	86.0, 1927.8	86.0, 2052.0
GM Fold-Rise [2]	1.01	832.87	1191.73	996.77	0.98	694.68	775.77	733.35
95% CI [2]	0.89, 1.15	732.84, 946.56	1048.98, 1353.91	908.78, 1093.28	0.85, 1.12	604.67, 798.09	673.49, 893.59	664.18, 809.72

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Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 209								
n[3]	74	80	90	170	80	90	84	174
GM Value [2]	0.96	100.34	138.11	118.81	0.87	90.72	122.27	104.78
95% CI [2]	0.77, 1.20	81.02, 124.26	112.88, 168.99	102.55, 137.64	0.70, 1.08	74.18, 110.94	99.28, 150.59	90.58, 121.21
Median	0.50	94.80	131.90	116.85	0.50	96.00	126.75	107.50
Min, Max	0.5, 467.3	29.0, 854.2	19.5, 1006.2	19.5, 1006.2	0.5, 446.9	13.5, 419.6	20.4, 1362.4	13.5, 1362.4
GM Fold-Rise [2]	1.45	151.90	209.08	179.85	1.29	134.27	180.97	155.08
95% CI [2]	1.16, 1.81	122.66, 188.10	170.88, 255.82	155.25, 208.36	1.04, 1.59	109.79, 164.20	146.94, 222.88	134.06, 179.39

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Table 14.2.1.2.12.1
Analysis of Binding Antibody Levels Specific to SARS-CoV-2 Spike Protein by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

bAb = Binding antibody. GM = Geometric Mean. CI = Confidence intervals. ELISA = enzyme-linked immunosorbent assay. 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 if actual values are not available. 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 14.2.2.1.1.1
Summary of Neutralizing Antibody Titers
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Antibody: MN Endpoint Titer

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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
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
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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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
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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	50 µg (N=89)	100 µg (N=91)	Total (N=180)
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

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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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
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
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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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
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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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

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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. 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] 95% CI is calculated based on the t-distribution of the log-transformed values for GMT, 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.

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

	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
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
Day 29				
n[3]	184	184	187	371
GMT	21.9	112.2	149.6	129.7
95% CI [2]	20.5, 23.5	94.9, 132.7	127.3, 175.9	115.4, 145.8
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
Day 43				
n[3]	180	174	181	355
GMT	21.2	1145.4	1185.8	1165.8
95% CI [2]	20.1, 22.4	1101.3, 1191.1	1142.9, 1230.3	1135.0, 1197.5
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280
Day 57				
n[3]	175	176	177	353
GMT	21.8	1090.6	1095.5	1093.1
95% CI [2]	20.4, 23.4	1038.9, 1144.9	1041.5, 1152.2	1055.6, 1131.8
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280

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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 209				
n[3]	153	171	174	345
GMT	85.3	254.4	354.8	300.9
95% CI [2]	80.6, 90.2	219.4, 294.9	309.2, 407.2	271.7, 333.2
Median	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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
Day 29								
n[3]	90	89	94	183	94	95	93	188
GMT	20.9	126.4	183.4	153.0	22.9	100.4	121.8	110.4
95% CI [2]	19.2, 22.7	100.8, 158.5	147.1, 228.7	130.6, 179.4	20.6, 25.5	78.3, 128.6	96.5, 153.8	93.2, 130.9
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
Day 43								
n[3]	87	83	94	177	93	91	87	178
GMT	20.0	1127.7	1232.7	1182.3	22.5	1161.7	1137.2	1149.7
95% CI [2]	NE, NE	1055.8, 1204.5	1201.8, 1264.3	1142.8, 1223.2	20.3, 24.9	1109.6, 1216.2	1058.9, 1221.4	1102.7, 1198.6
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GMT	21.5	1066.9	1135.2	1101.1	22.1	1112.8	1058.5	1085.6
95% CI [2]	19.4, 23.9	988.5, 1151.5	1072.4, 1201.6	1050.4, 1154.2	20.1, 24.3	1045.4, 1184.5	973.9, 1150.3	1031.1, 1143.0
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
Day 209								
n[3]	74	81	90	171	79	90	84	174
GMT	85.6	273.2	375.3	322.9	85.0	238.6	334.1	280.7
95% CI [2]	78.7, 93.0	221.6, 336.8	313.1, 449.9	281.2, 370.8	78.8, 91.7	193.0, 294.8	270.3, 413.0	241.5, 326.3
Median	80.0	240.0	400.0	320.0	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280	80, 960	80, 1280	80, 1280	80, 1280

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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

	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
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
Day 29				
n[3]	184	184	187	371
GMT	49.231	173.750	227.433	199.004
95% CI [2]	46.355, 52.285	148.550, 203.225	194.207, 266.343	177.992, 222.496
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
Day 43				
n[3]	180	174	181	355
GMT	48.059	1761.660	1813.480	1787.893
95% CI [2]	45.820, 50.408	1690.216, 1836.124	1741.280, 1888.673	1736.969, 1840.310
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
Day 57				
n[3]	175	176	177	353
GMT	49.141	1632.442	1656.064	1644.244
95% CI [2]	46.267, 52.194	1550.245, 1718.998	1570.464, 1746.330	1584.736, 1705.987
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

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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 209				
n[3]	153	171	174	345
GMT	167.002	401.508	538.798	465.710
95% CI [2]	159.249, 175.133	350.667, 459.720	472.772, 614.045	423.548, 512.069
Median	159.230	339.411	678.823	495.361
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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
Day 29								
n[3]	90	89	94	183	94	95	93	188
GMT	47.301	184.278	272.772	225.405	51.152	164.433	189.259	176.278
95% CI [2]	43.885, 50.982	147.555, 230.140	220.239, 337.837	192.975, 263.285	46.555, 56.203	131.409, 205.756	150.303, 238.312	150.281, 206.773
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	164.468
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
Day 43								
n[3]	87	83	94	177	93	91	87	178
GMT	45.550	1727.866	1902.388	1818.457	50.532	1793.060	1722.081	1758.010
95% CI [2]	NE, NE	1610.014, 1854.343	1844.760, 1961.817	1751.994, 1887.442	46.091, 55.400	1710.583, 1879.514	1594.239, 1860.175	1681.683, 1837.802
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	1917.830
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GMT	48.508	1584.249	1704.173	1644.169	49.733	1677.724	1610.851	1644.315
95% CI [2]	44.389, 53.009	1459.163, 1720.058	1602.726, 1812.040	1562.671, 1729.917	45.745, 54.069	1571.714, 1790.885	1477.046, 1756.777	1558.391, 1734.977
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
Day 209								
n[3]	74	81	90	171	79	90	84	174
GMT	167.803	435.677	558.848	496.678	166.255	373.053	518.114	437.158
95% CI [2]	155.864, 180.658	359.609, 527.836	468.470, 666.661	436.142, 565.615	156.199, 176.960	307.612, 452.415	425.305, 631.174	380.508, 502.241
Median	159.230	452.548	678.823	565.685	159.230	339.411	622.254	452.548
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

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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. 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. Vast majority samples at Baseline, Day 29, Day 43 and Day 57 were tested using the first viral lot; all samples at Day 209 were tested using the new viral lot.
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 for GMT, 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.

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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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
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

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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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

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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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
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

Notes are listed on last page.
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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=181)	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

Notes are listed on last page.
Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\t140202020101.sas 19JUL2021 20:34 Database Lock Date: 10JUN2021

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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	Placebo (N=92)	50 µg (N=90)	100 µg (N=95)	Total (N=185)	Placebo (N=89)	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]	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

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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. 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 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

	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
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	184	187	371
GMT [2]	21.9	112.8	149.9	130.2
95% CI [2]	19.1, 25.1	98.3, 129.5	130.7, 171.9	118.0, 143.6
Median	20.0	120.0	160.0	160.0
Min, Max	20, 960	20, 1280	20, 1280	20, 1280
Day 43				
n[3]	180	174	181	355
GMT [2]	21.2	1145.9	1187.2	1166.8
95% CI [2]	20.3, 22.1	1097.5, 1196.5	1138.0, 1238.5	1132.1, 1202.6
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 960	240, 1280	160, 1280	160, 1280

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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GMT [2]	21.8	1092.2	1095.1	1093.7
95% CI [2]	20.6, 23.1	1032.3, 1155.6	1035.3, 1158.4	1051.0, 1138.1
Median	20.0	1280.0	1280.0	1280.0
Min, Max	20, 640	240, 1280	200, 1280	200, 1280
Day 209				
n[3]	153	171	174	345
GMT [2]	85.5	255.0	353.8	300.7
95% CI [2]	75.1, 97.3	225.6, 288.2	313.3, 399.5	275.6, 328.2
Median	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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	95	93	188
GMT [2]	20.9	125.8	183.8	152.9	22.7	101.6	121.7	111.1
95% CI [2]	17.3, 25.3	104.0, 152.2	152.8, 221.3	133.7, 174.9	18.6, 27.7	83.2, 124.0	99.5, 148.9	96.4, 128.0
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
Day 43								
n[3]	87	83	94	177	93	91	87	178
GMT [2]	20.0	1126.5	1233.3	1182.1	22.3	1168.7	1136.3	1152.7
95% CI [2]	19.2, 20.8	1082.3, 1172.6	1187.8, 1280.5	1149.7, 1215.5	20.8, 24.1	1084.9, 1258.8	1053.1, 1226.0	1093.1, 1215.5
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GMT [2]	21.6	1065.3	1136.0	1100.8	22.0	1119.2	1055.7	1087.3
95% CI [2]	19.9, 23.4	982.3, 1155.3	1049.1, 1230.1	1040.0, 1165.0	20.3, 23.8	1034.2, 1211.1	974.8, 1143.4	1028.0, 1150.0
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
Day 209								
n[3]	74	81	90	171	79	90	84	174
GMT [2]	85.4	274.4	374.5	323.3	85.1	238.5	333.7	280.4
95% CI [2]	71.4, 102.1	231.1, 325.8	318.3, 440.6	286.9, 364.3	70.5, 102.8	200.0, 284.4	278.0, 400.6	246.6, 318.8
Median	80.0	240.0	400.0	320.0	80.0	240.0	400.0	320.0
Min, Max	80, 960	80, 1280	80, 1280	80, 1280	80, 960	80, 1280	80, 1280	80, 1280

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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

	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
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	184	187	371
GMT [2]	49.051	174.958	227.611	199.776
95% CI [2]	43.023, 55.923	153.457, 199.472	199.858, 259.218	182.053, 219.225
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
Day 43				
n[3]	180	174	181	355
GMT [2]	47.946	1764.932	1814.532	1790.055
95% CI [2]	45.983, 49.993	1691.449, 1841.608	1740.446, 1891.773	1737.574, 1844.122
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

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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

	Overall			
		mRNA-1273		
Timepoint Statistic	Placebo (N=186)	50 µg (N=185)	100 µg (N=189)	Total (N=374)
Day 57				
n[3]	175	176	177	353
GMT [2]	49.074	1635.961	1654.778	1645.375
95% CI [2]	46.467, 51.828	1549.257, 1727.518	1567.369, 1747.061	1583.380, 1709.798
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
Day 209				
n[3]	153	171	174	345
GMT [2]	167.419	402.347	537.509	465.552
95% CI [2]	148.454, 188.807	359.154, 450.734	480.217, 601.636	429.365, 504.790
Median	159.230	339.411	678.823	495.361
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
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	95	93	188
GMT [2]	47.408	183.418	273.390	225.238	50.431	167.057	188.918	177.545
95% CI [2]	39.454, 56.966	152.431, 220.704	228.419, 327.215	197.640, 256.690	41.826, 60.806	138.684, 201.234	156.547, 227.982	155.559, 202.639
Median	45.550	226.274	339.411	282.843	45.550	159.230	169.706	164.468
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
Day 43								
n[3]	87	83	94	177	93	91	87	178
GMT [2]	45.578	1725.526	1903.571	1818.079	50.224	1806.617	1719.761	1763.590
95% CI [2]	43.670, 47.570	1651.450, 1802.924	1826.845, 1983.519	1763.466, 1874.384	46.822, 53.873	1682.904, 1939.424	1599.520, 1849.040	1676.439, 1855.271
Median	45.550	2031.870	2031.870	2031.870	45.550	2031.870	1917.830	1917.830
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

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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

	Cohort 1 (Age >= 18 and age < 55)				Cohort 2 (Age >= 55)			
		mRNA-1273				mRNA-1273		
Timepoint Statistic	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)
Day 57								
n[3]	84	84	87	171	91	92	90	182
GMT [2]	48.534	1582.543	1705.075	1643.863	49.531	1689.694	1605.779	1647.610
95% CI [2]	44.898, 52.464	1463.766, 1710.959	1579.487, 1840.648	1556.454, 1736.180	45.865, 53.491	1565.152, 1824.145	1486.310, 1734.851	1560.455, 1739.632
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
Day 209								
n[3]	74	81	90	171	79	90	84	174
GMT [2]	167.630	436.589	558.271	497.014	166.673	372.775	517.305	436.539
95% CI [2]	141.600, 198.446	371.423, 513.188	479.048, 650.595	444.431, 555.817	140.200, 198.145	317.246, 438.024	437.643, 611.468	388.040, 491.100
Median	159.230	452.548	678.823	565.685	159.230	339.411	622.254	452.548
Min, Max	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83	159.23, 1357.65	159.23, 1917.83	159.23, 1917.83	159.23, 1917.83

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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. 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. Vast majority samples at Baseline, Day 29, Day 43 and Day 57 were tested using the first viral lot; all samples at Day 209 were tested using the new viral lot.
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 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 14.2.3.1
Summary of SARS-CoV-2 Test by RT-PCR
Safety Set

	Overall			
		mRNA-1273		
	Placebo (N=200) n (%)	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	23 (11.5)	3 (1.5)	2 (1.0)	5 (1.3)
Not Detected	177 (88.5)	197 (98.5)	198 (99.0)	395 (98.8)
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)
Day 71 or Beyond				
n [2]	47 (23.5)	59 (29.5)	39 (19.5)	98 (24.5)
Detected	19 (9.5)	2 (1.0)	2 (1.0)	4 (1.0)
Not Detected	28 (14.0)	57 (28.5)	37 (18.5)	94 (23.5)

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 (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 (%)
Overall [1]								
n [2]	100 (100)	100 (100)	100 (100)	200 (100)	100 (100)	100 (100)	100 (100)	200 (100)
Detected	15 (15.0)	3 (3.0)	1 (1.0)	4 (2.0)	8 (8.0)	0	1 (1.0)	1 (0.5)
Not Detected	85 (85.0)	97 (97.0)	99 (99.0)	196 (98.0)	92 (92.0)	100 (100)	99 (99.0)	199 (99.5)
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)
Day 71 or Beyond								
n [2]	27 (27.0)	38 (38.0)	21 (21.0)	59 (29.5)	20 (20.0)	21 (21.0)	18 (18.0)	39 (19.5)
Detected	12 (12.0)	2 (2.0)	1 (1.0)	3 (1.5)	7 (7.0)	0	1 (1.0)	1 (0.5)
Not Detected	15 (15.0)	36 (36.0)	20 (20.0)	56 (28.0)	13 (13.0)	21 (21.0)	17 (17.0)	38 (19.0)

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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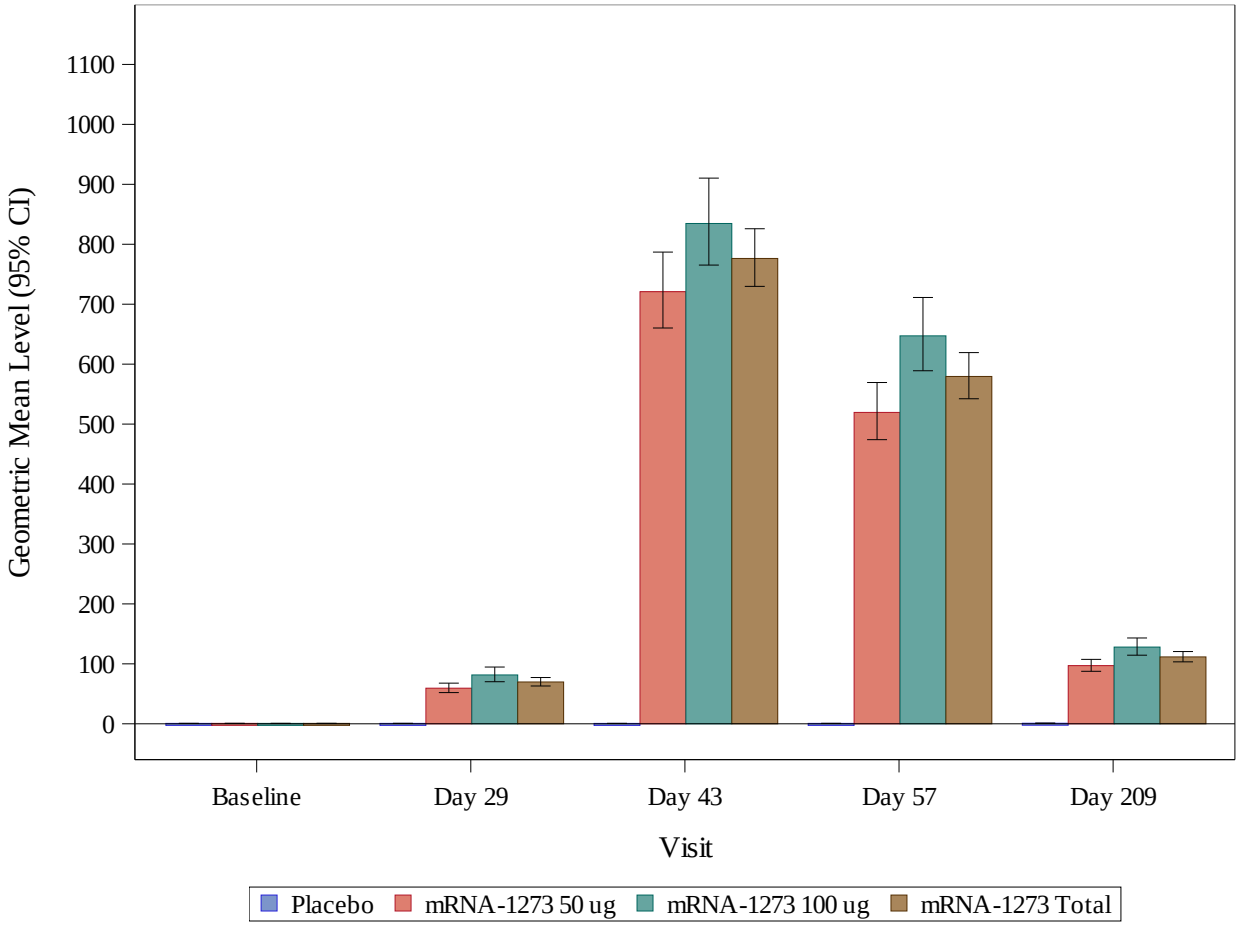
Figure 14.2.1.11.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

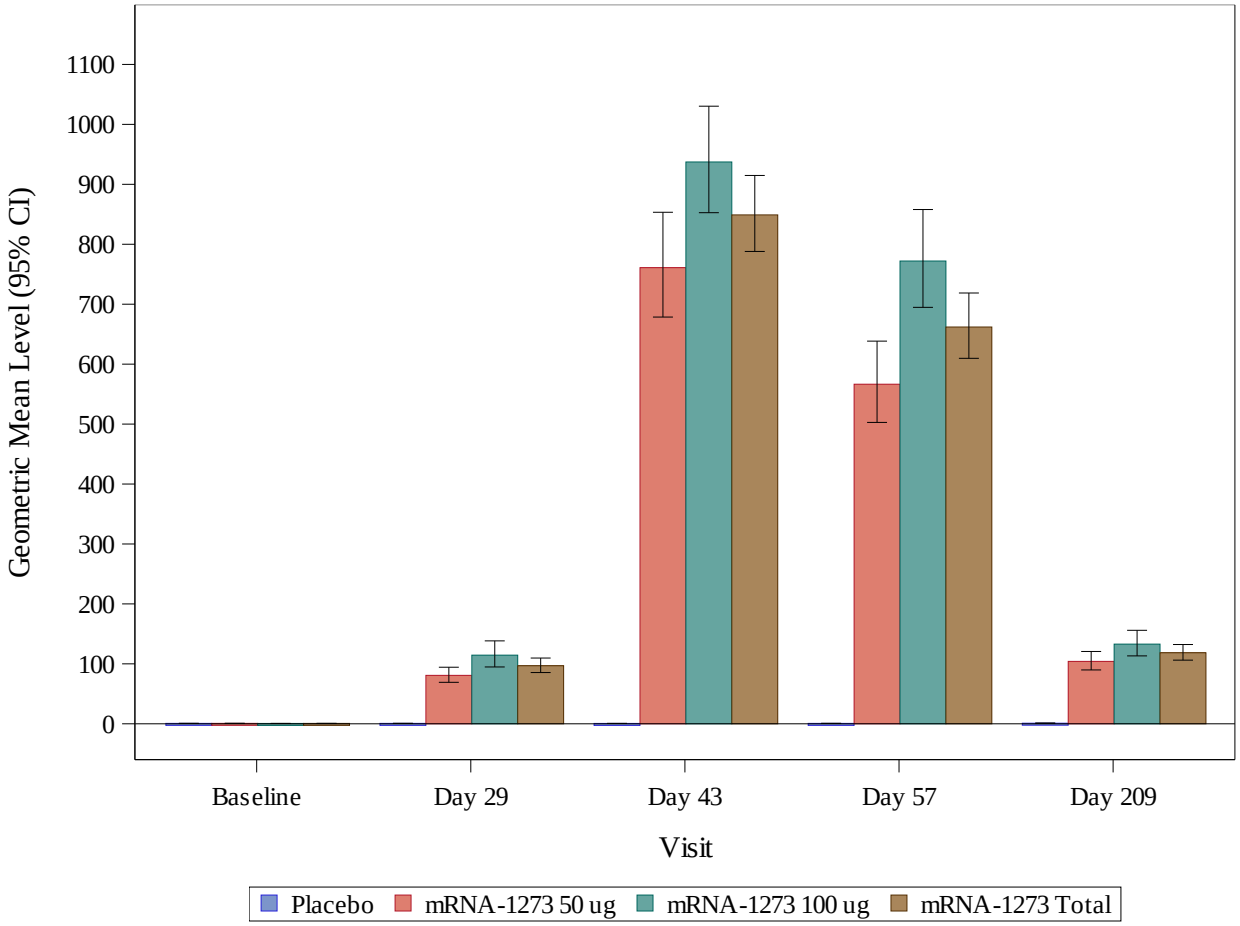


Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402011101.sas 19JUL2021 22:57 Database Lock Date: 10JUN2021

Figure 14.2.1.11.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

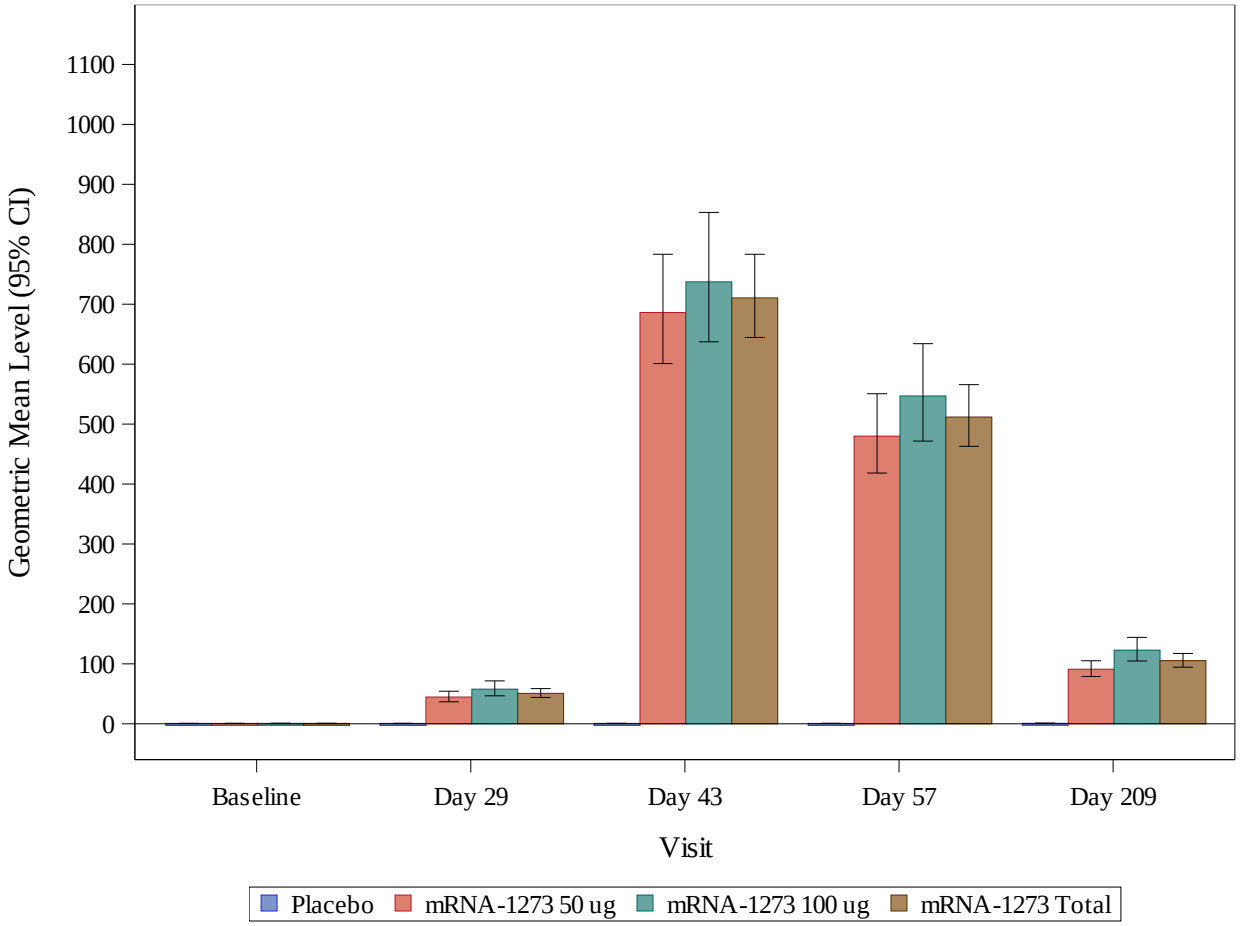


Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402011101.sas 19JUL2021 22:57 Database Lock Date: 10JUN2021

Figure 14.2.1.11.1
Geometric Mean Levels of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

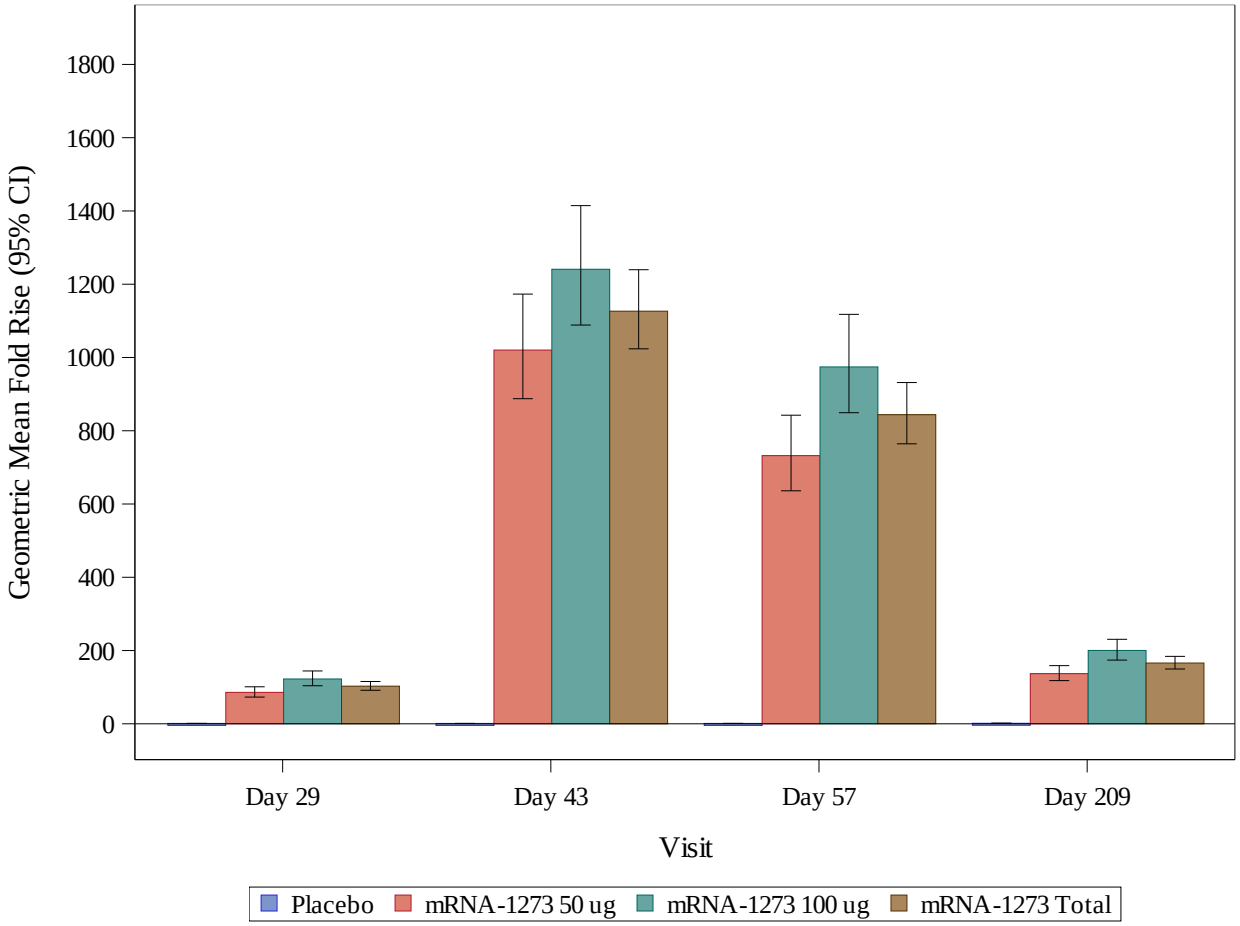


Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402011101.sas 19JUL2021 22:57 Database Lock Date: 10JUN2021

Figure 14.2.2.11.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

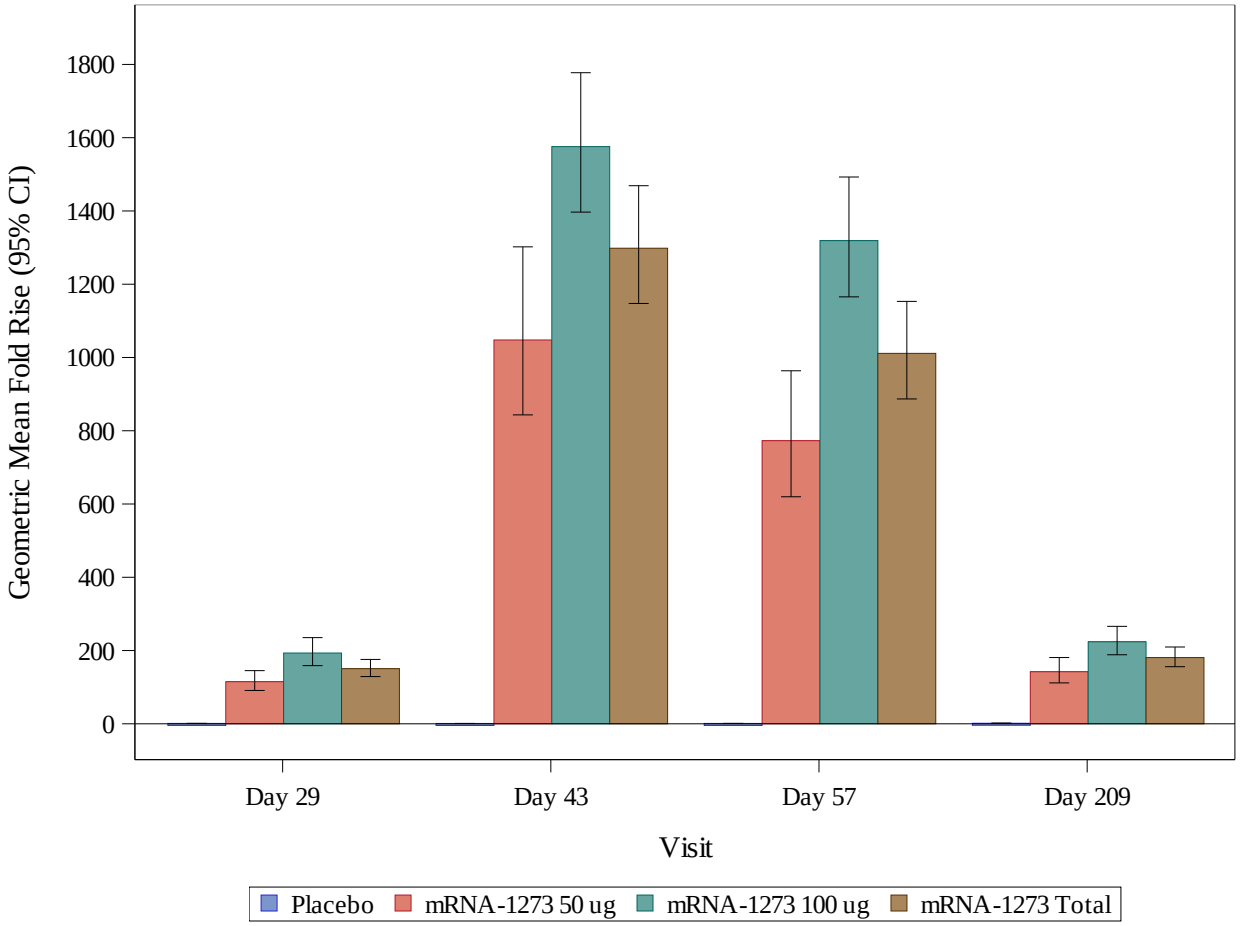
Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.
Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Figure 14.2.2.11.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)

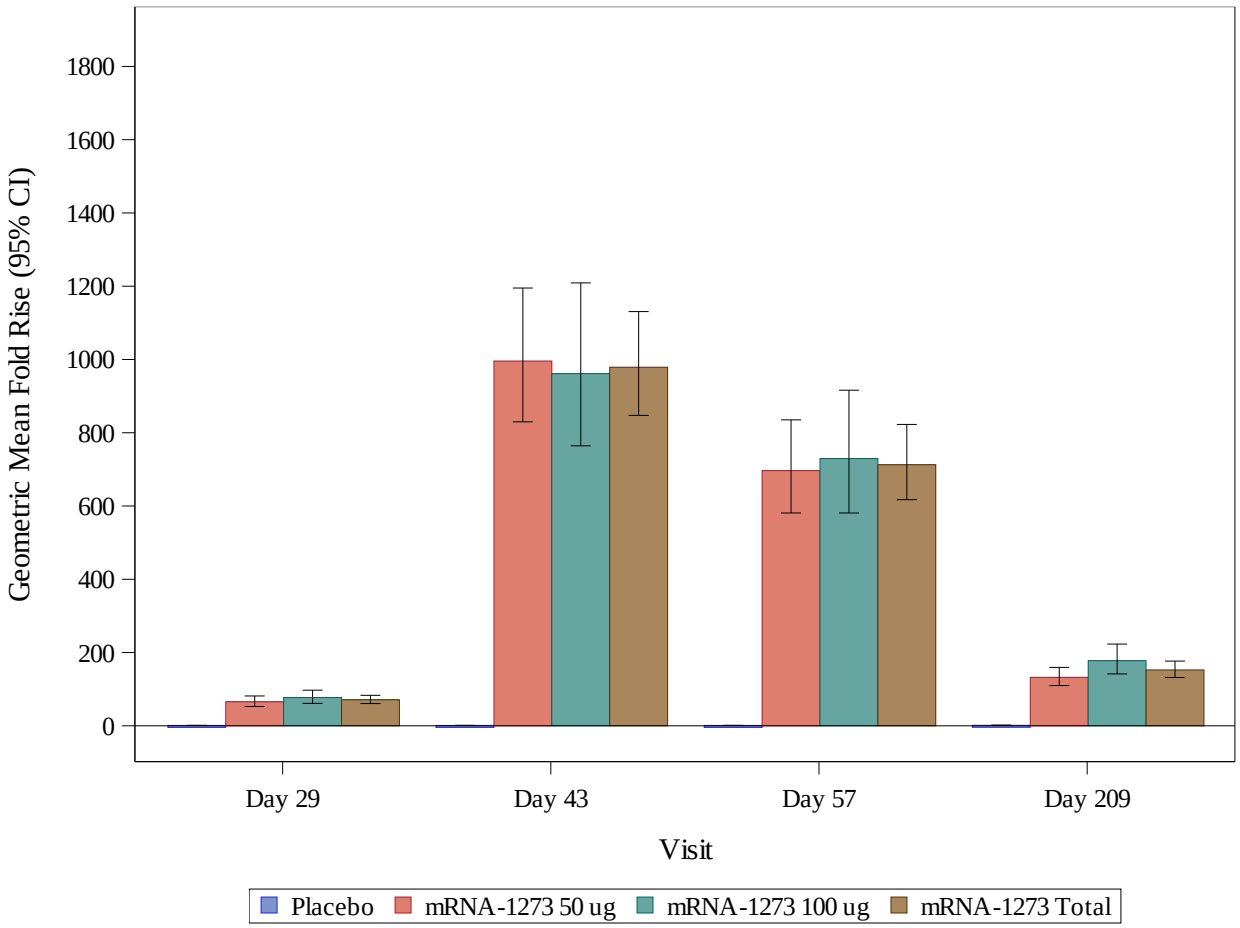


Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Confidence intervals (CIs) are calculated using t-distribution of log transformed values then back transformed to the original scale for presentation.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402021101.sas 19JUL2021 22:57 Database Lock Date: 10JUN2021

Figure 14.2.2.11.1
Geometric Mean Fold Rise of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



Source table: T14.2.1.1.12.1
bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.
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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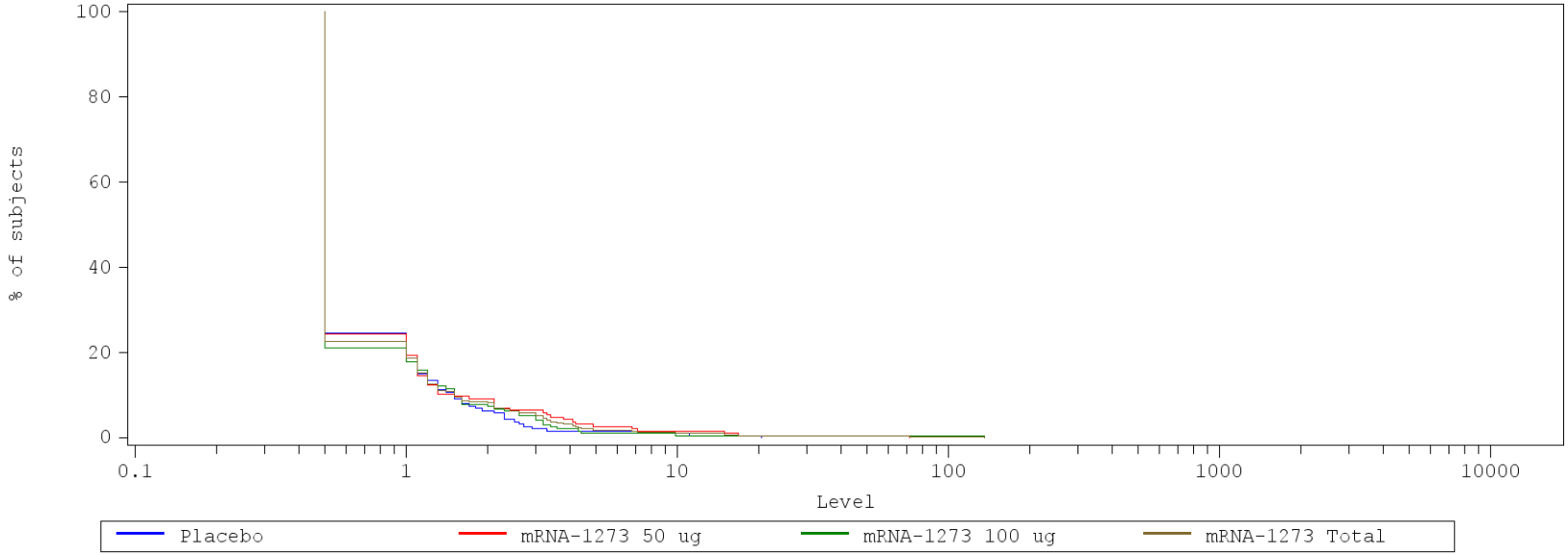
Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Baseline

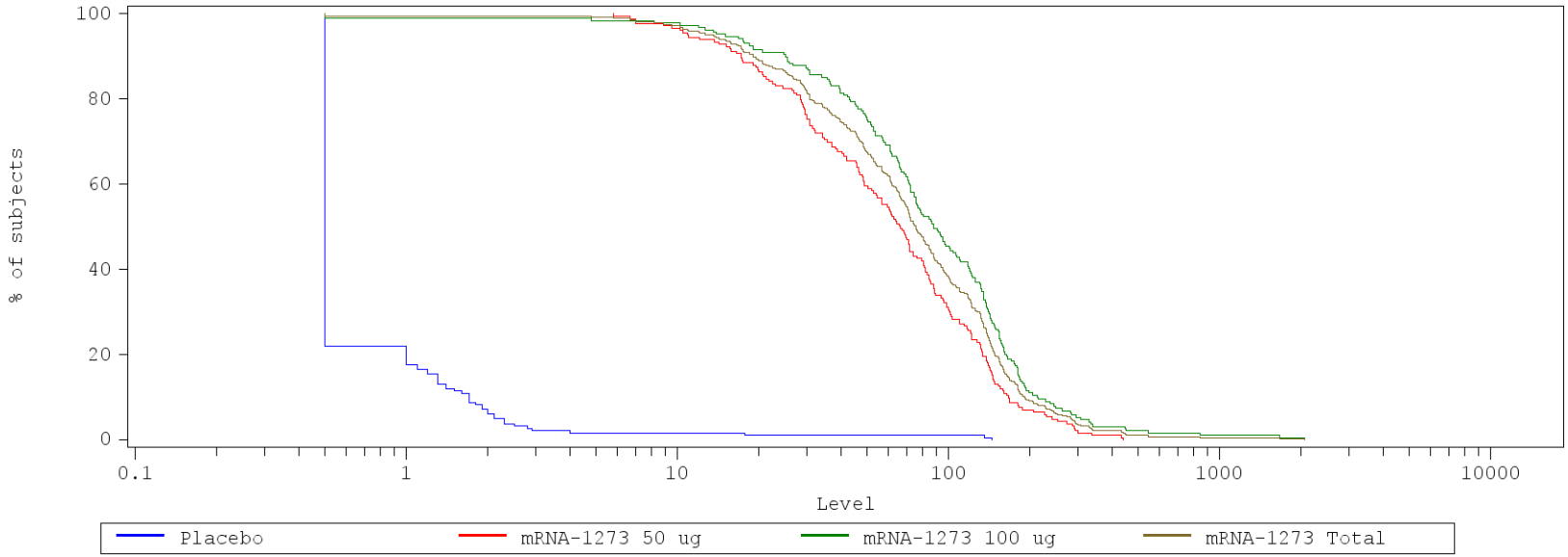


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 29

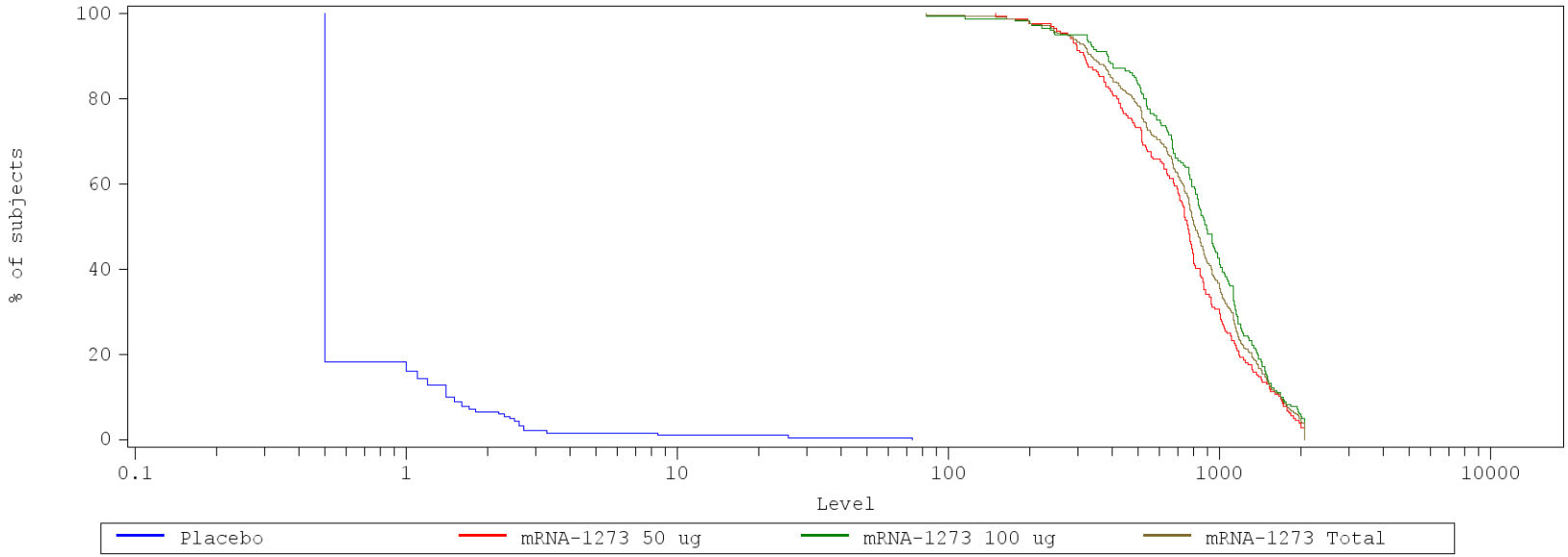


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 43

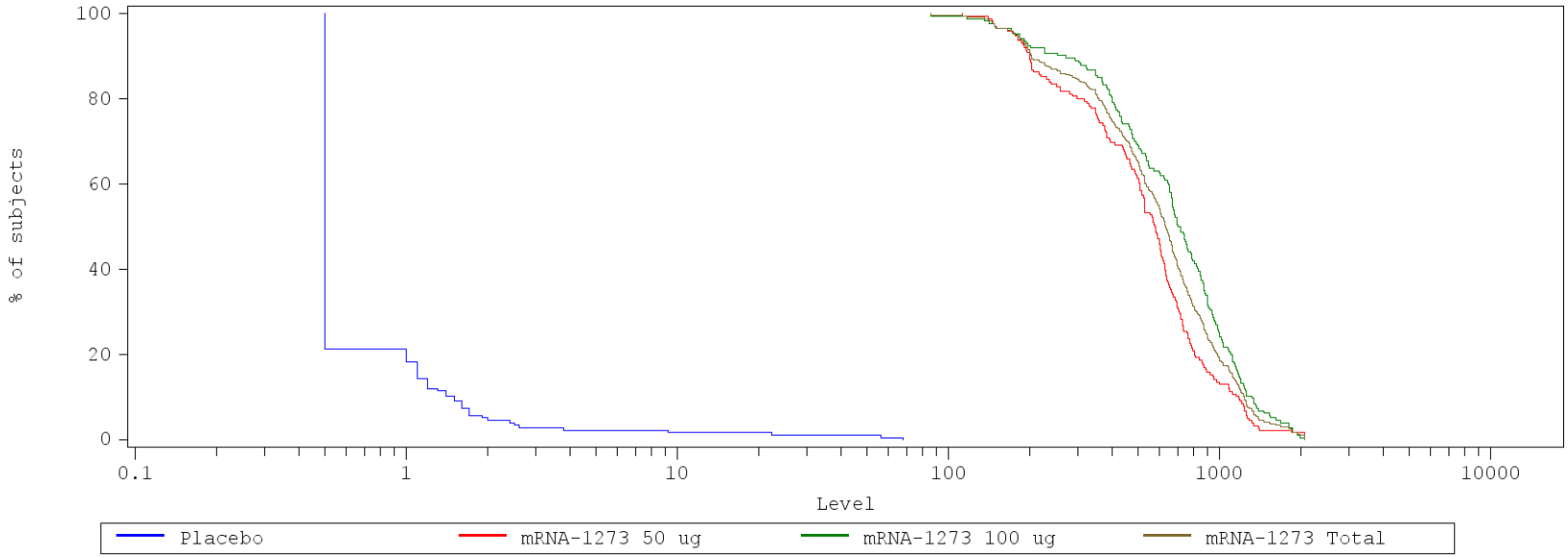


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 57

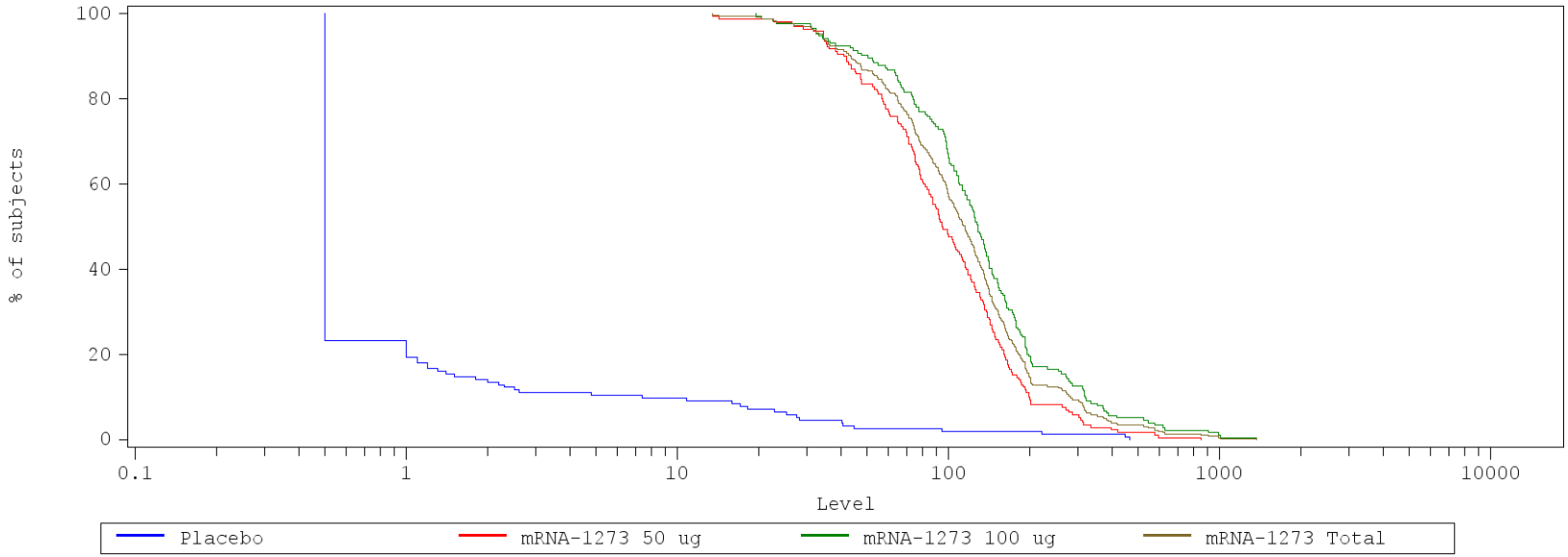


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort Overall
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 209

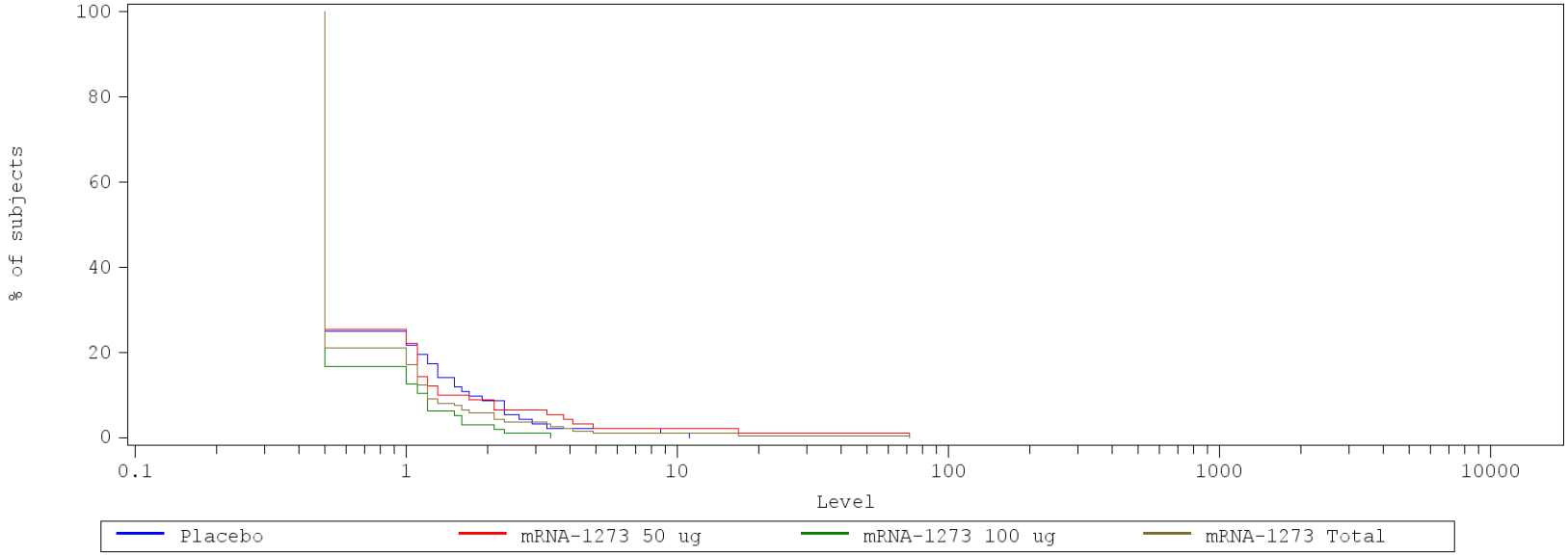


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Baseline

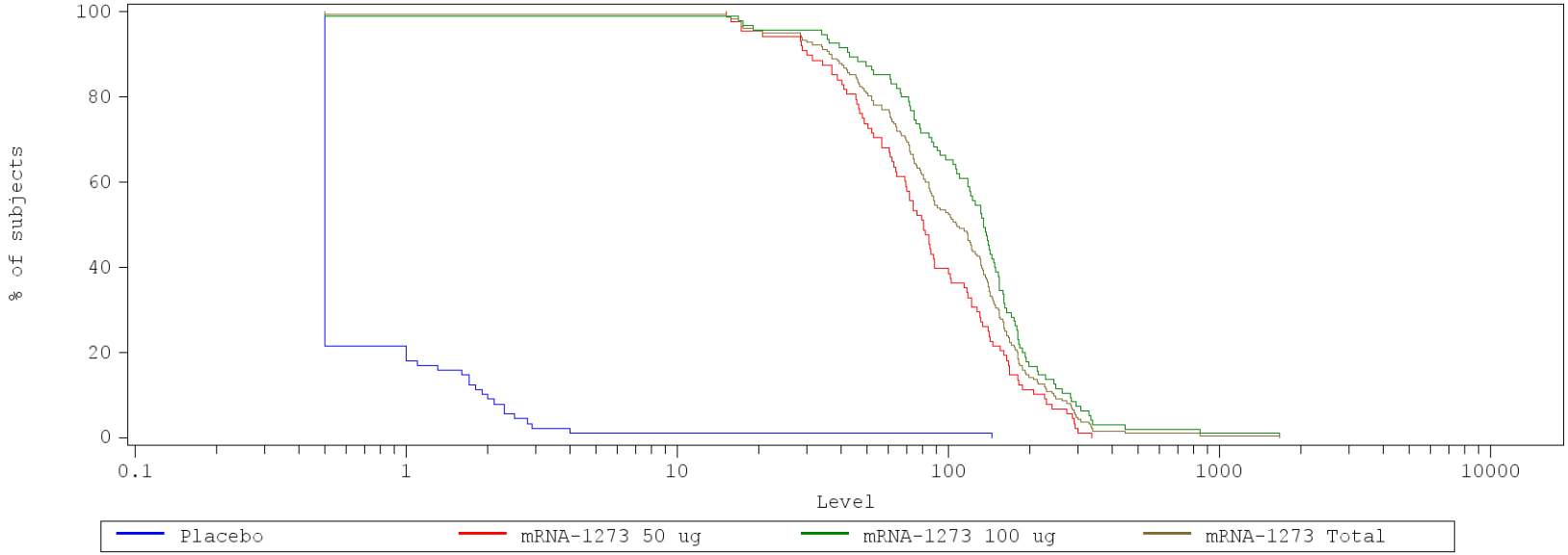


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 29

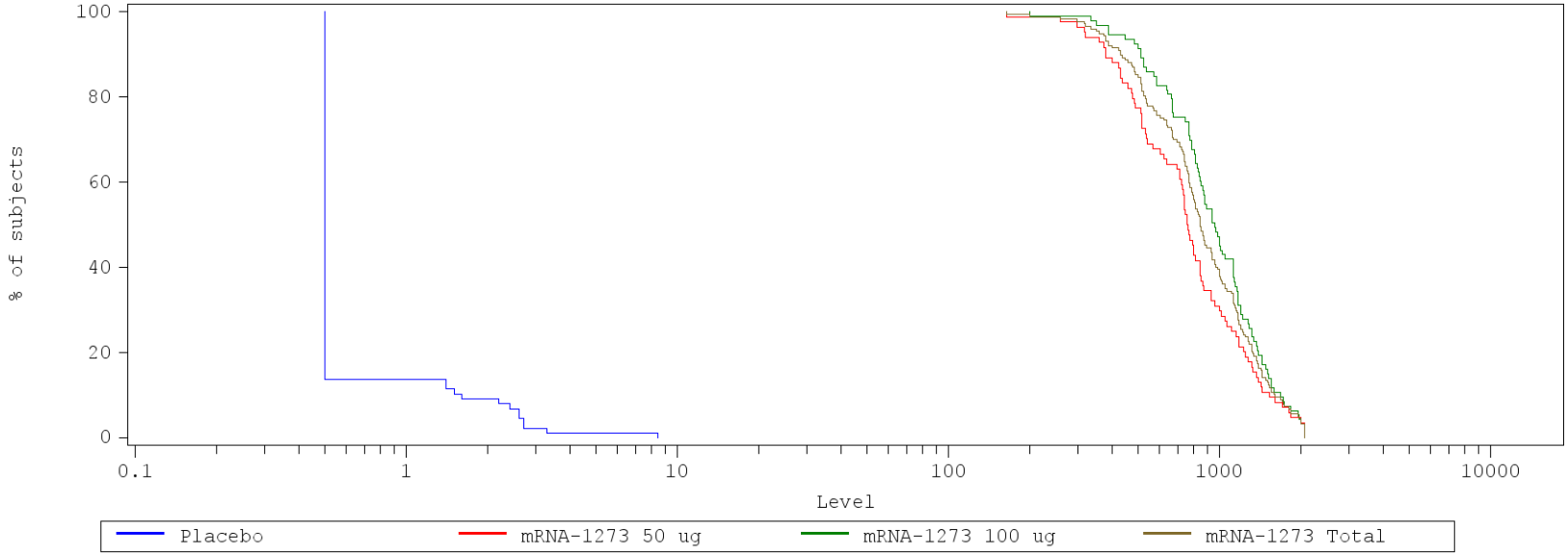


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 43

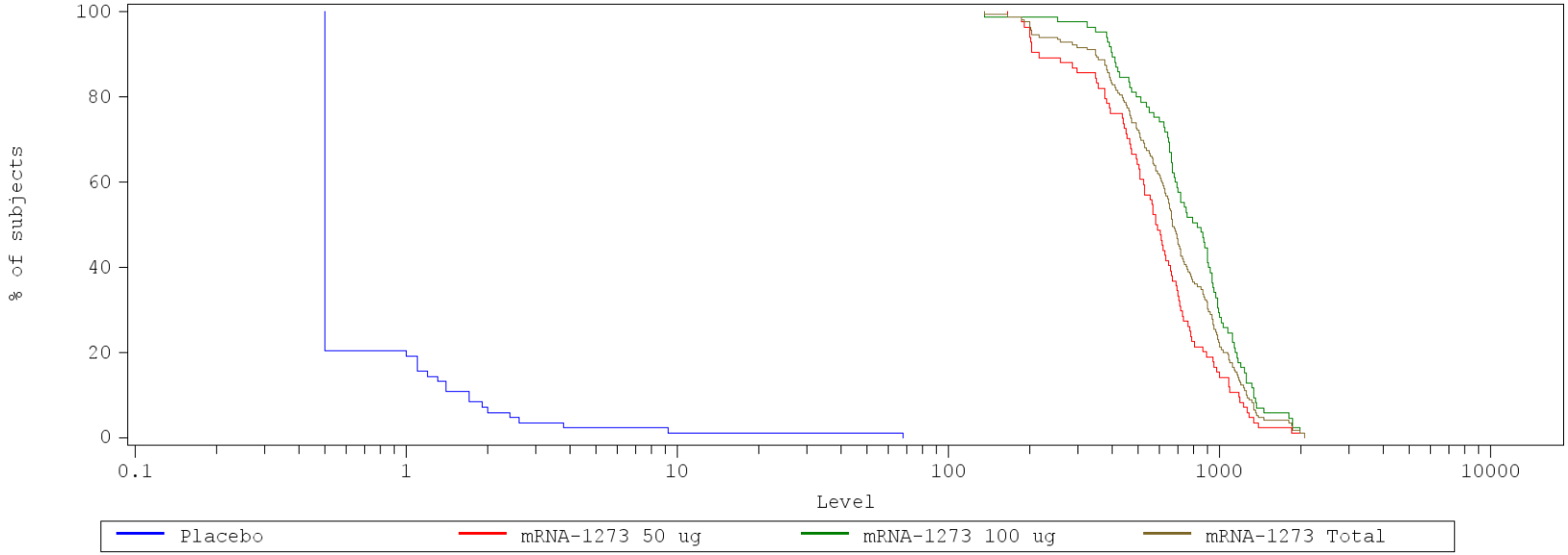


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 57

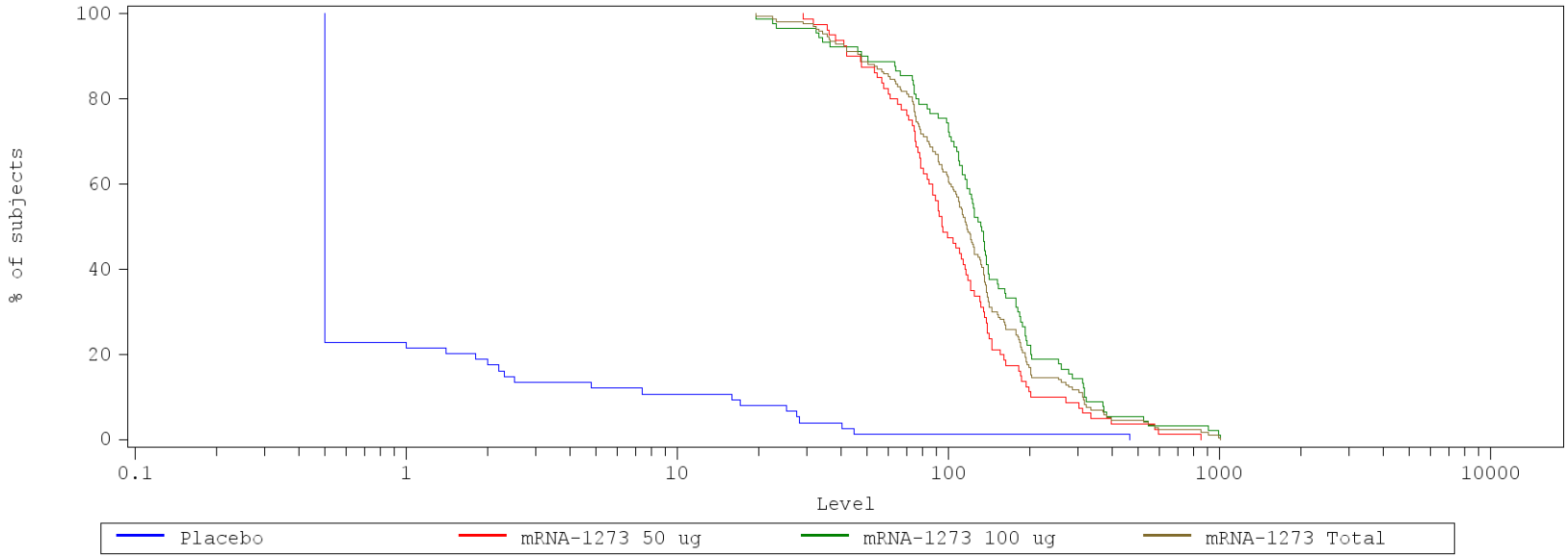


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 1 (>=18 and <55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 209

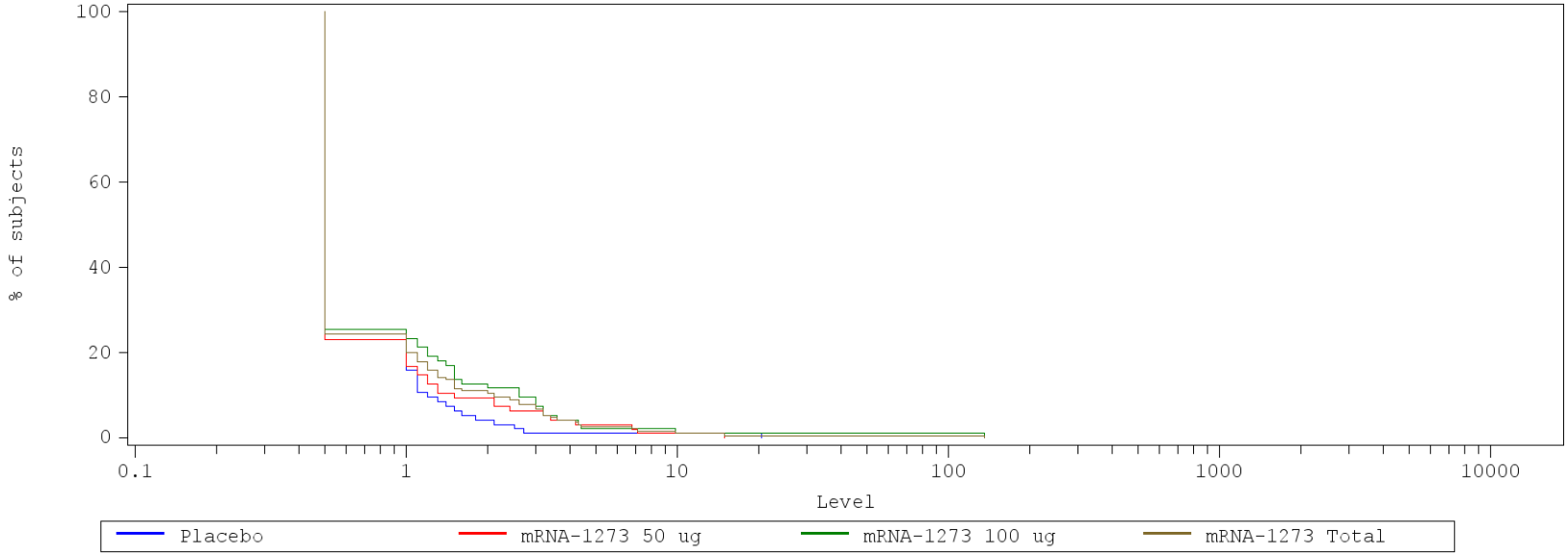


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Baseline

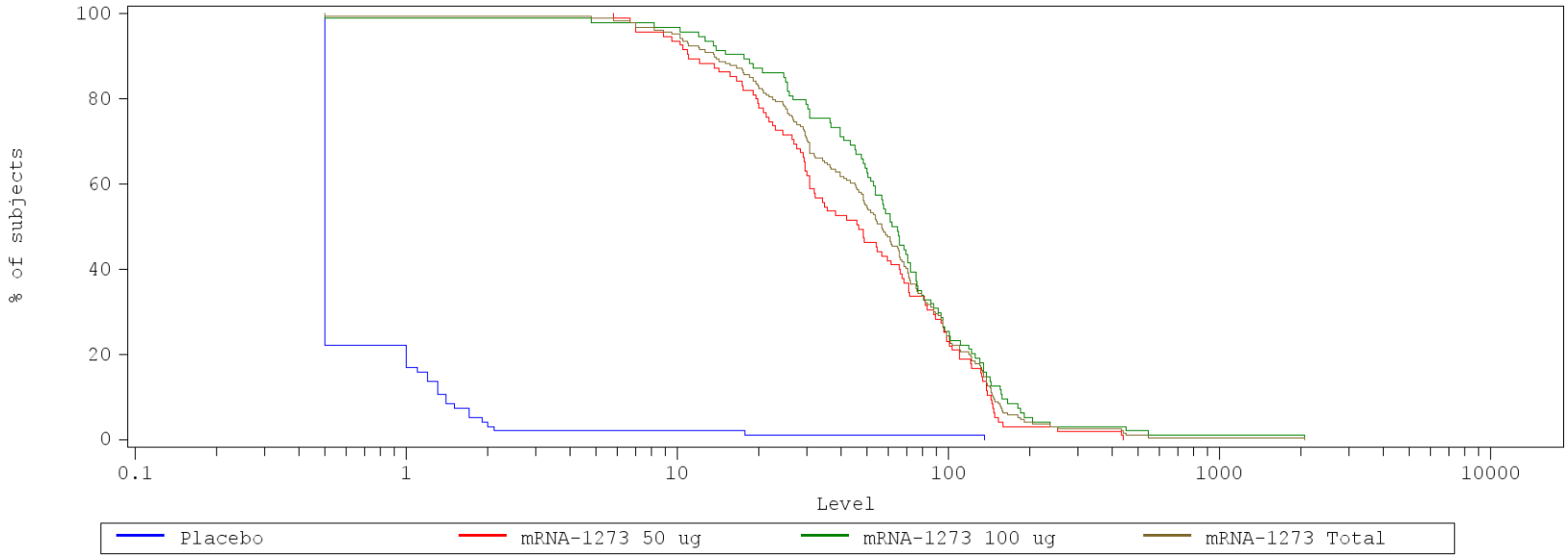


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 29

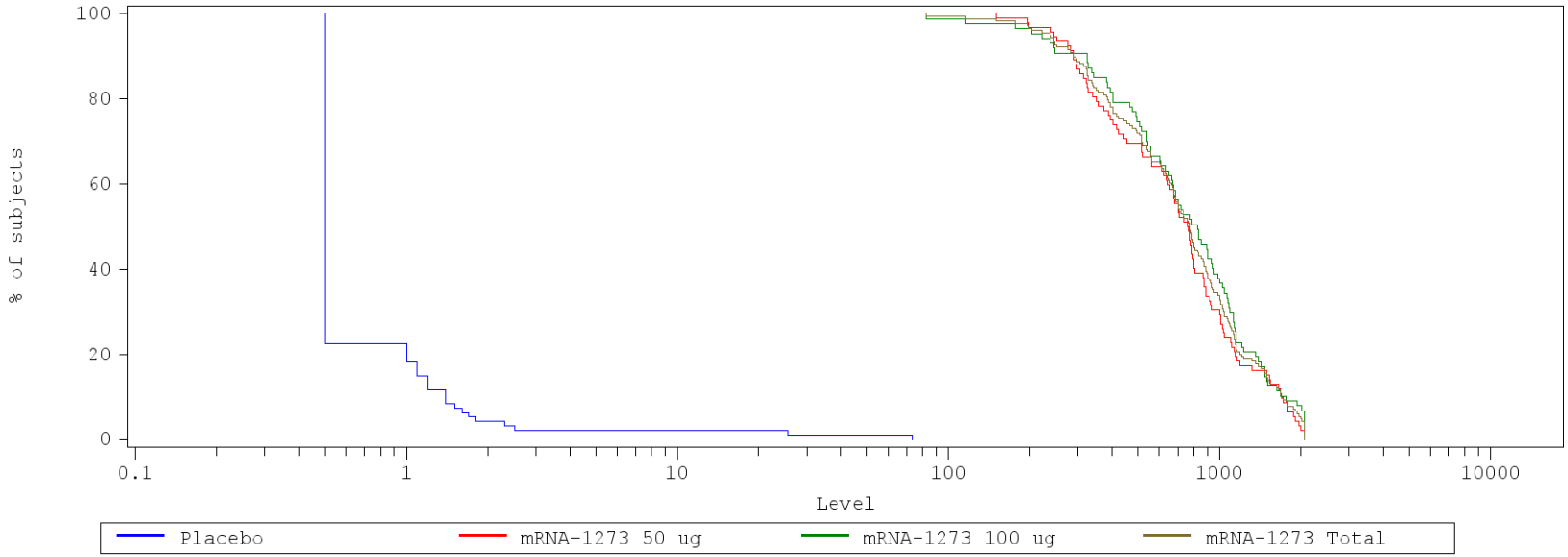


bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific bAb with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402031101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 43



bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.

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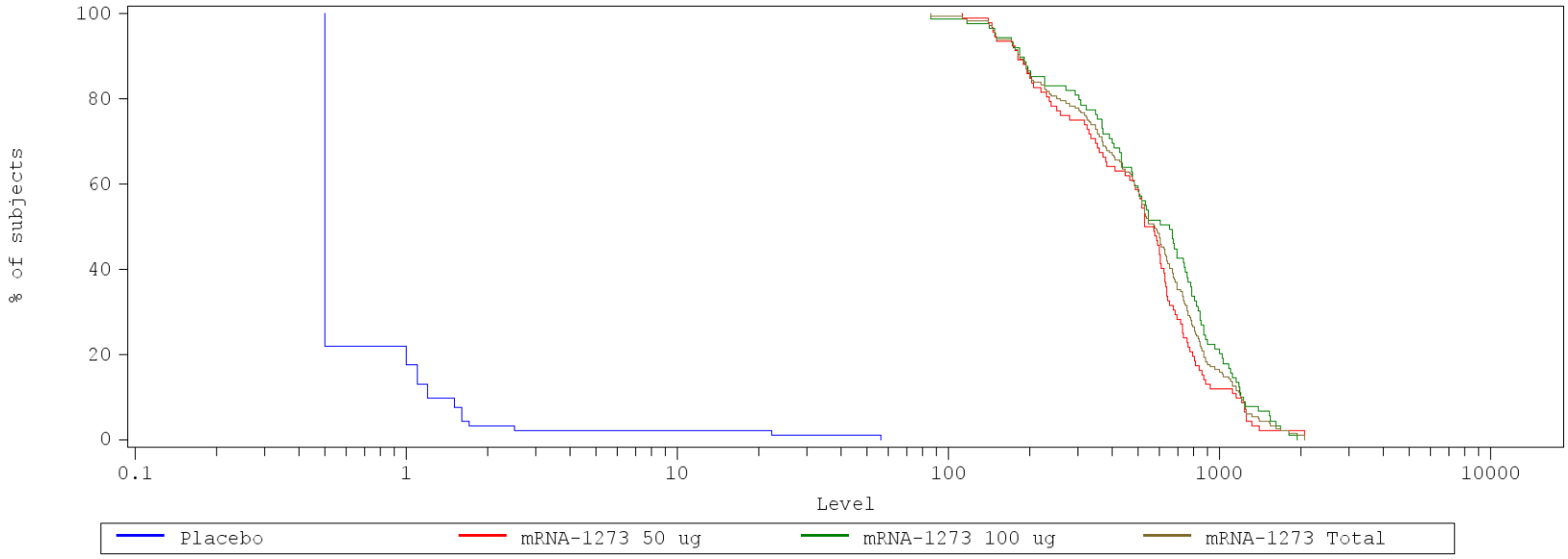
Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 57



bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.

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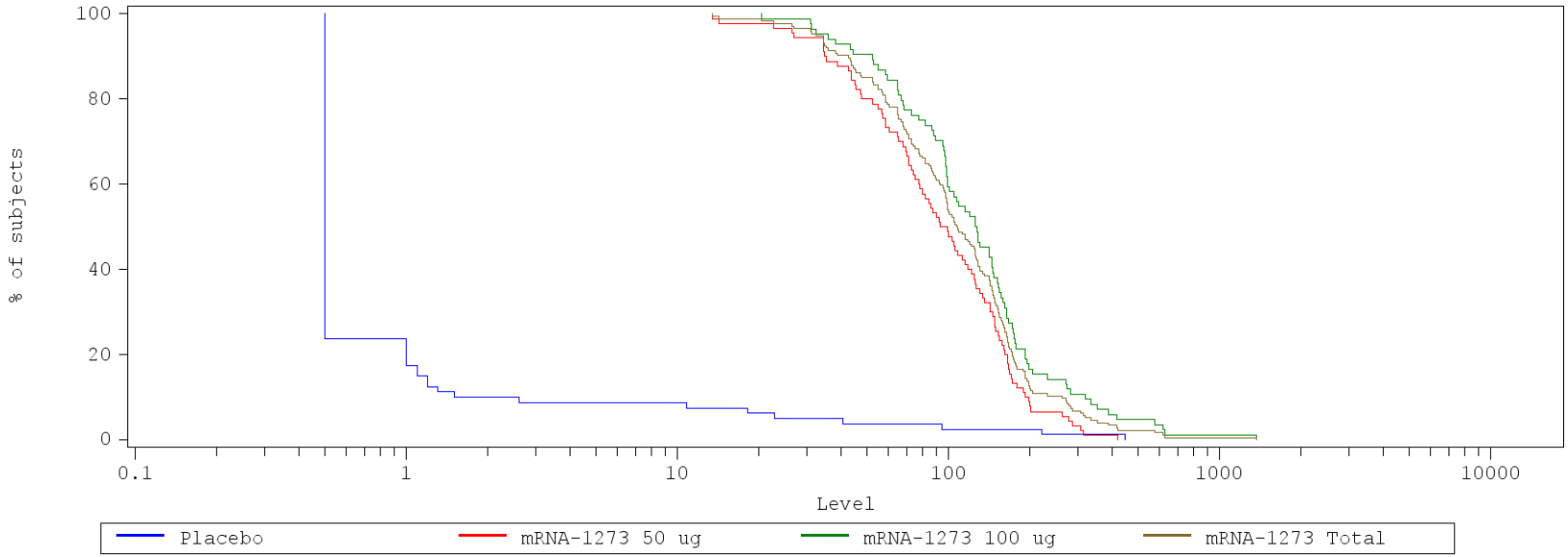
Figure 14.2.3.11.1
Reverse Cumulative Distribution Function of Binding Antibody Immunogenicity Results by ELISA
Per-Protocol Set for SARS-CoV-2-specific bAb

Cohort 2 (>=55 Years)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)
Day 209



bAb = Binding antibody, ELISA = enzyme-linked immunosorbent assay.
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 if actual values are not available.

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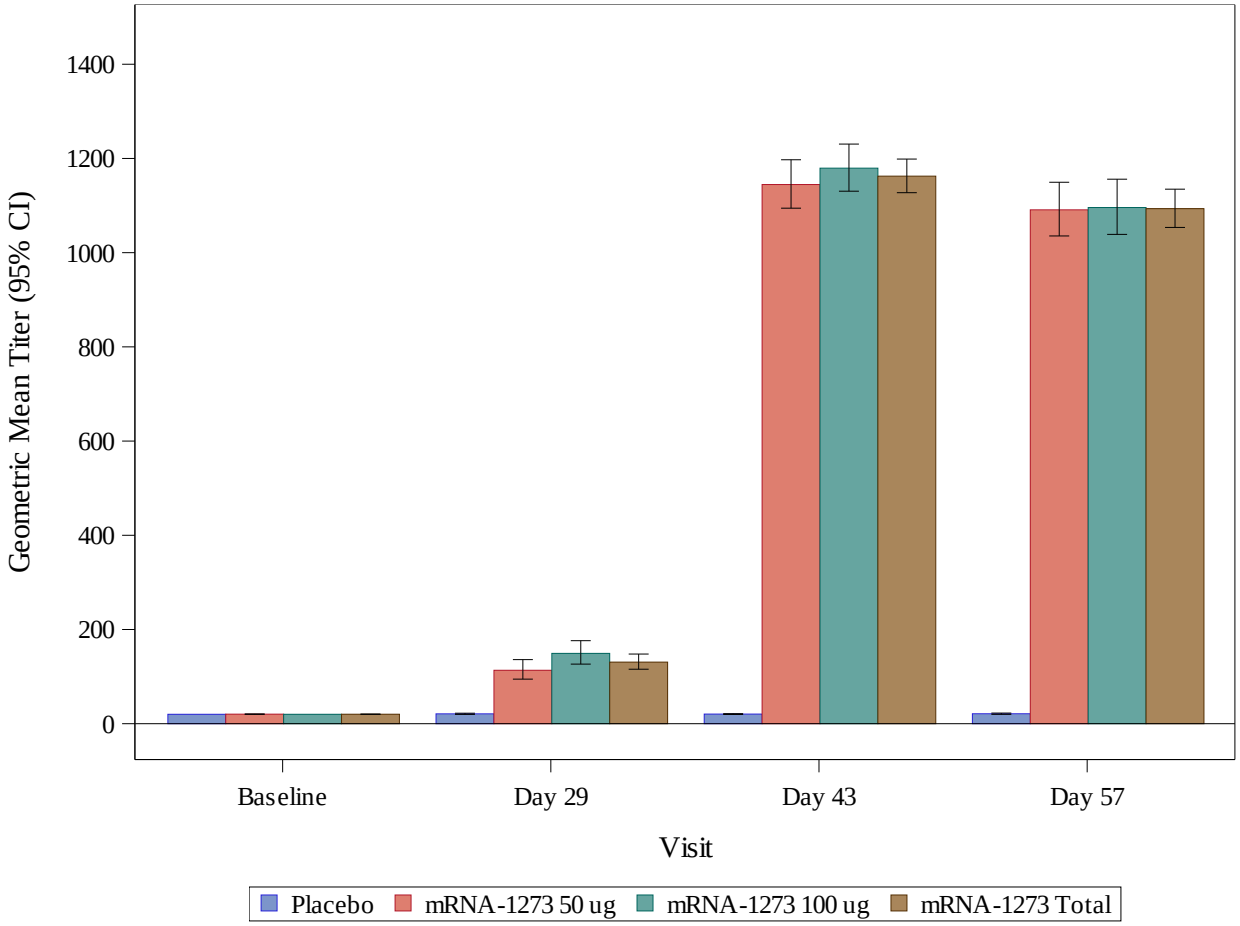
Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

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.

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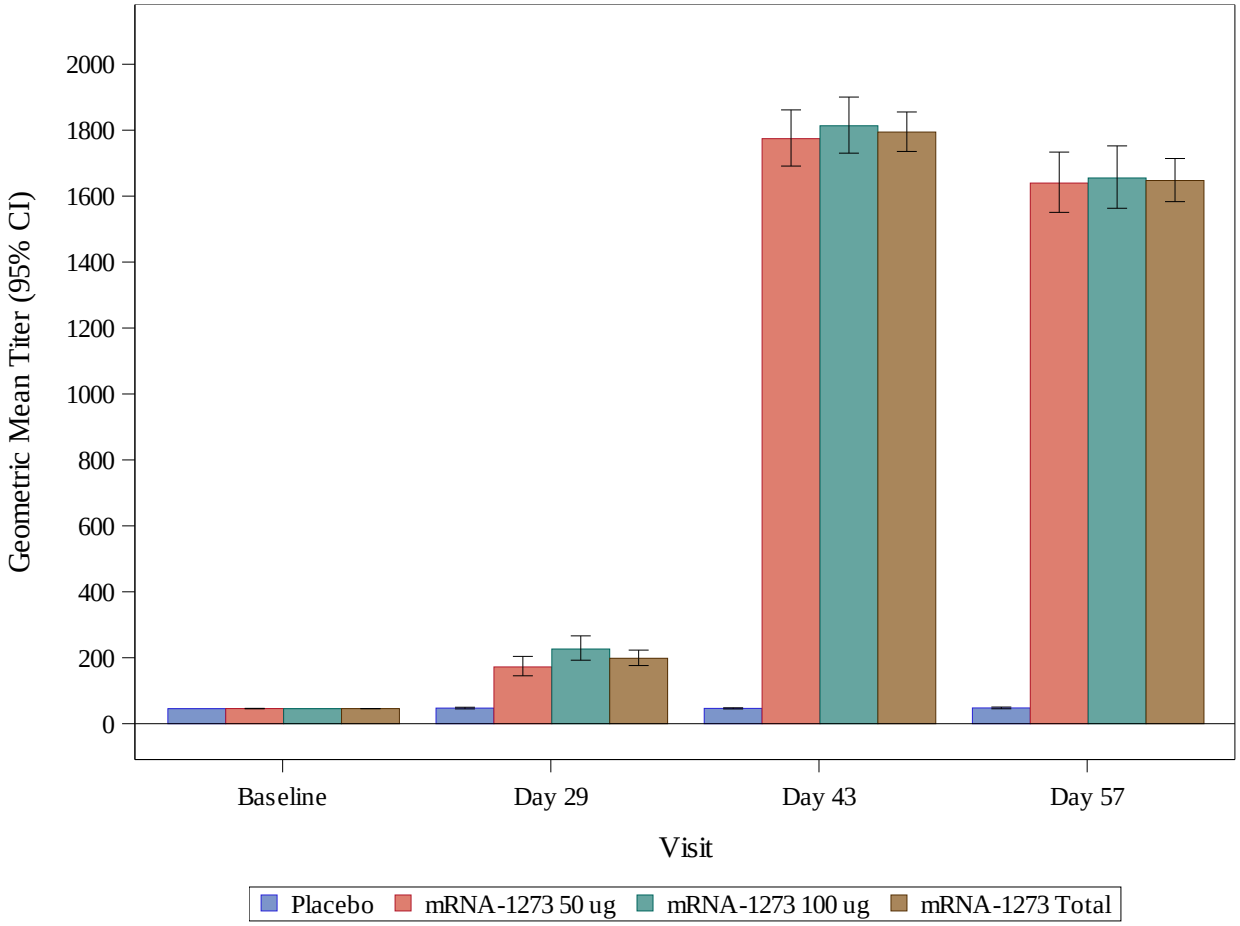
Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort Overall
Antibody: MN50

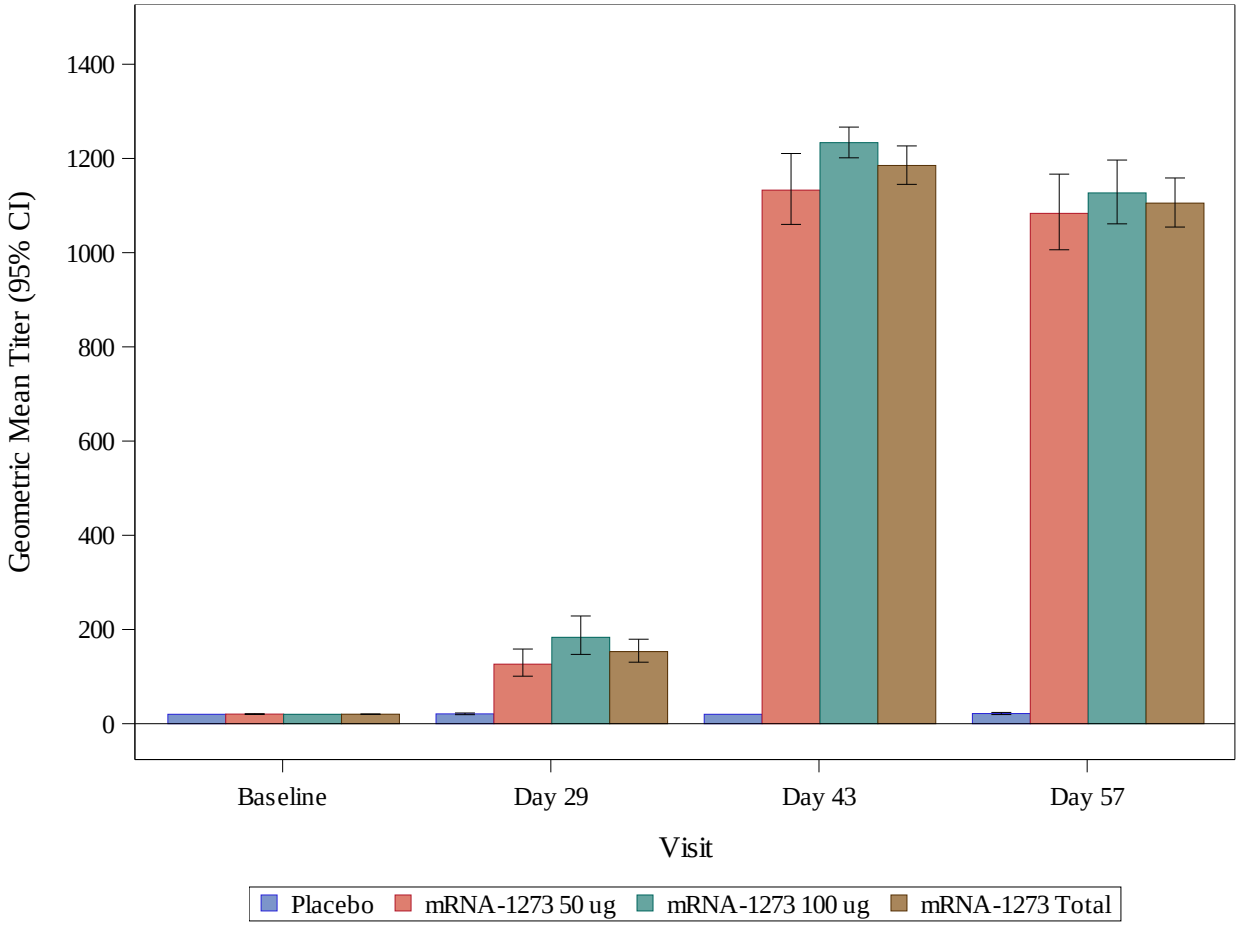


Source table: T14.2.2.1.1.1
nAb = Neutralizing antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402040101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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 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.

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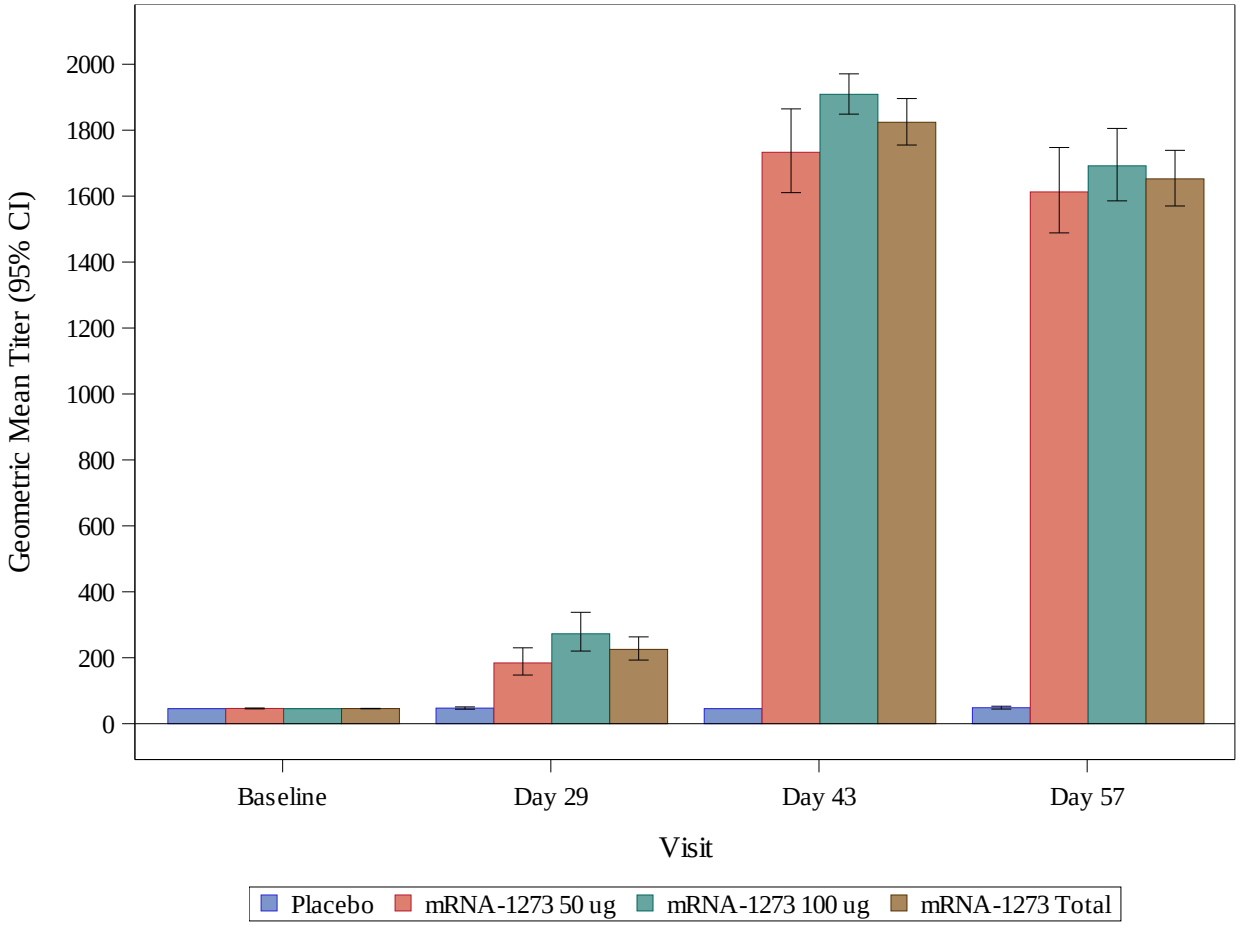
Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

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 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.

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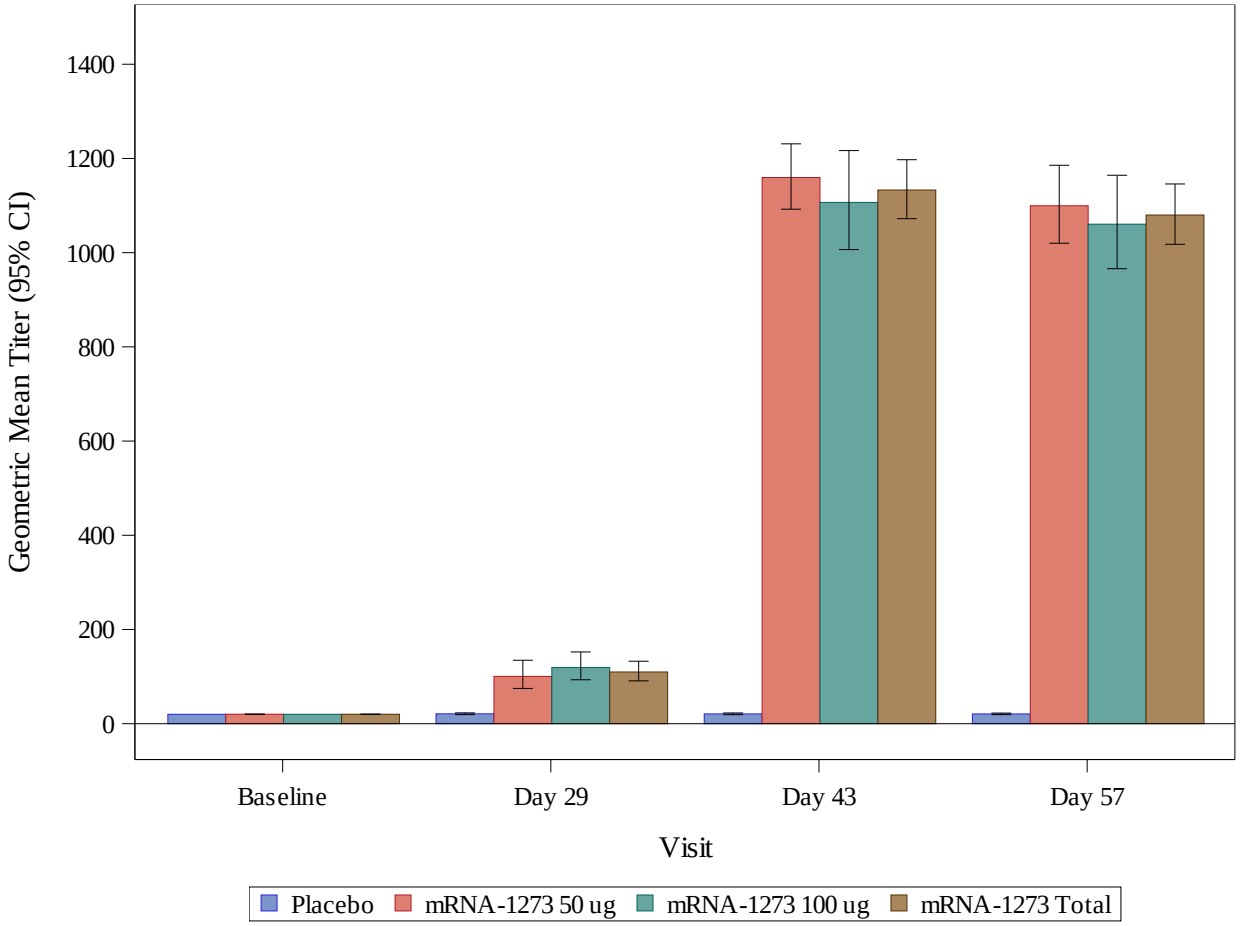
Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

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 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.

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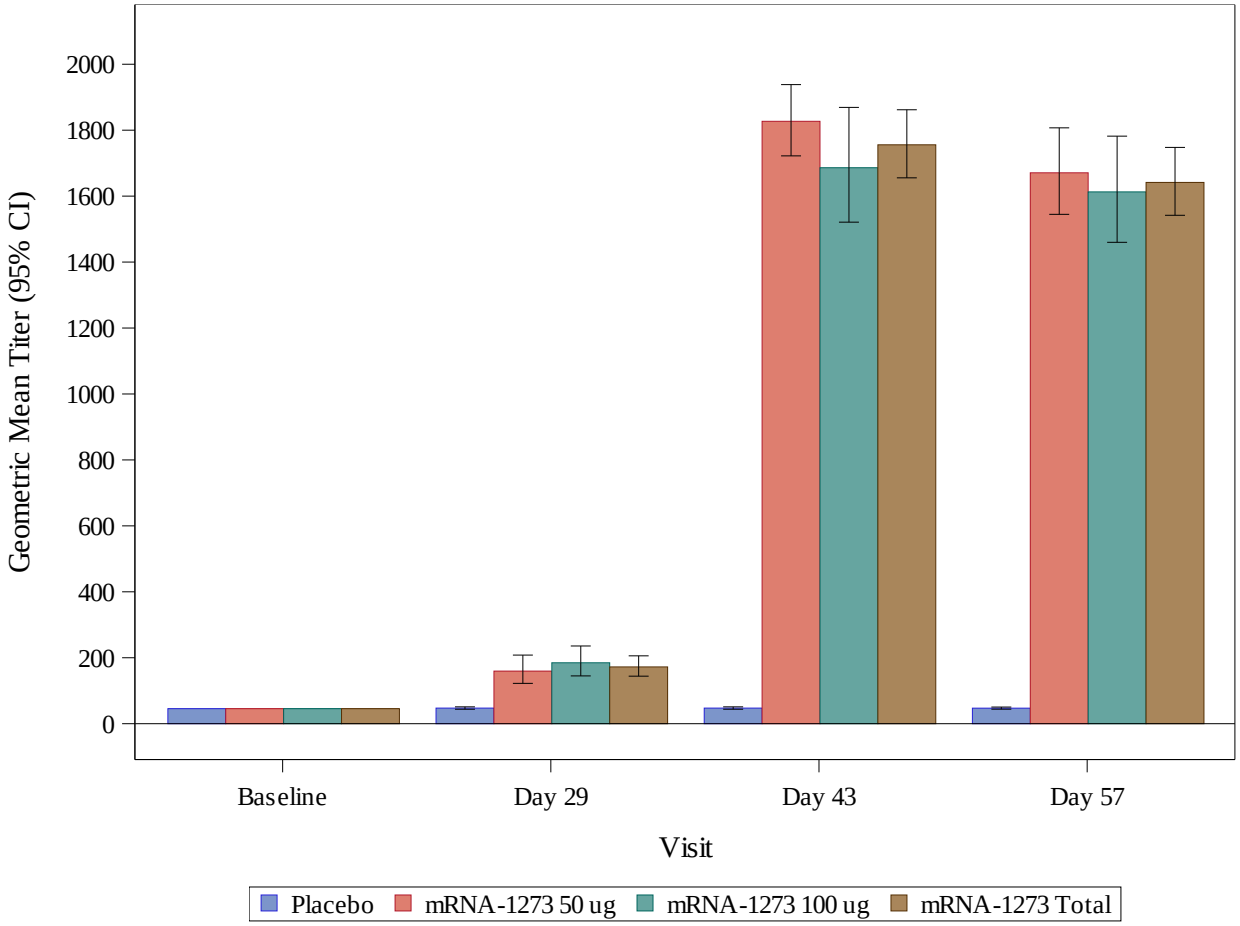
Figure 14.2.4.1.1
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

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 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.

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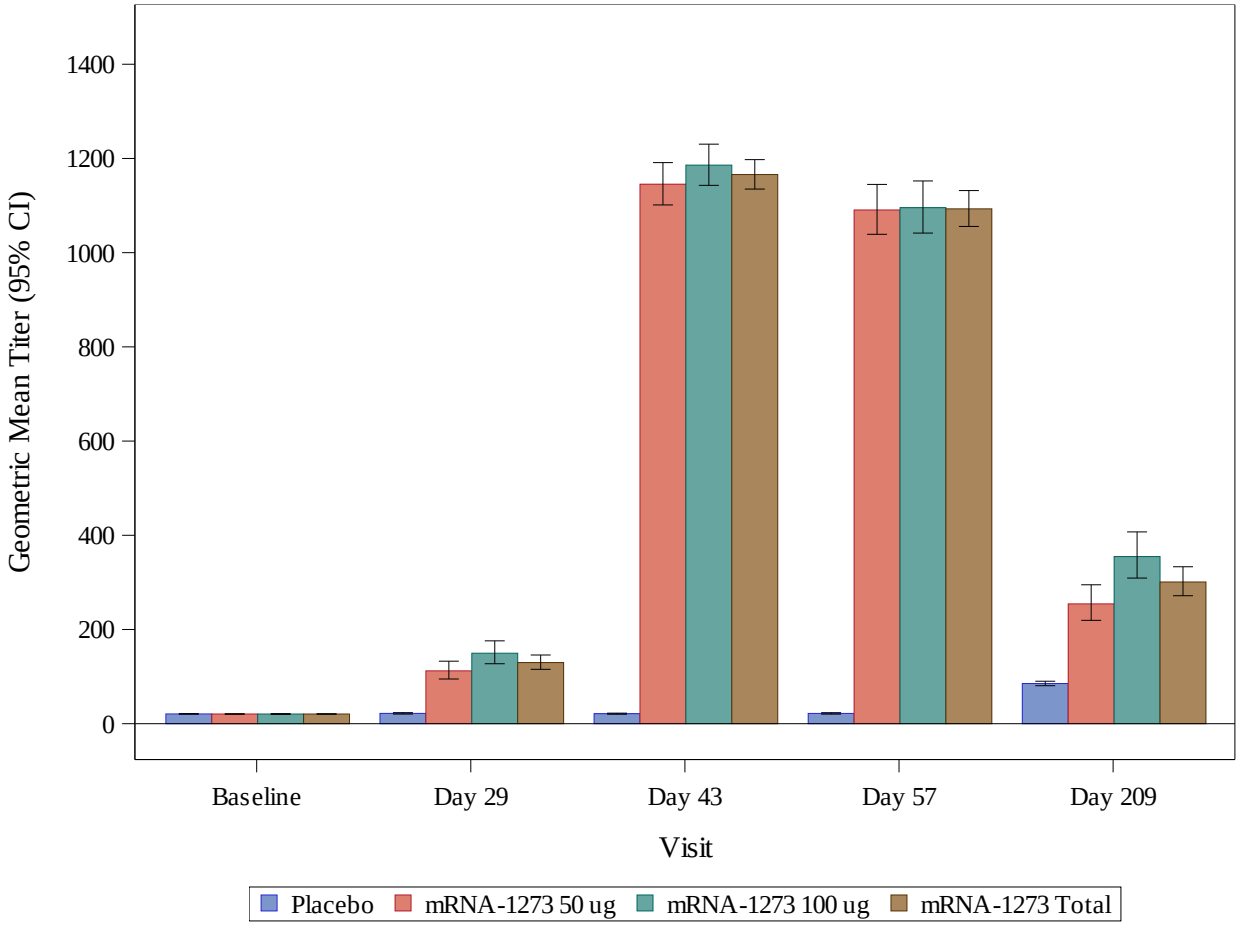
Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer

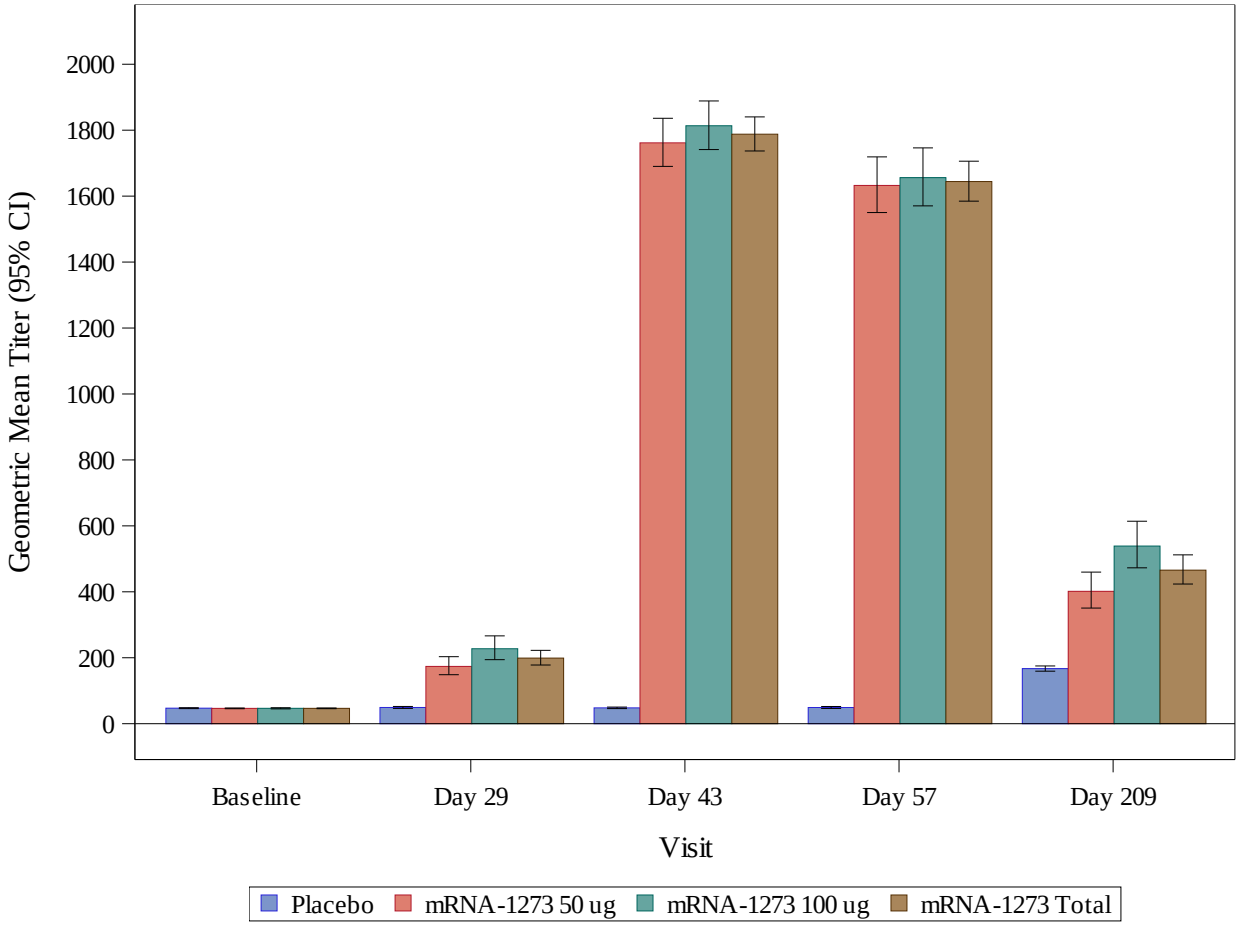


Source table: T14.2.2.1.1.2
nAb = Neutralizing antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
For MN Endpoint Titer (the First Lot): LLOQ=40 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402040102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

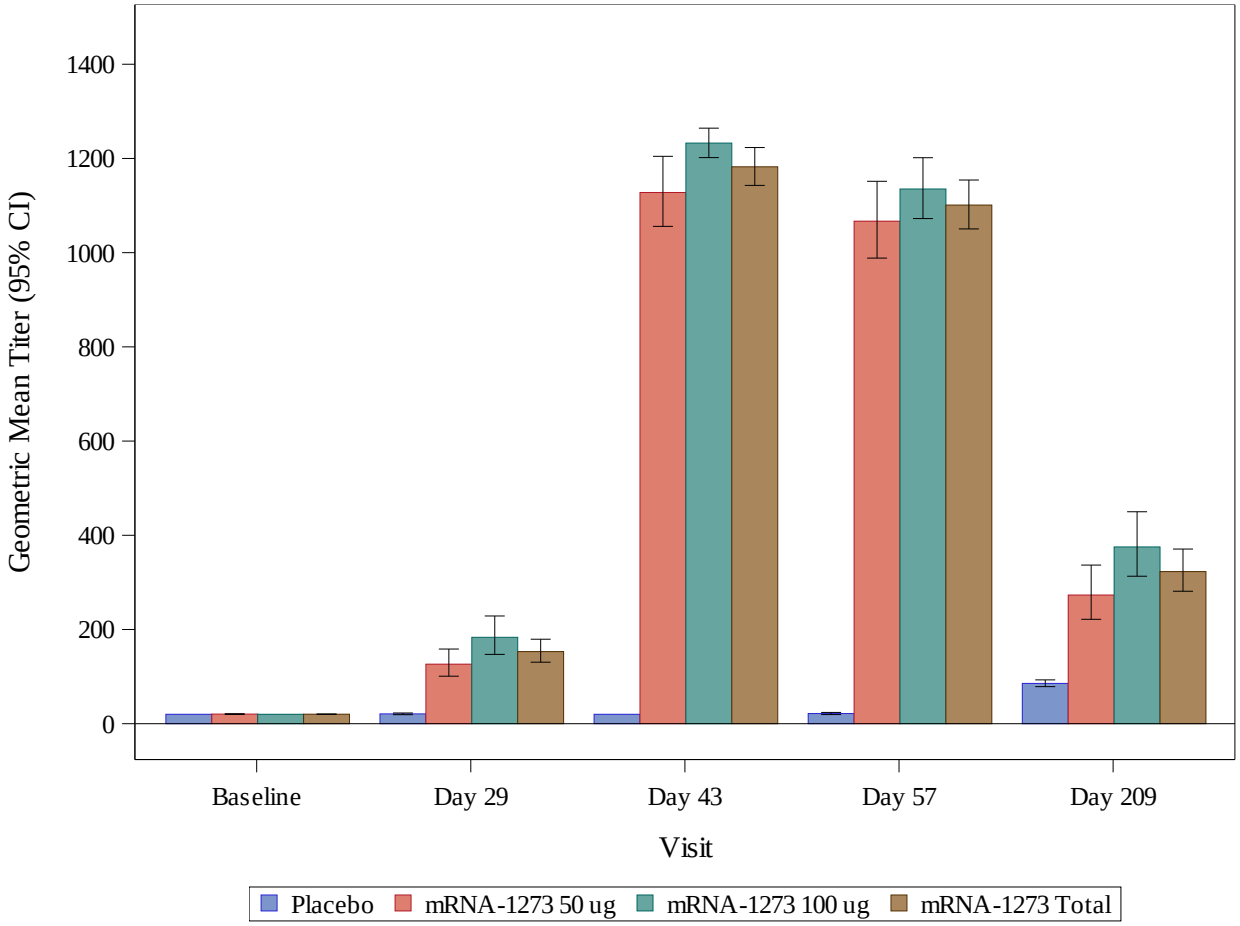


Source table: T14.2.2.1.1.2
nAb = Neutralizing antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
For MN Endpoint Titer (the First Lot): LLOQ=40 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402040102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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 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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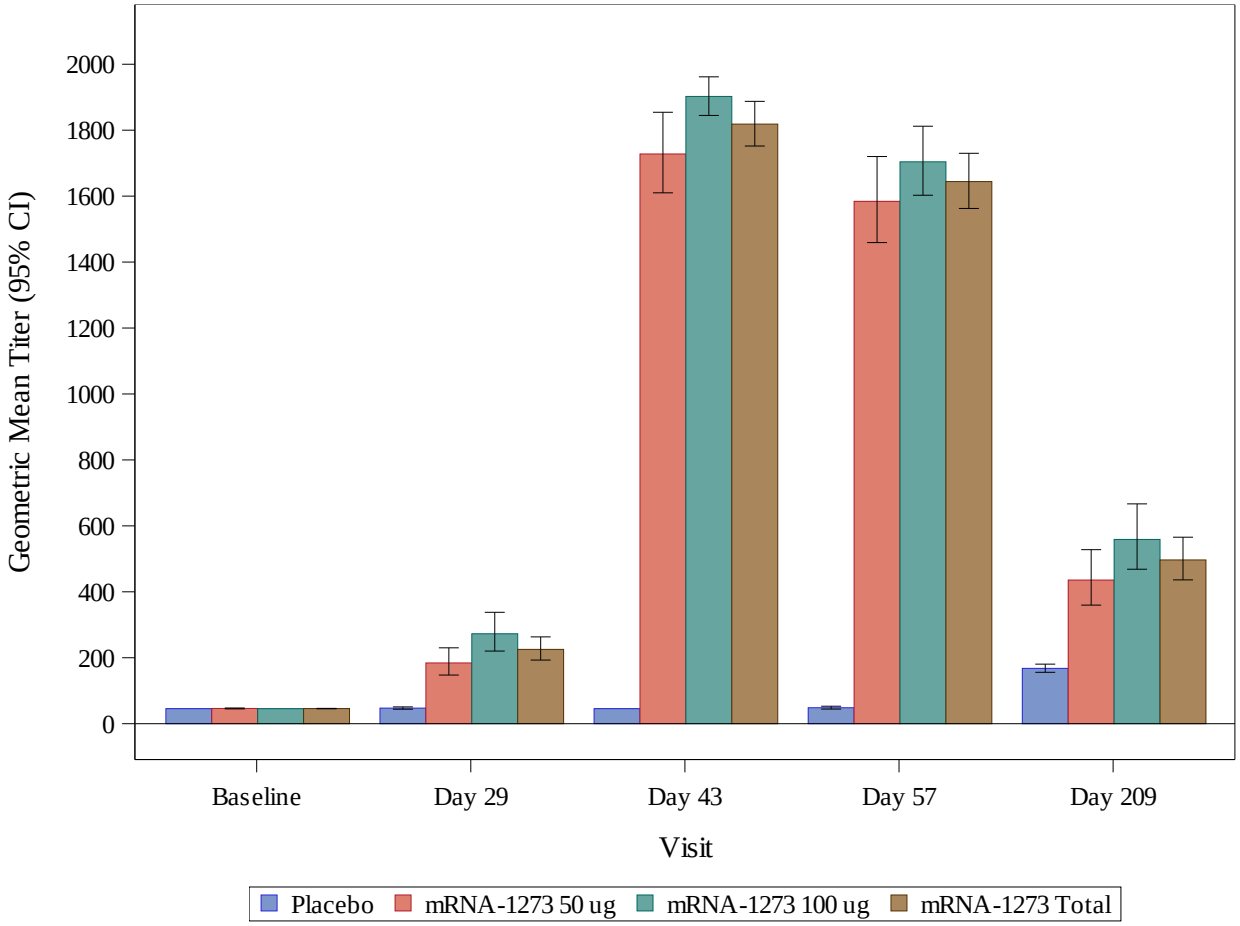
Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: 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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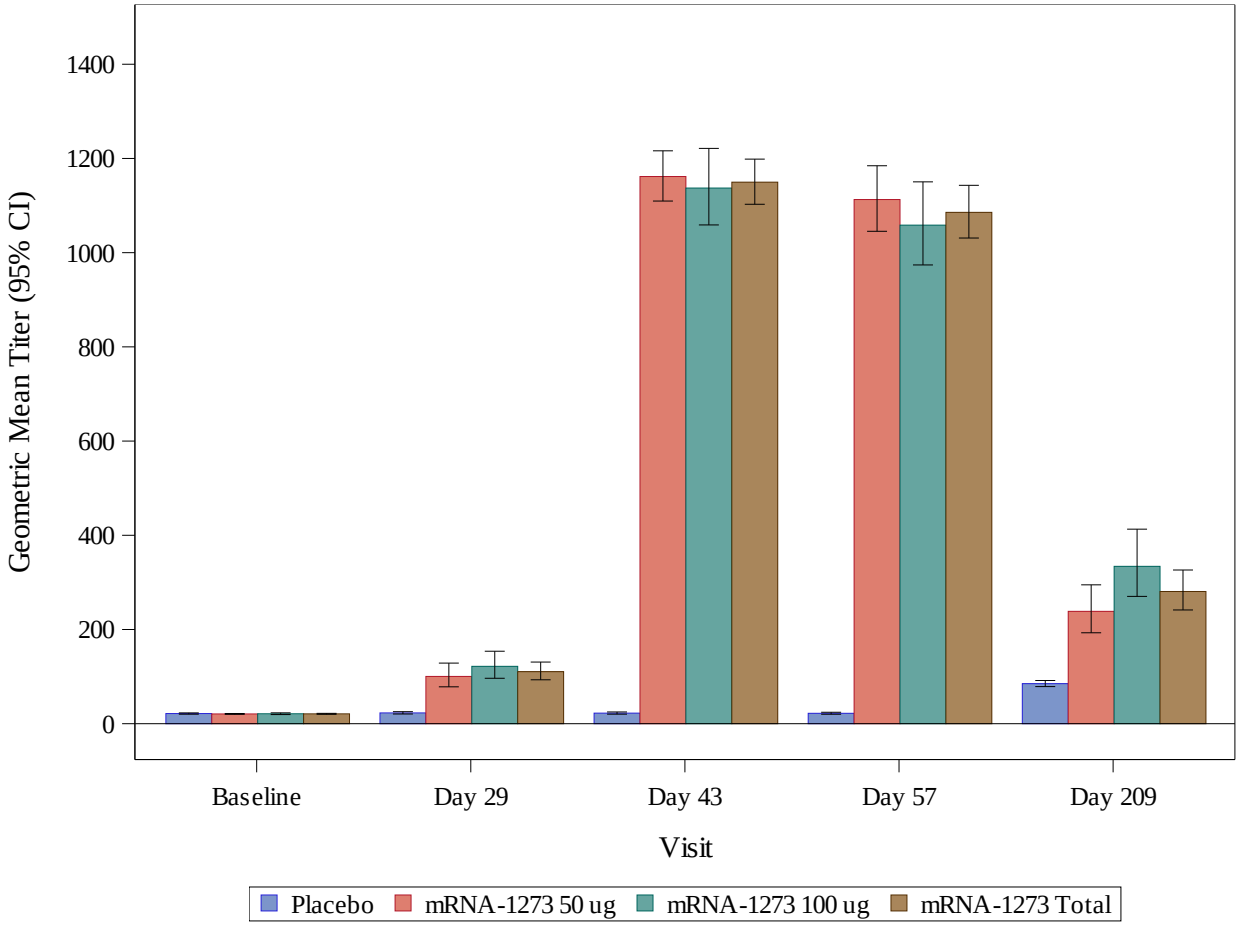
Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 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 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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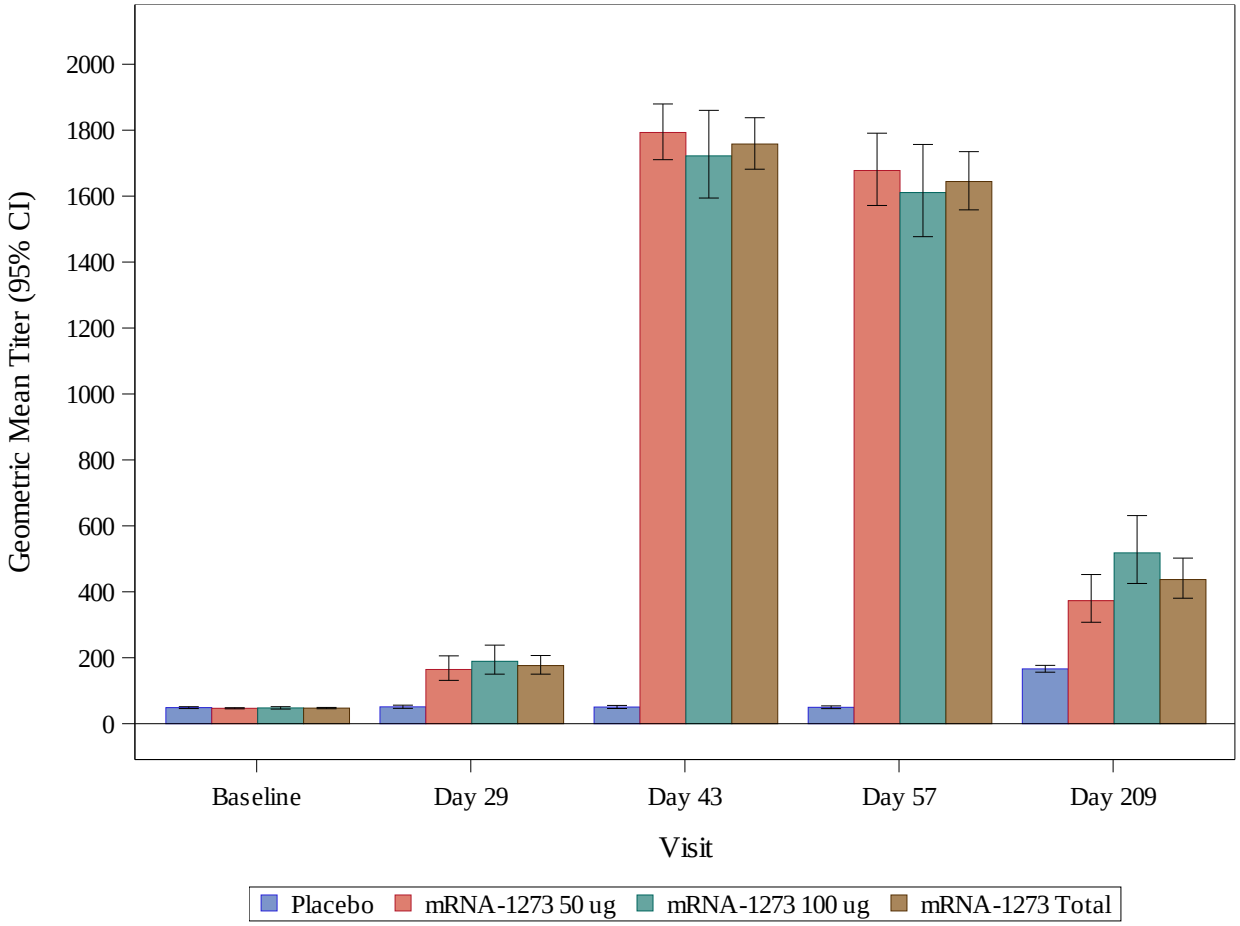
Figure 14.2.4.1.2
Geometric Mean Titers of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (>=55 Years)
Antibody: MN50

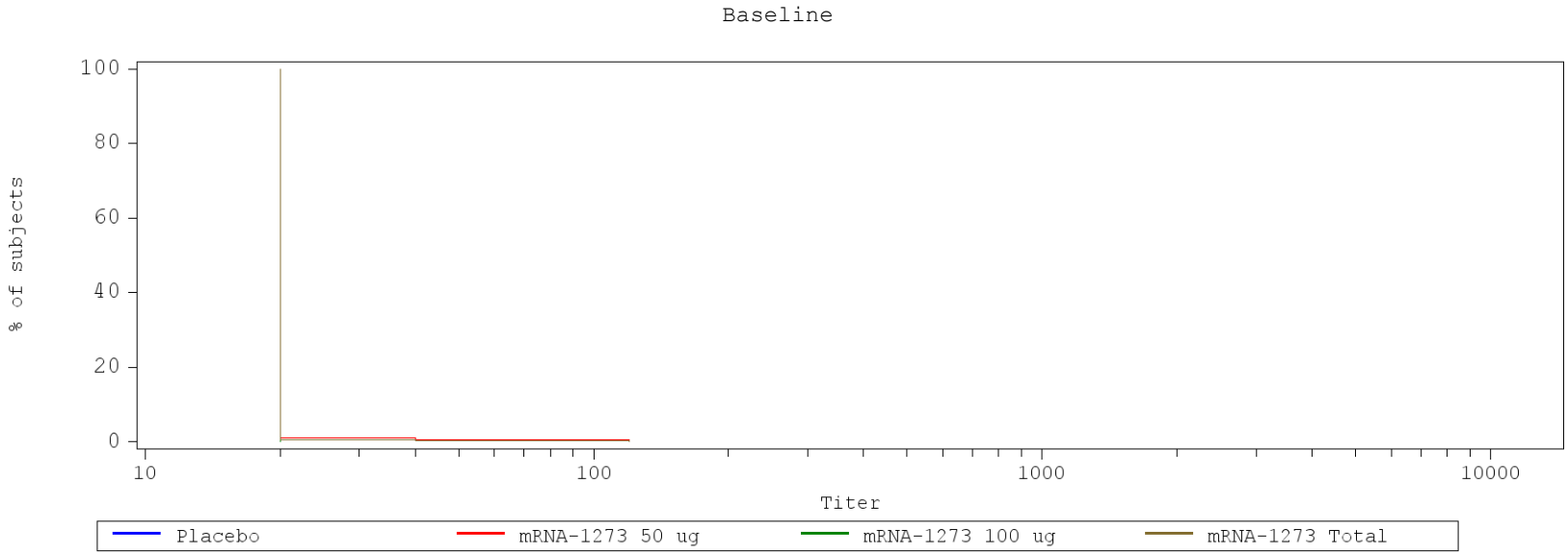


Source table: T14.2.2.1.1.2
nAb = Neutralizing antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
For MN Endpoint Titer (the First Lot): LLOQ=40 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\Part A end of Part A\TLF\f1402040102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



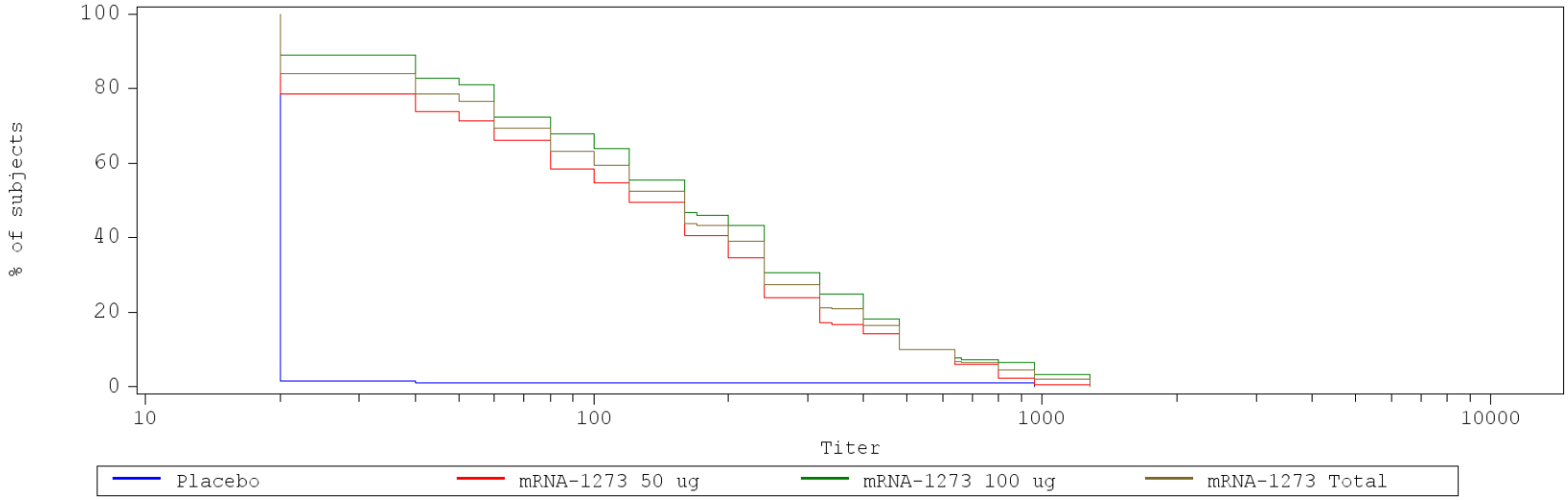
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 29

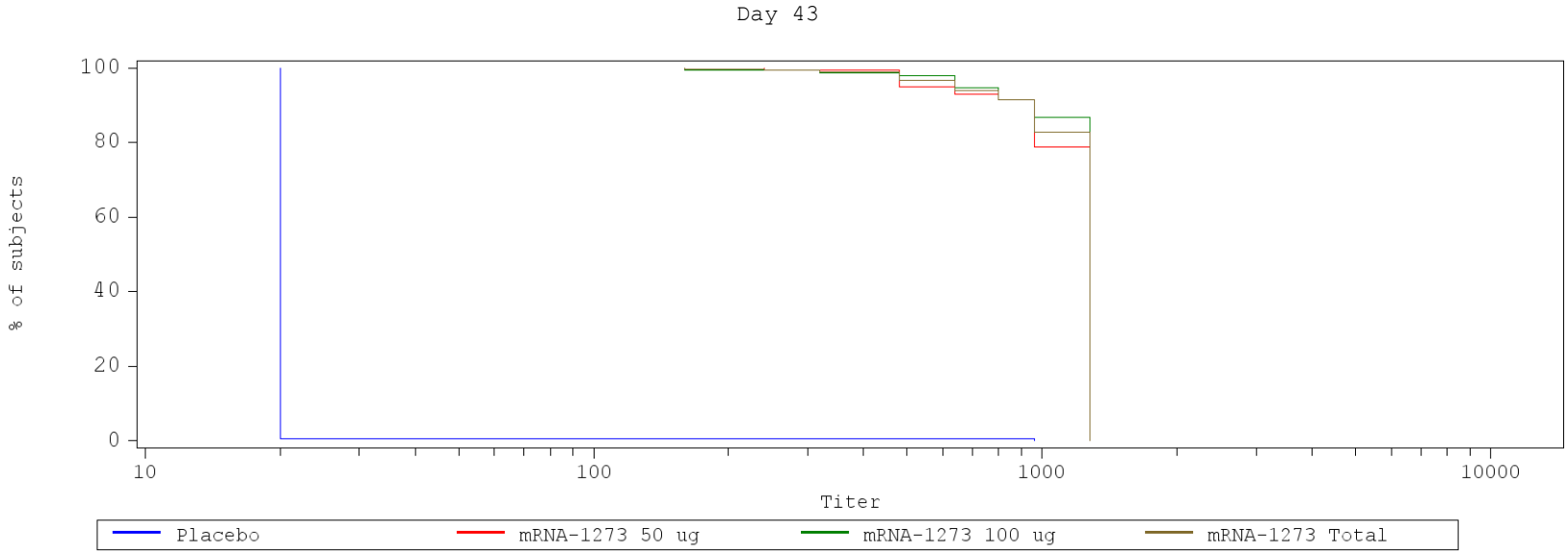


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

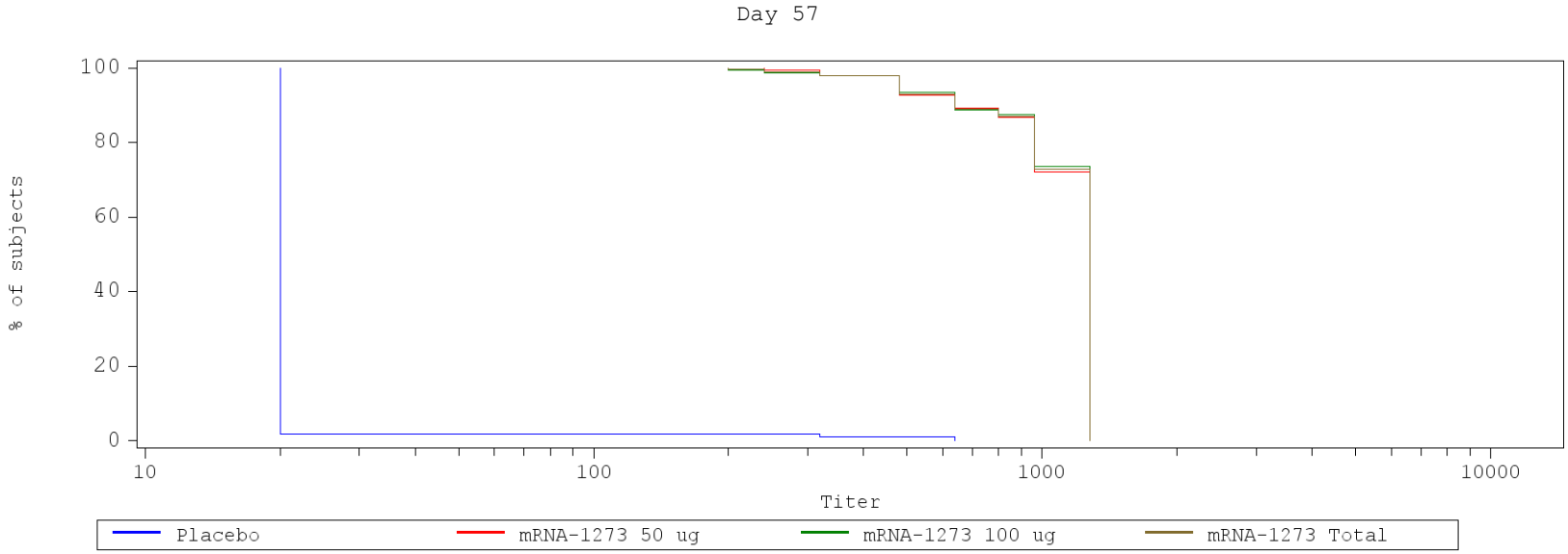


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

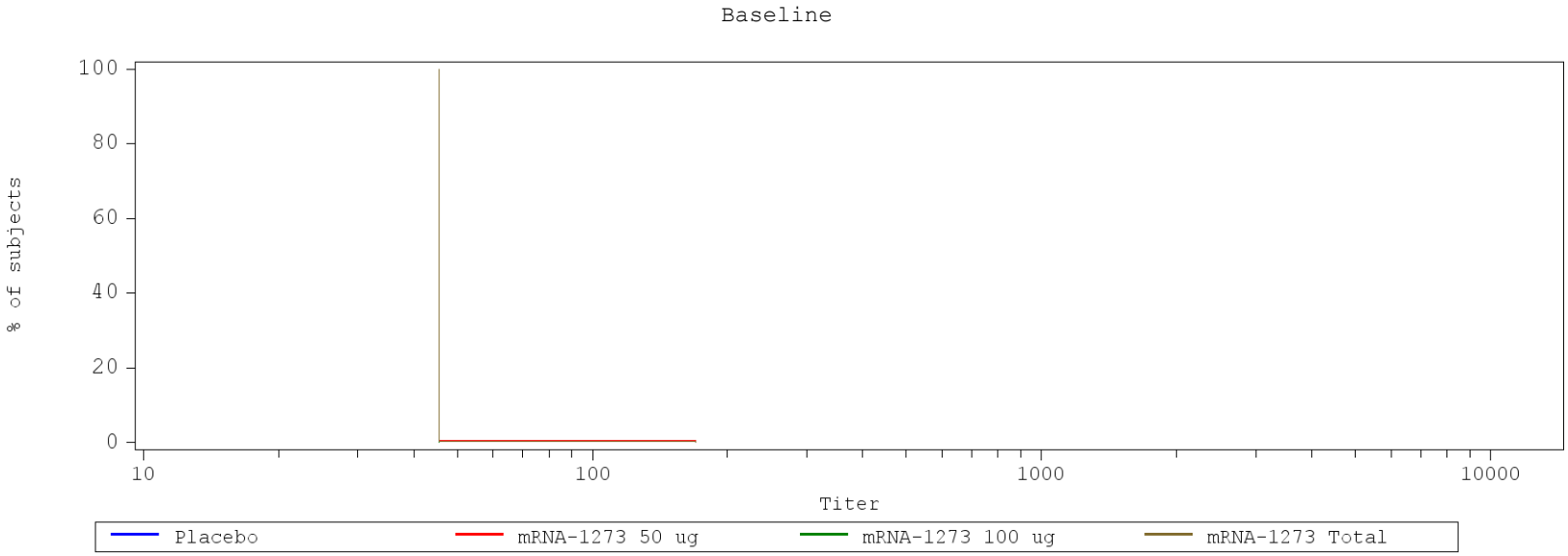


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



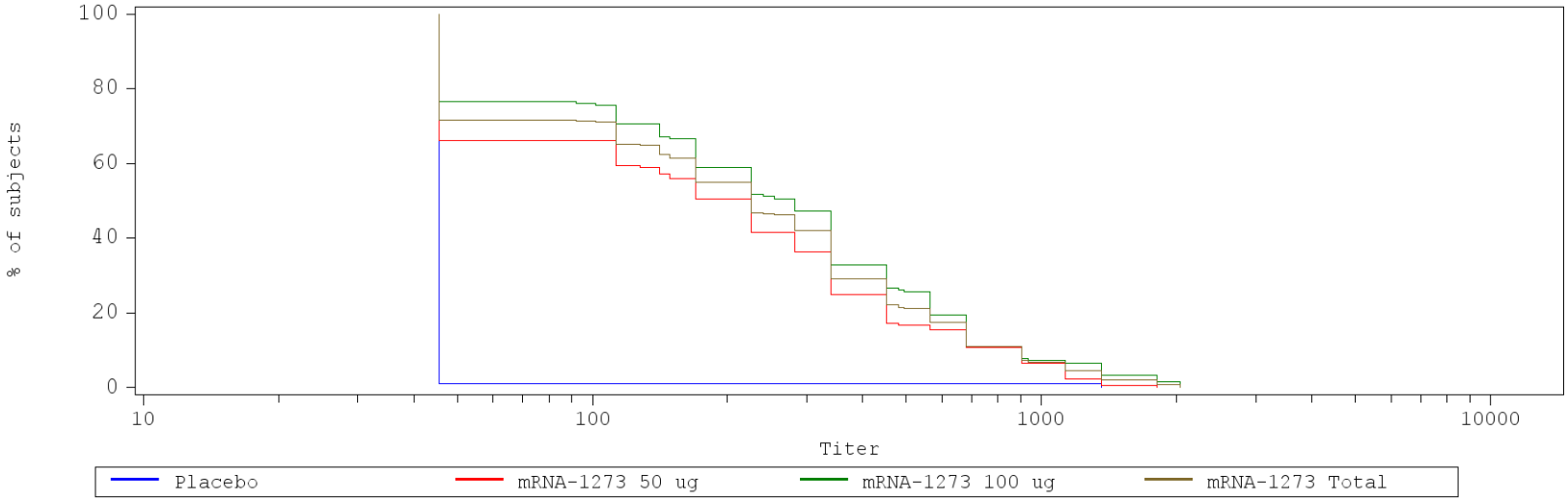
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 29

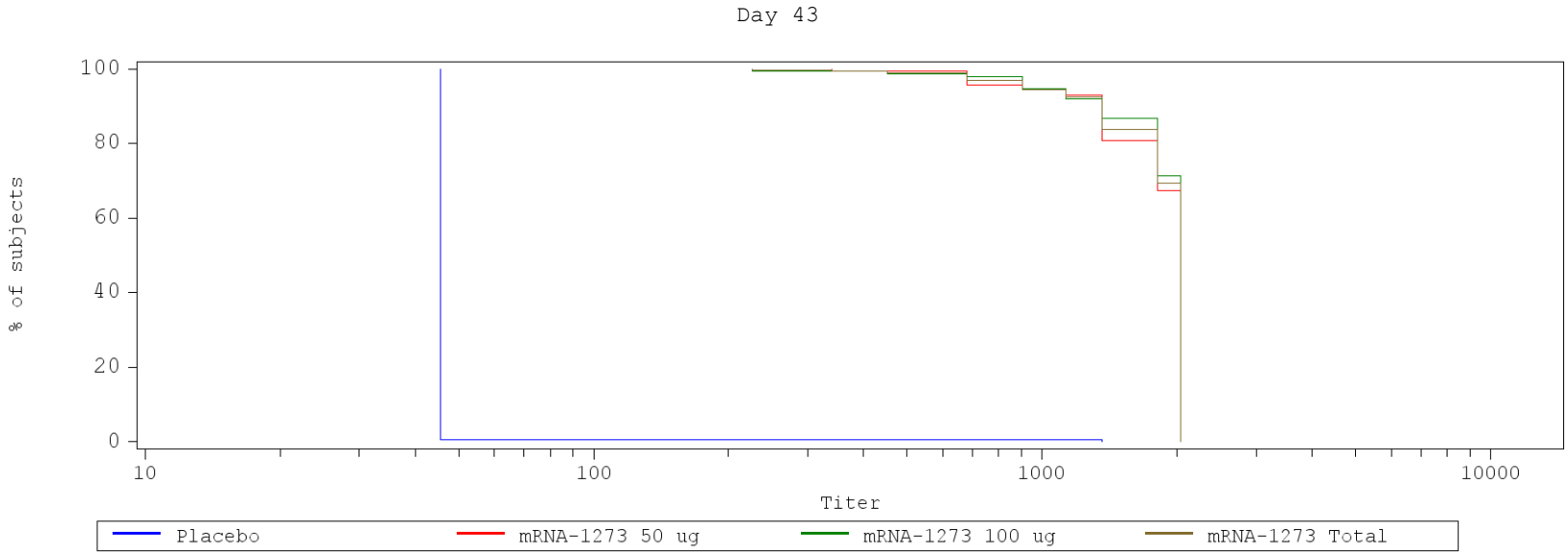


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

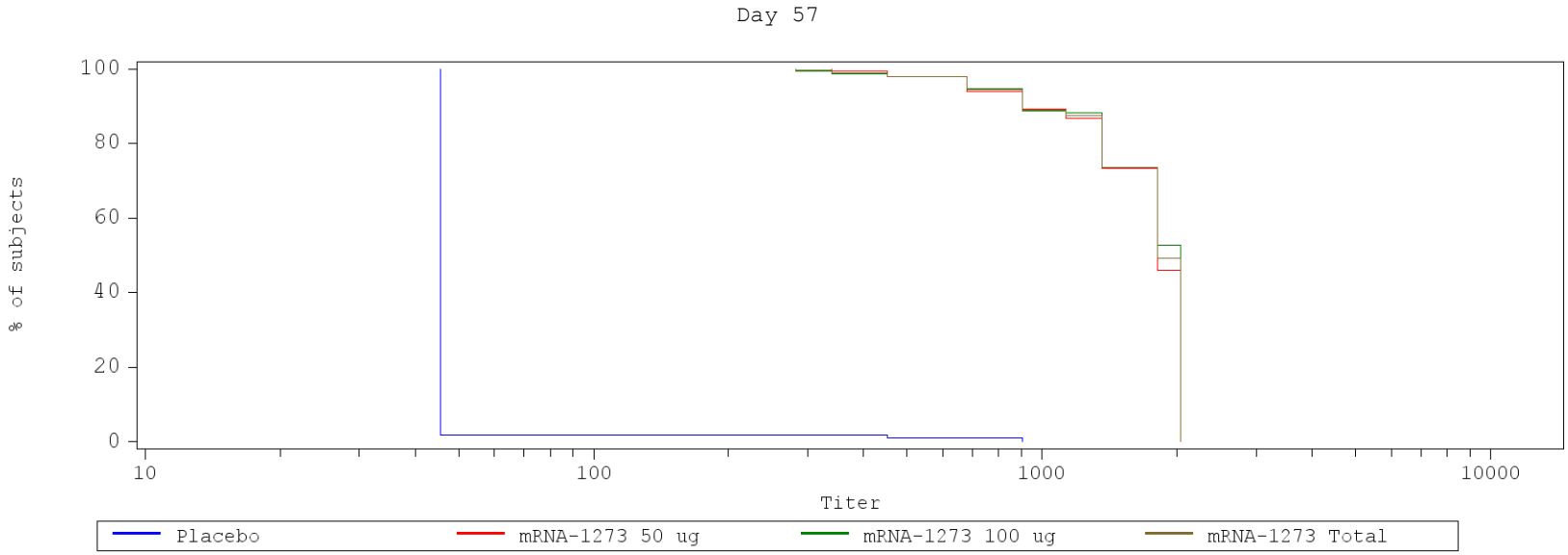


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

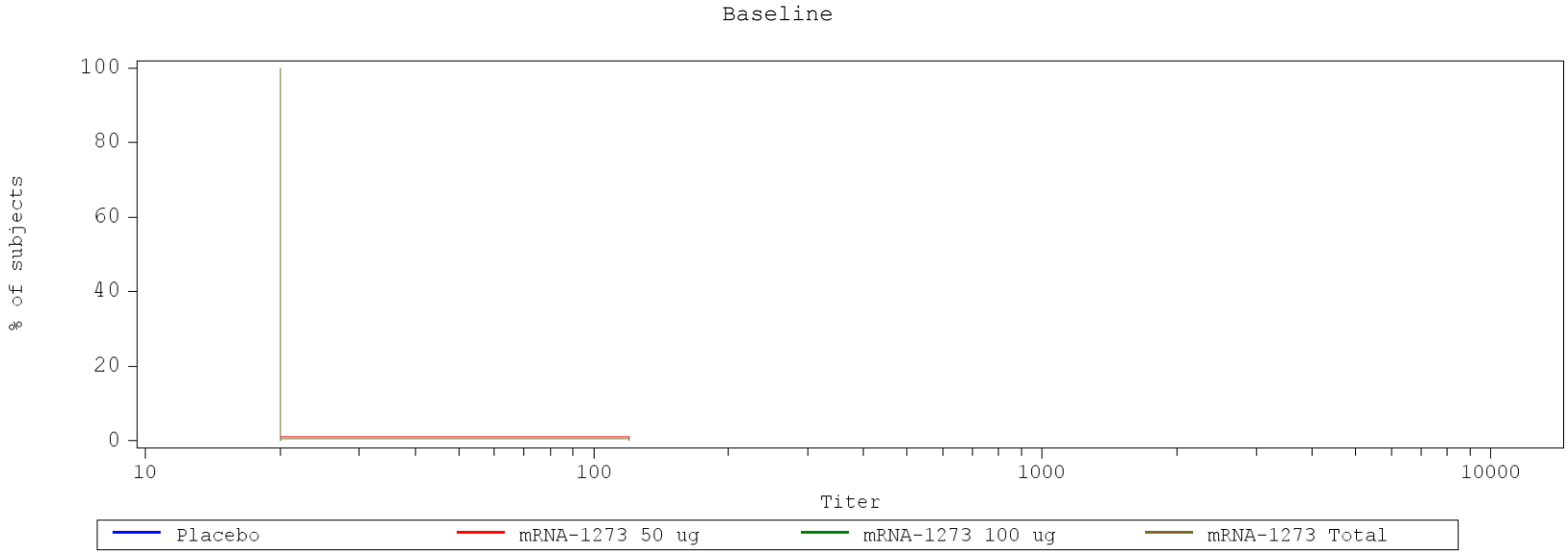


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



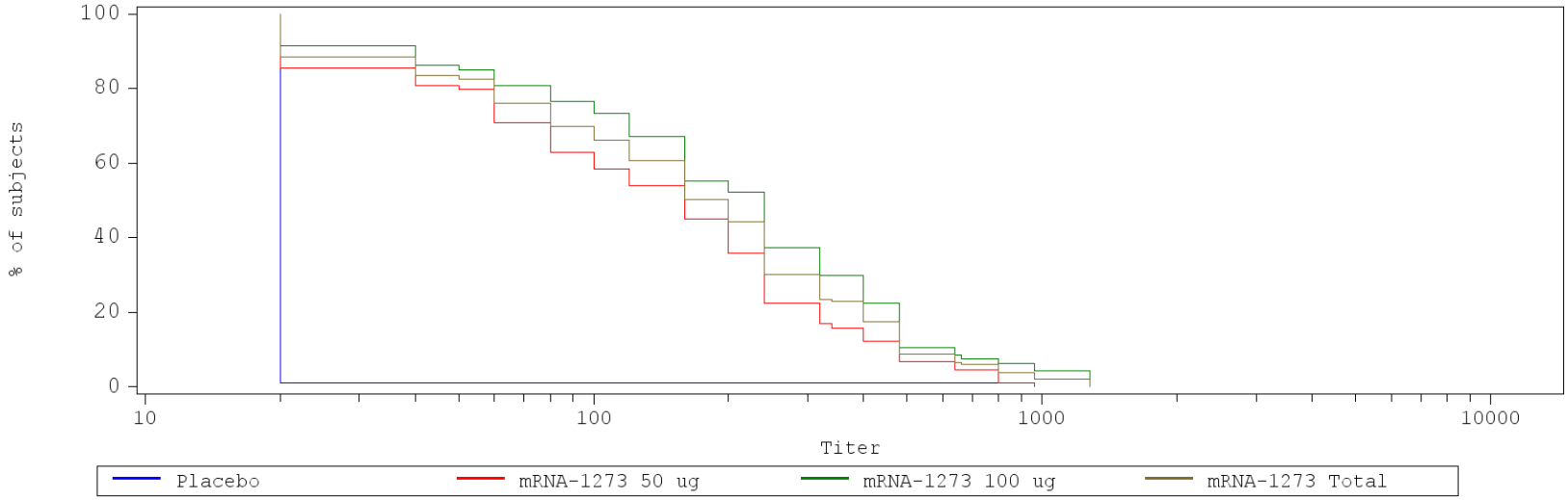
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

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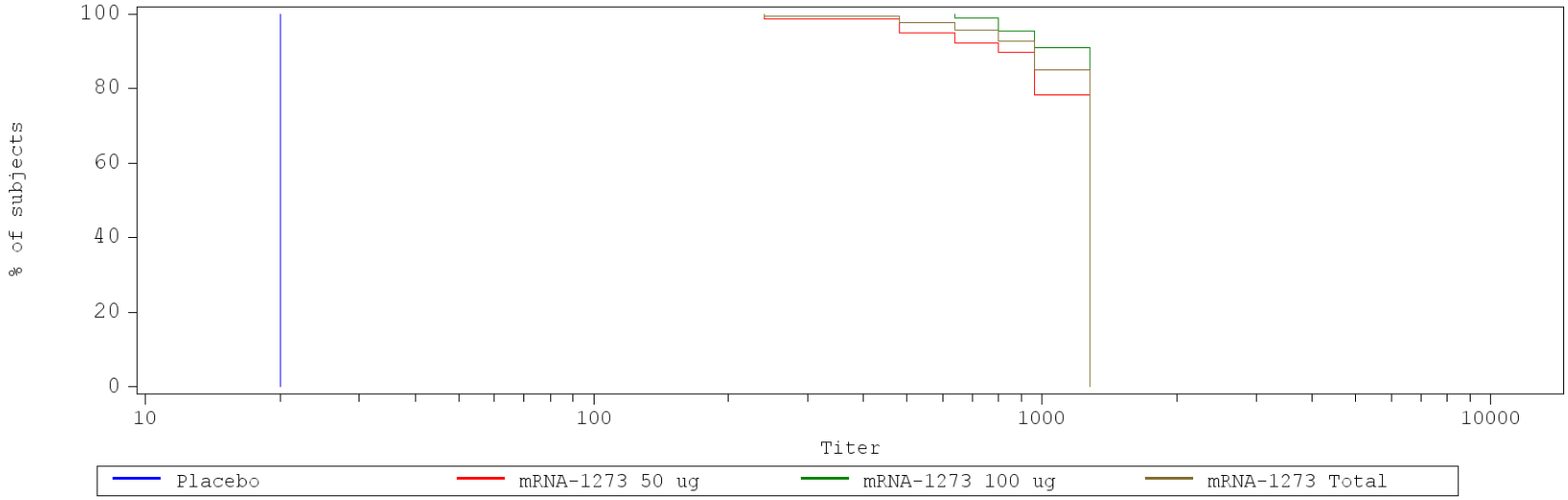
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 43



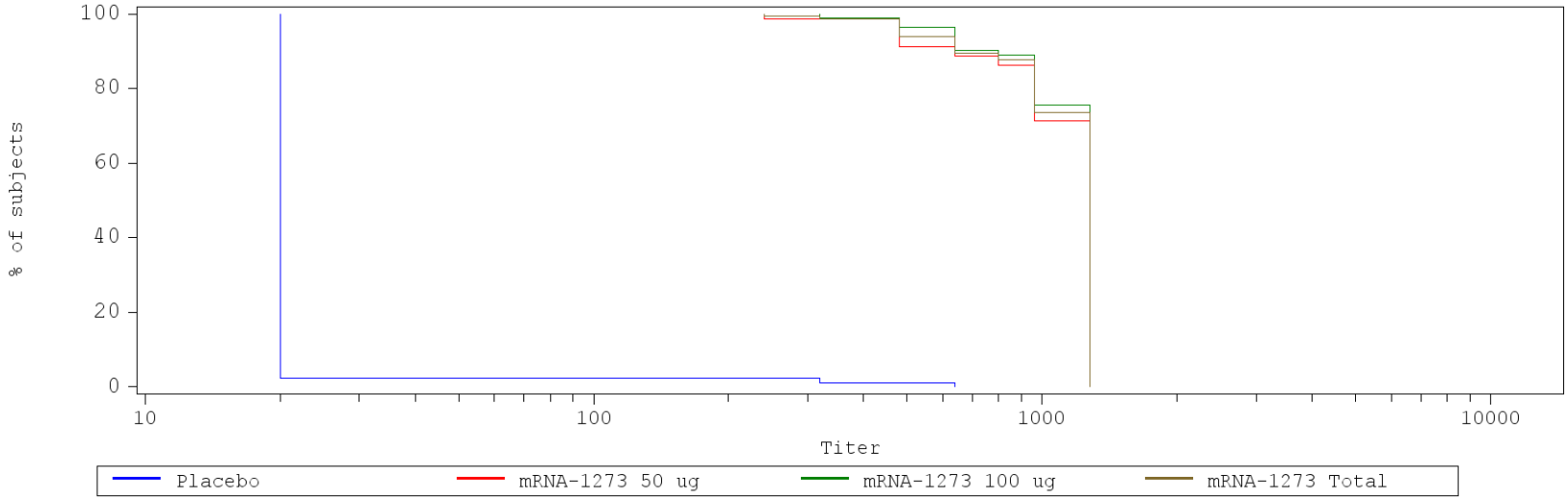
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 57

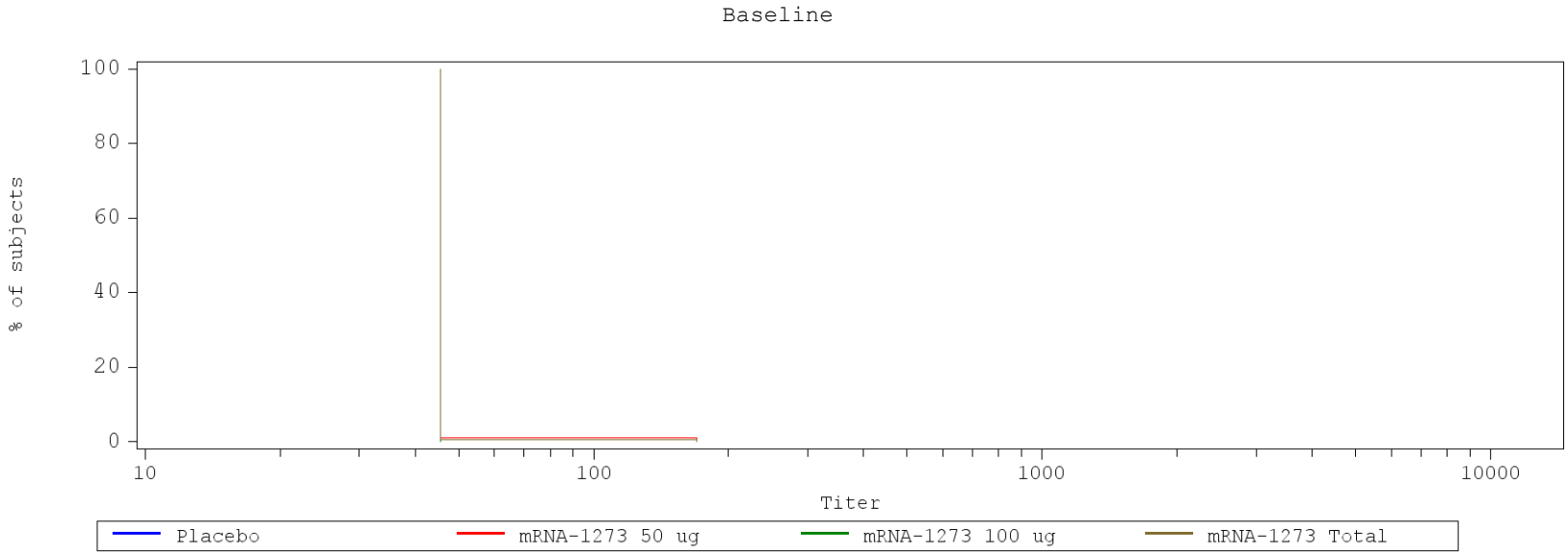


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



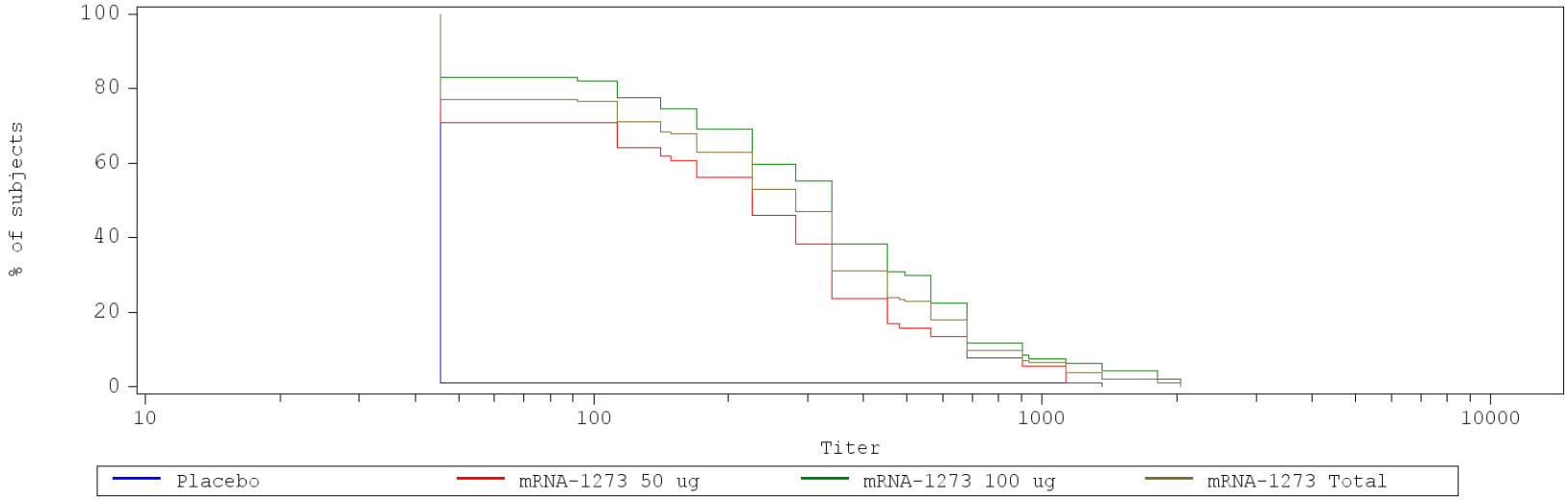
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 29



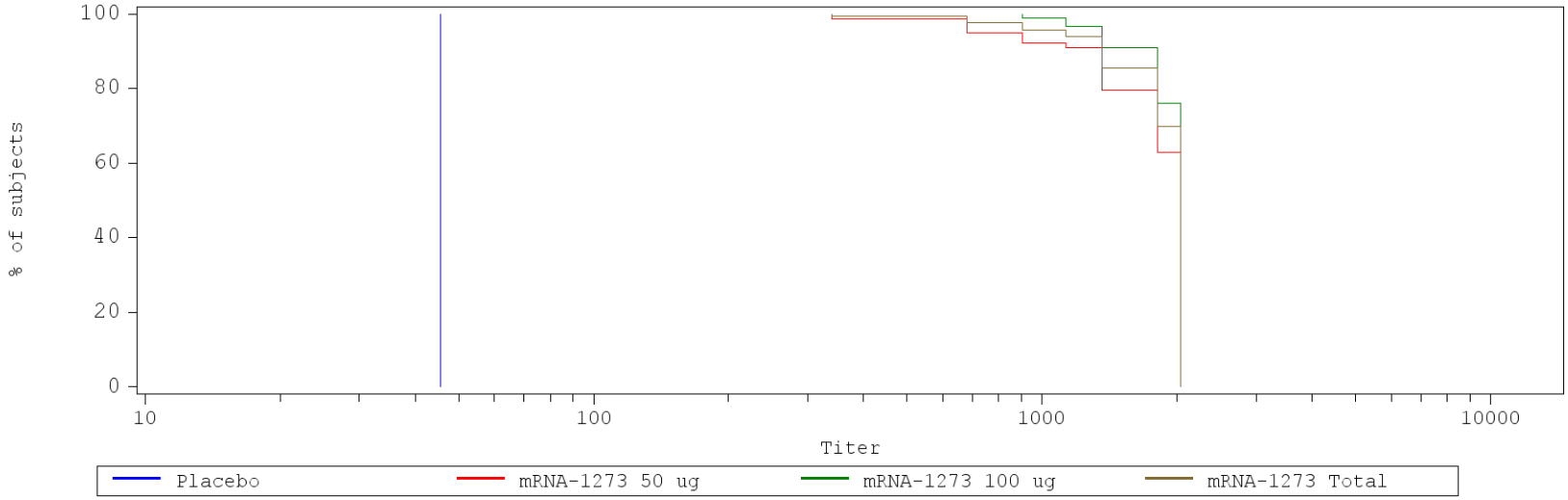
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 43



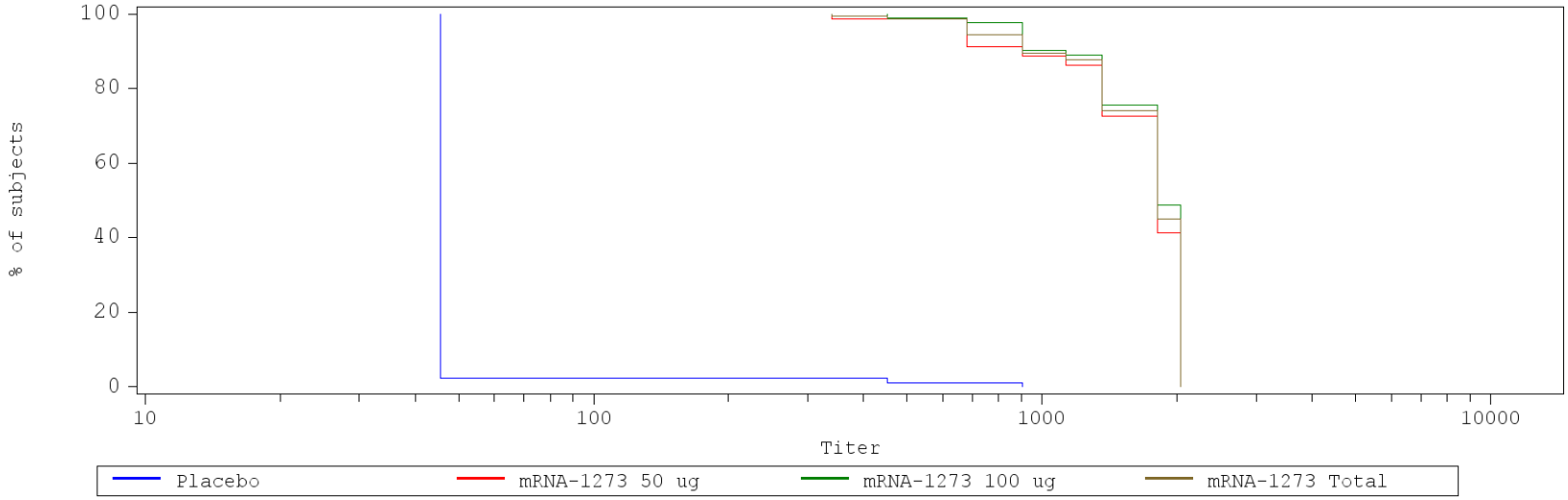
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 57

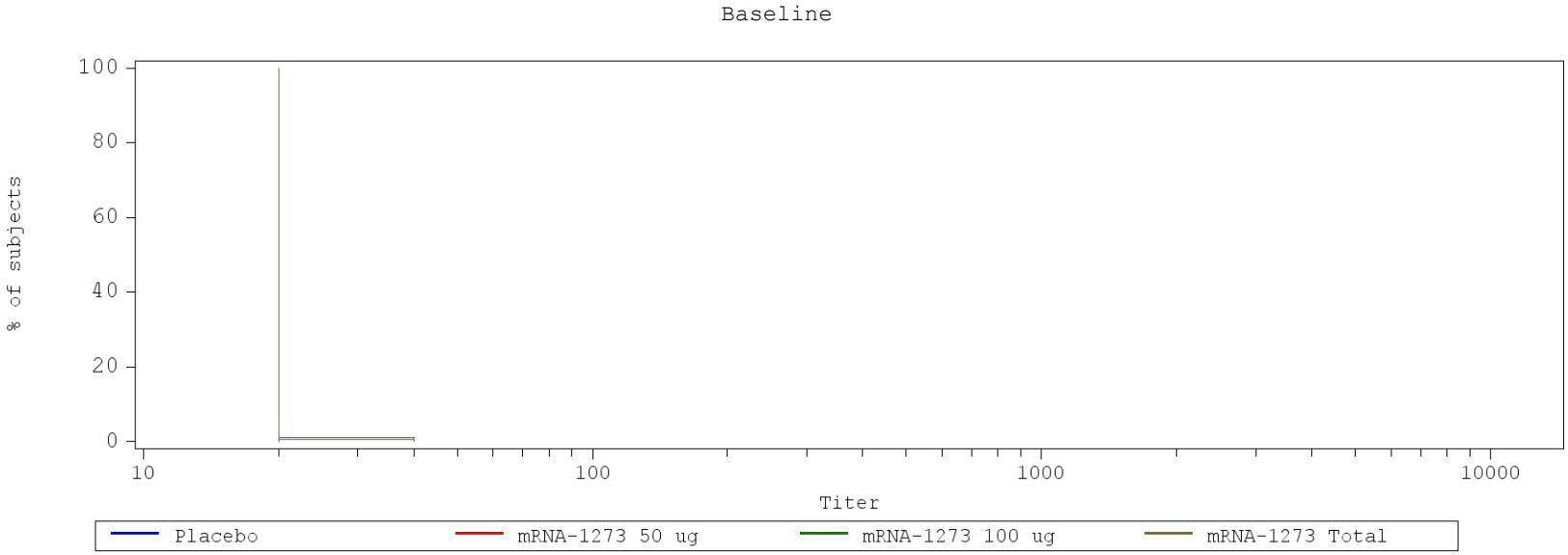


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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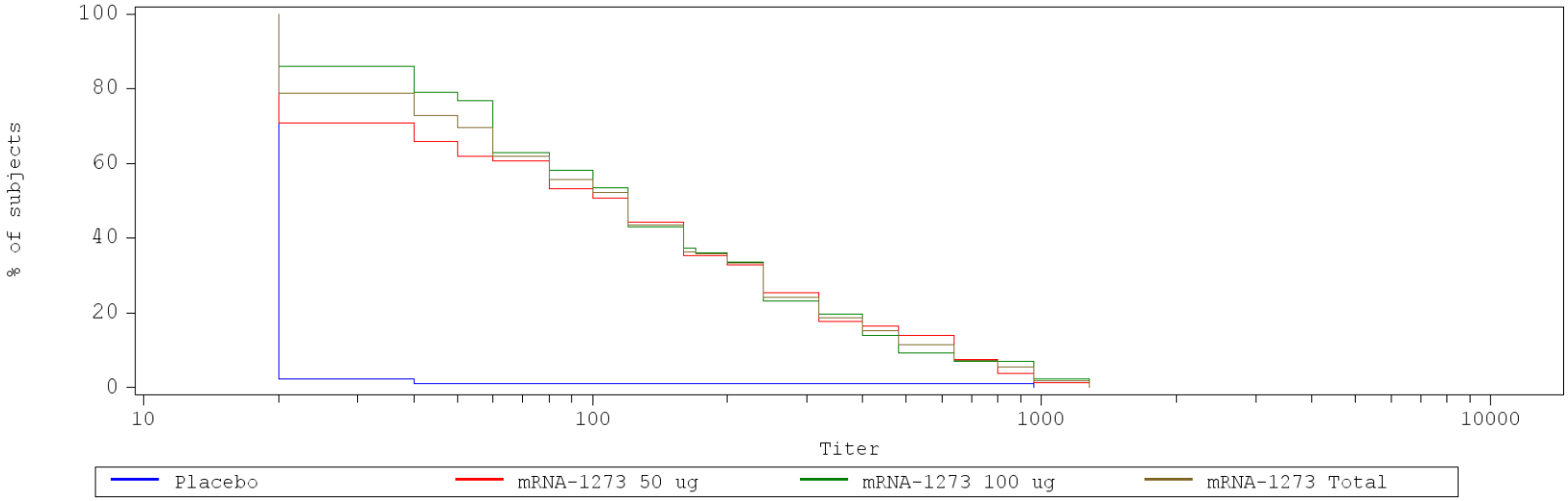
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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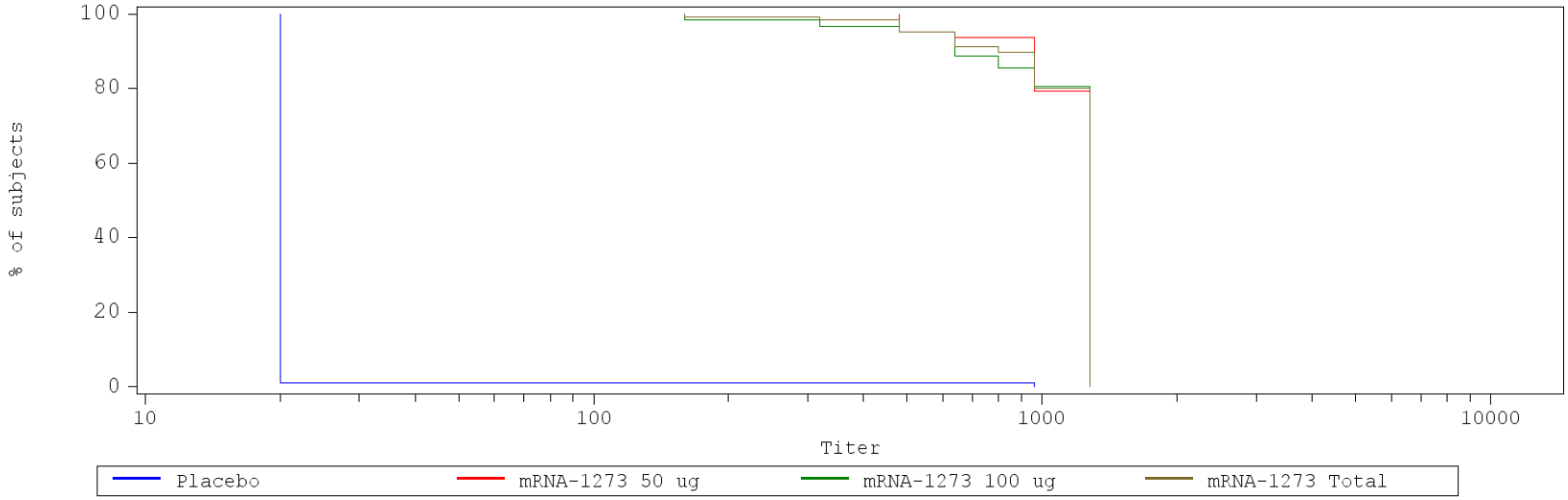
For MN Endpoint Titer: LLOQ=40 and ULOQ=1280. For MN50: LLOQ=91.10 and ULOQ=2031.87.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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 43



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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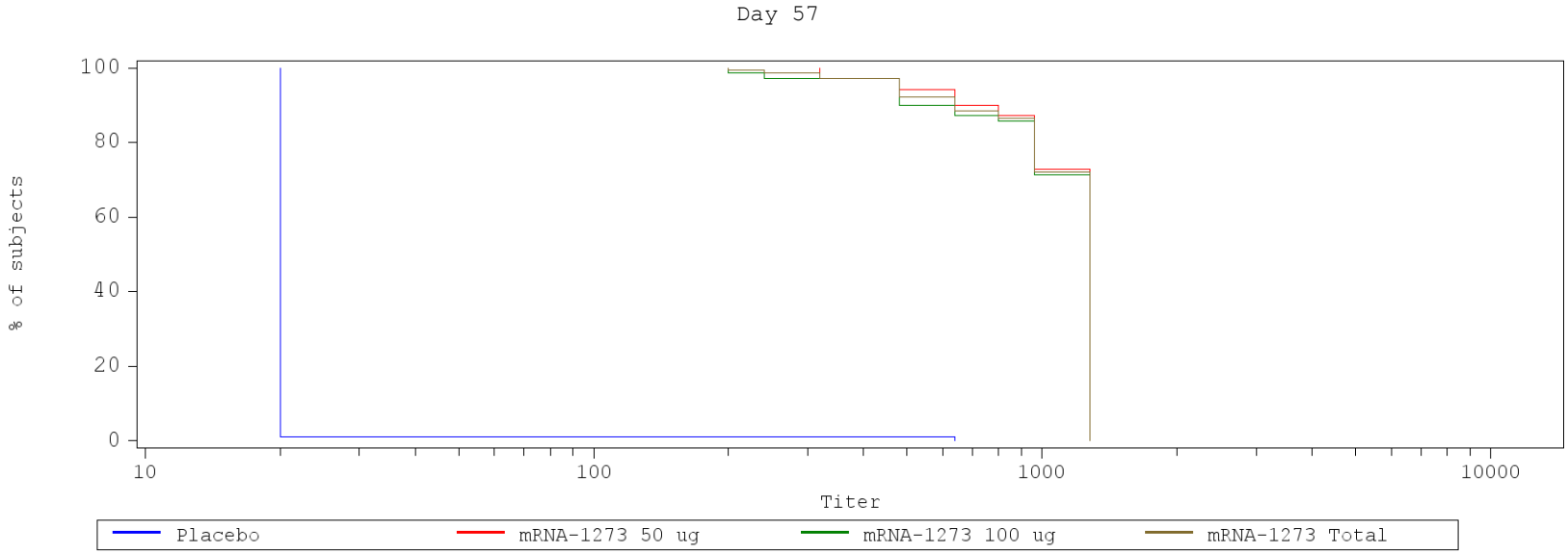
Figure 14.2.6.1.1
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot

Cohort 2 (>=55 Years)
Antibody: MN Endpoint Titer

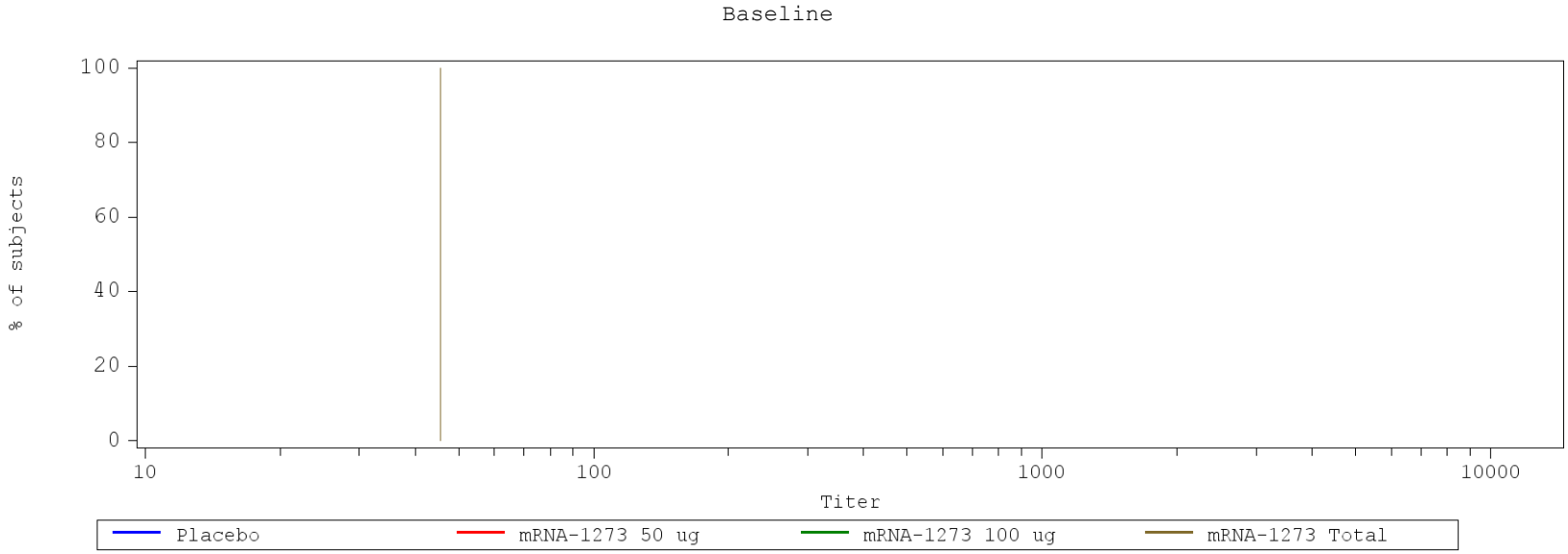


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



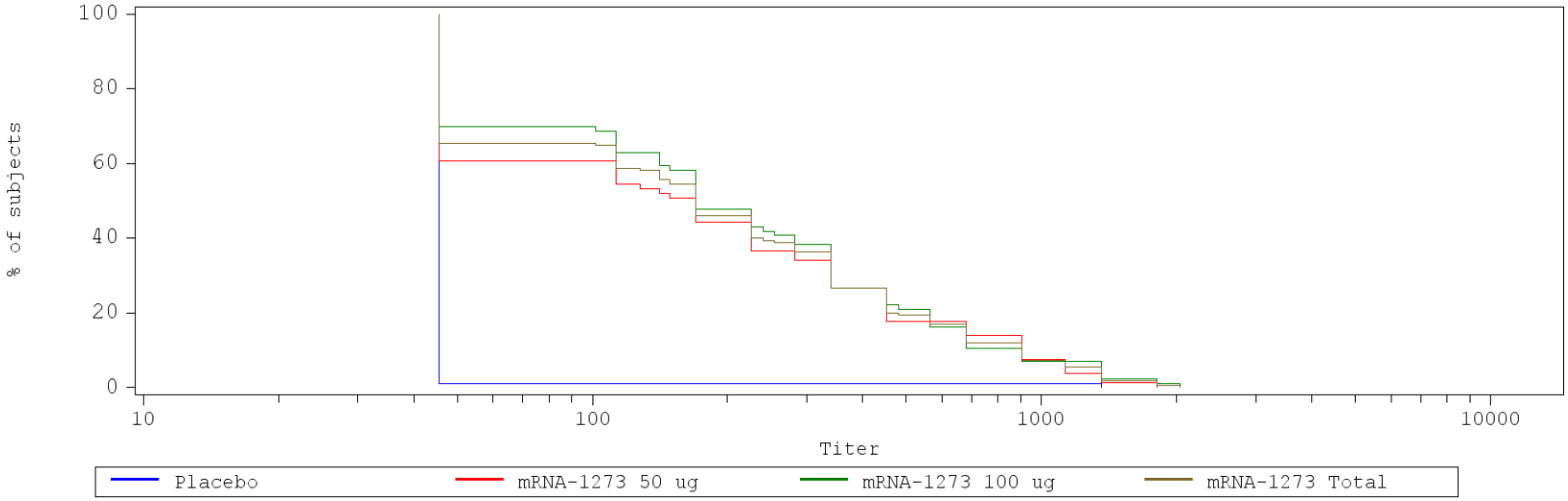
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 29

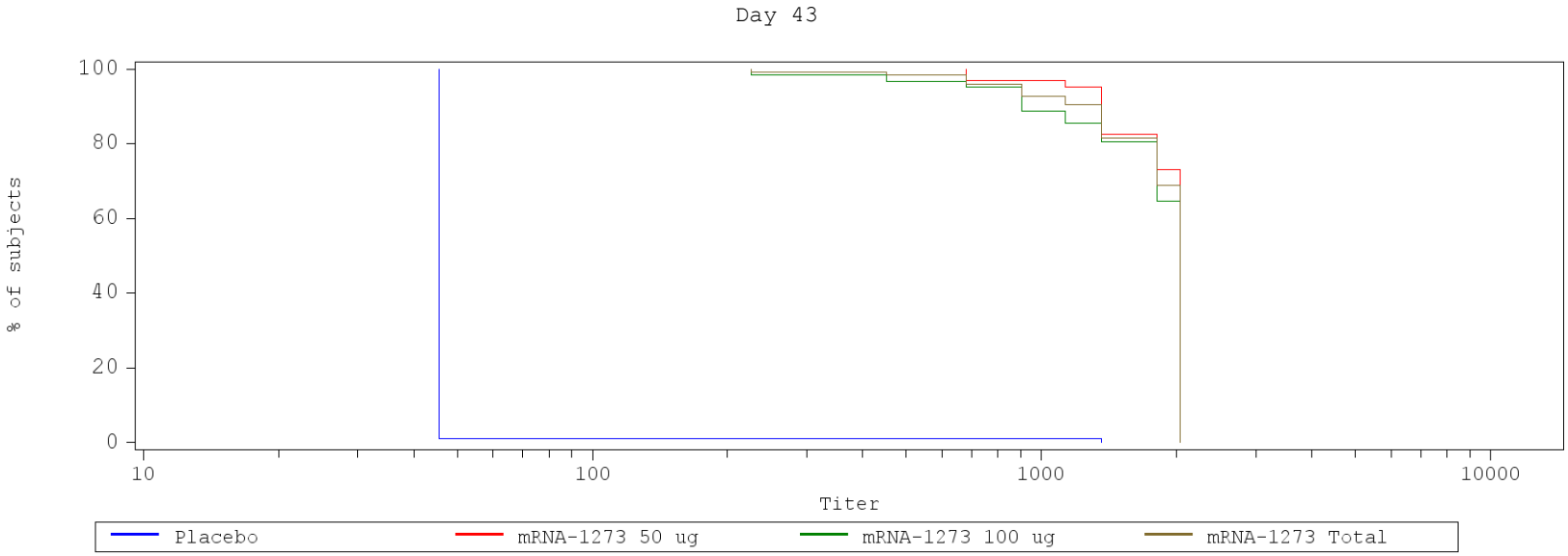


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

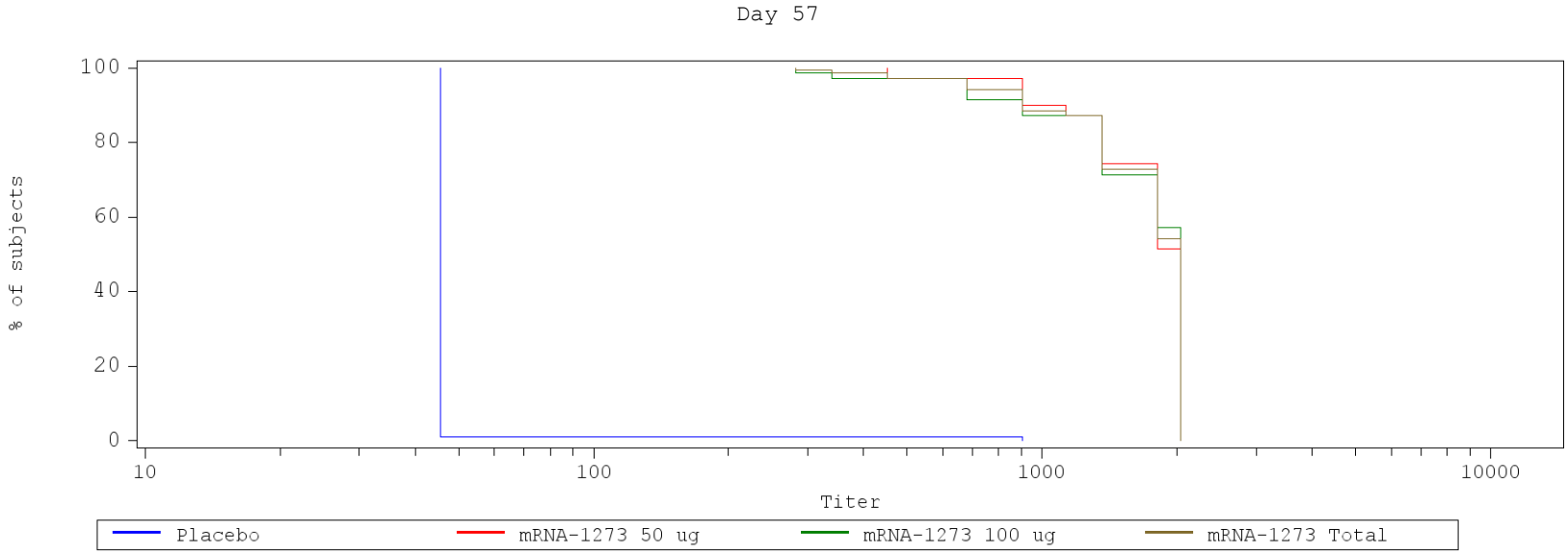


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

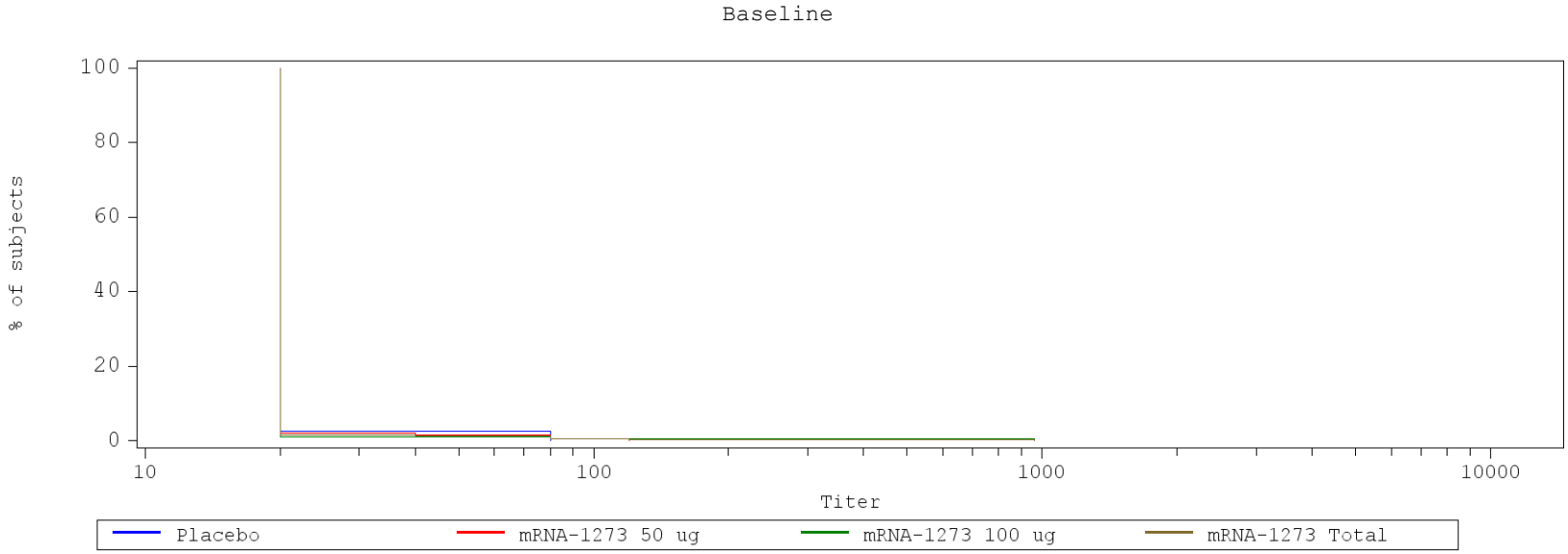


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from the First Lot with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060101.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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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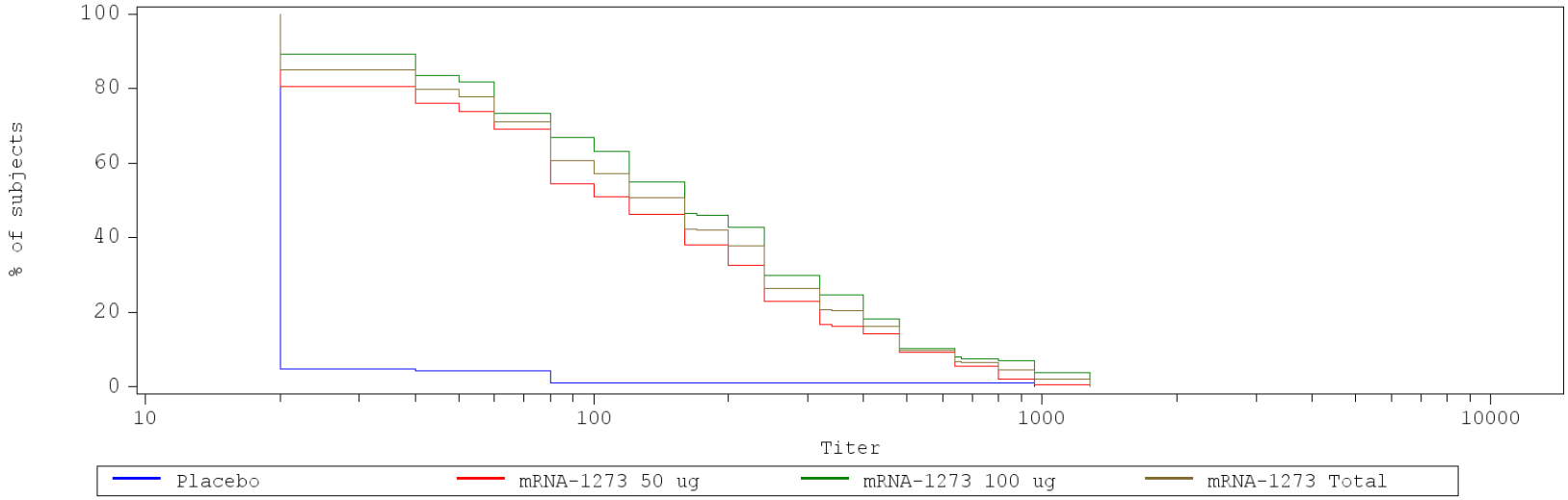
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN Endpoint Titer

Day 29

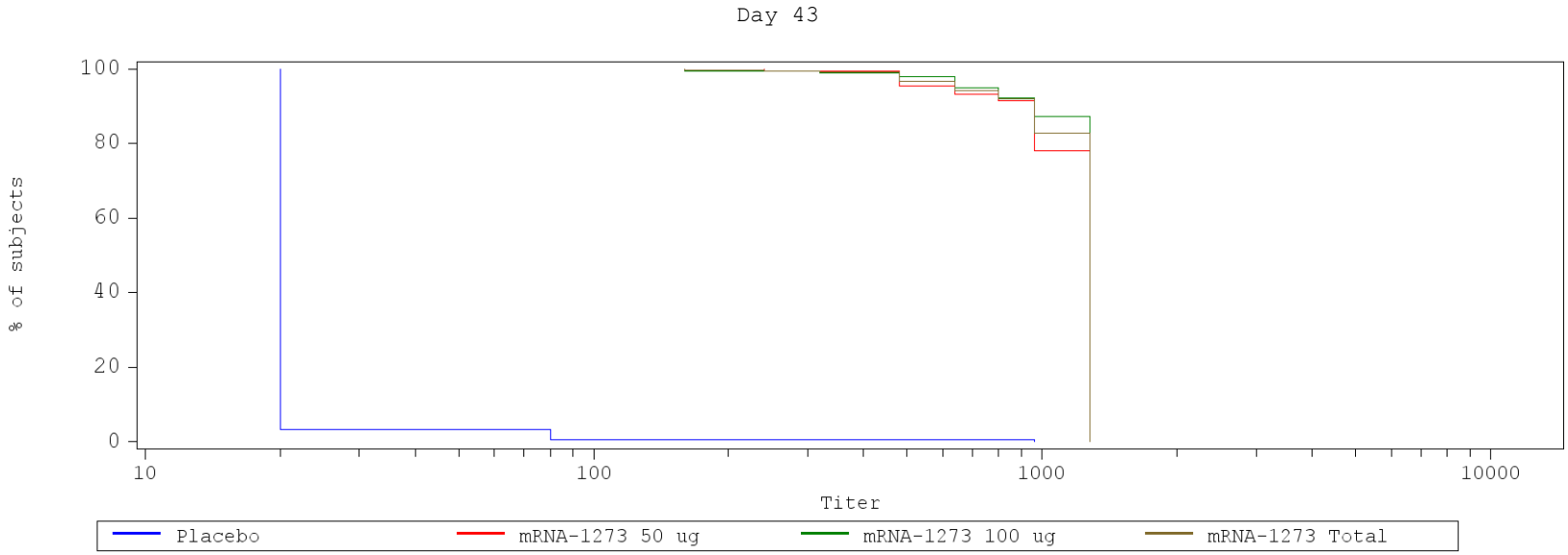


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

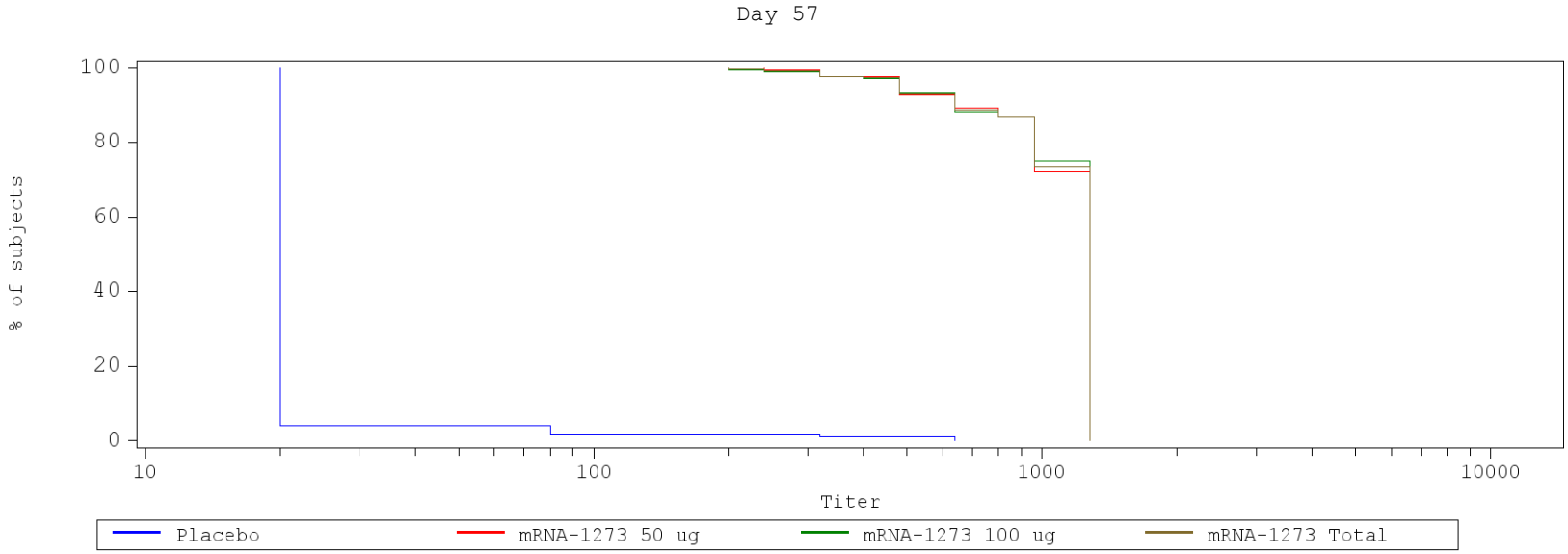


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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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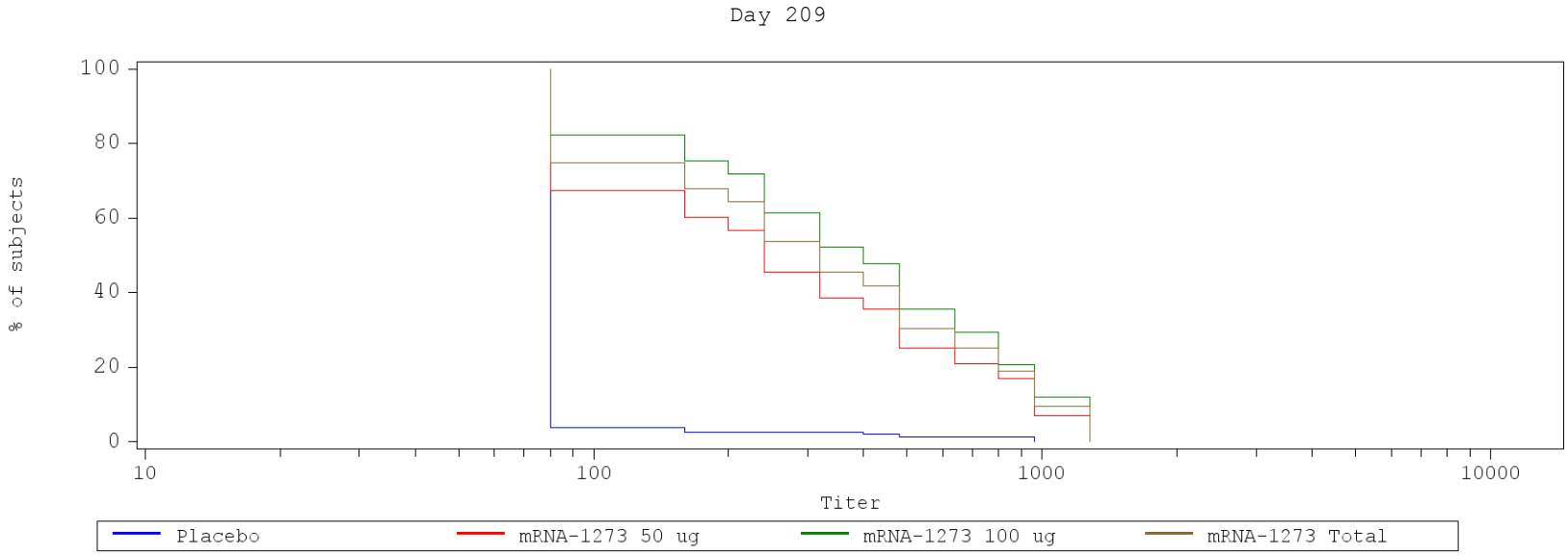
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: 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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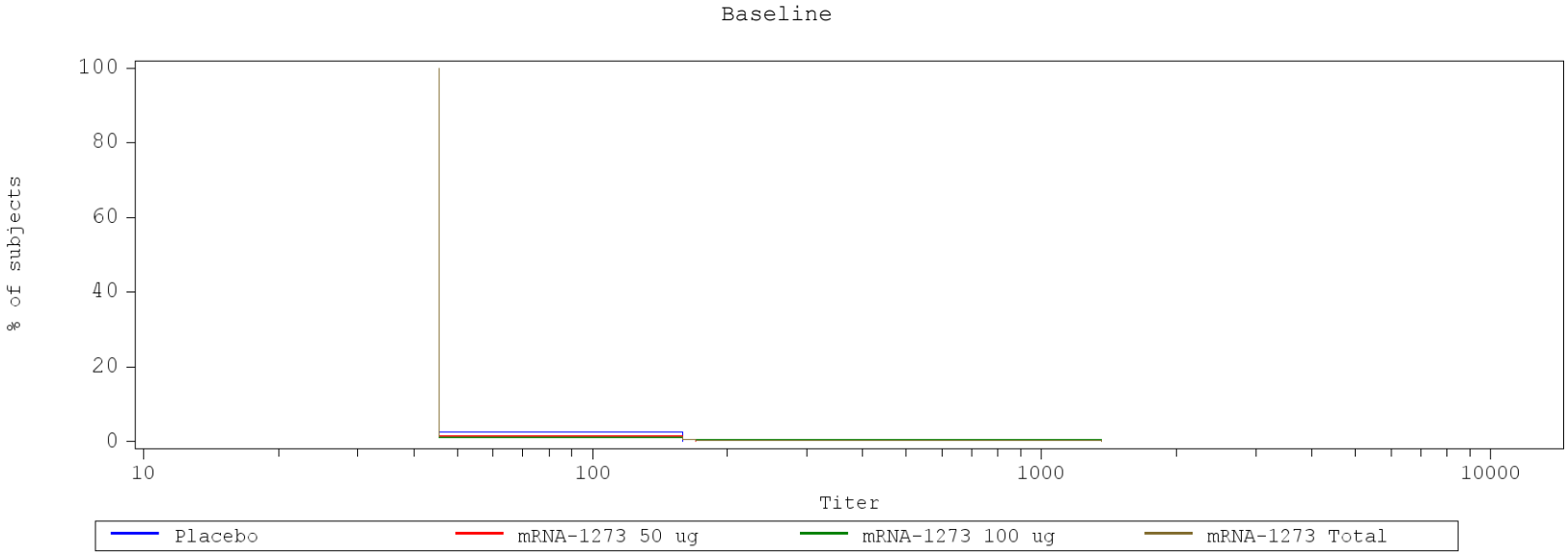
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50



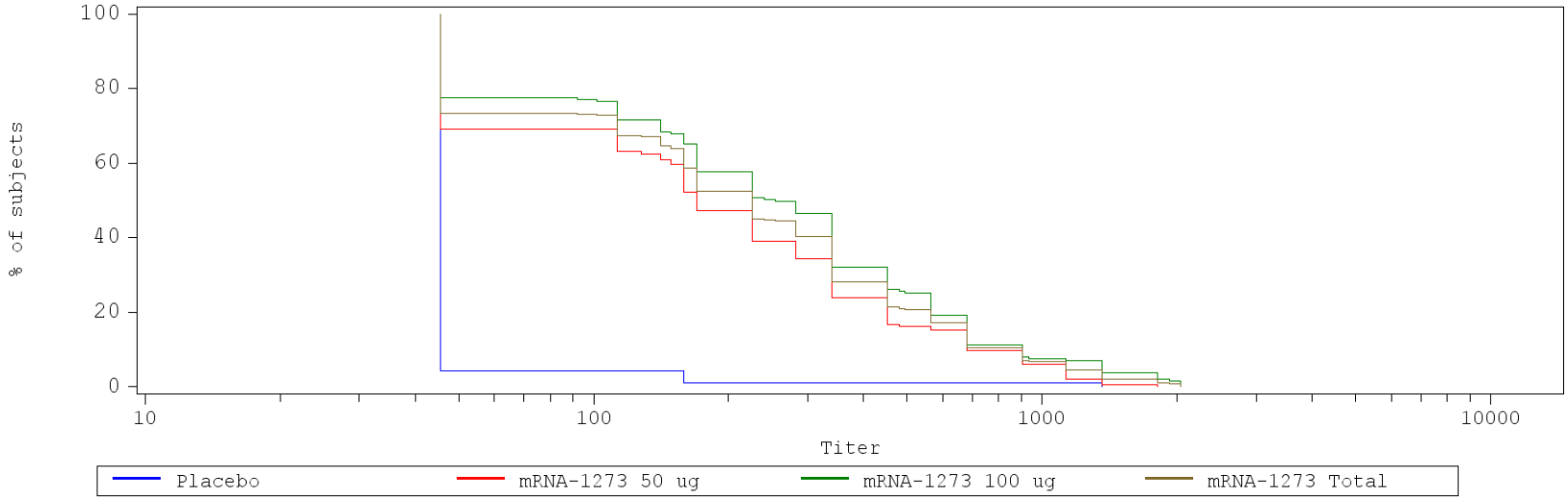
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

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 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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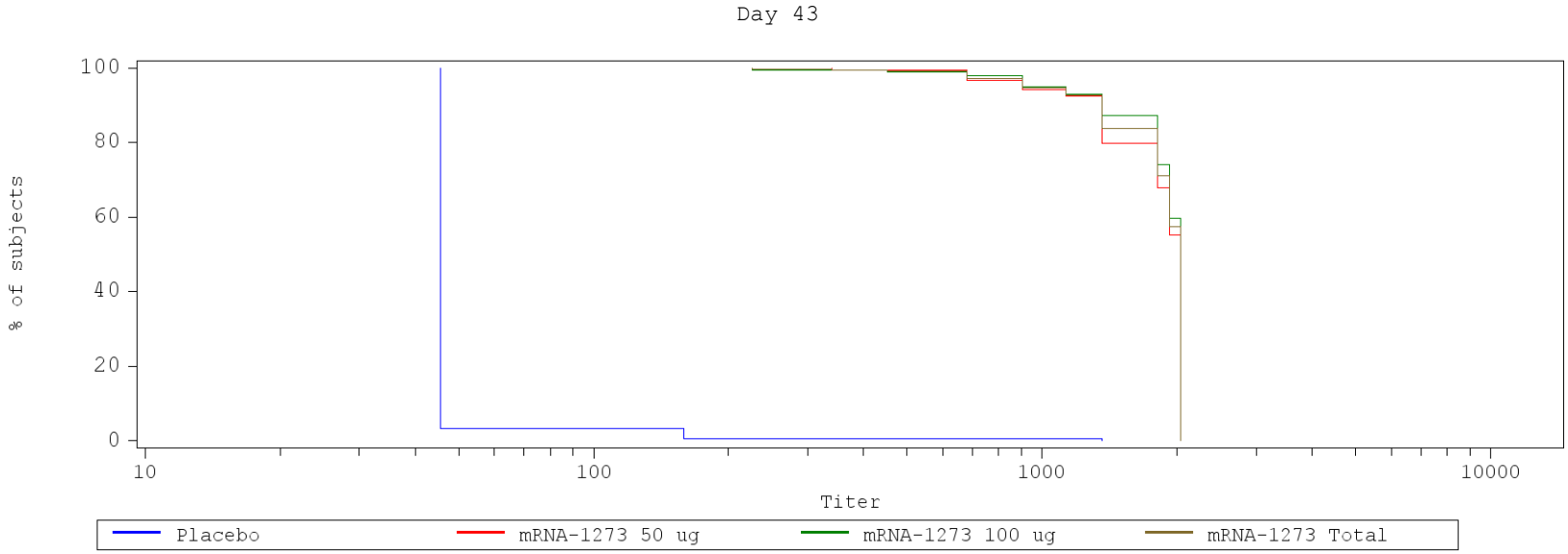
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50

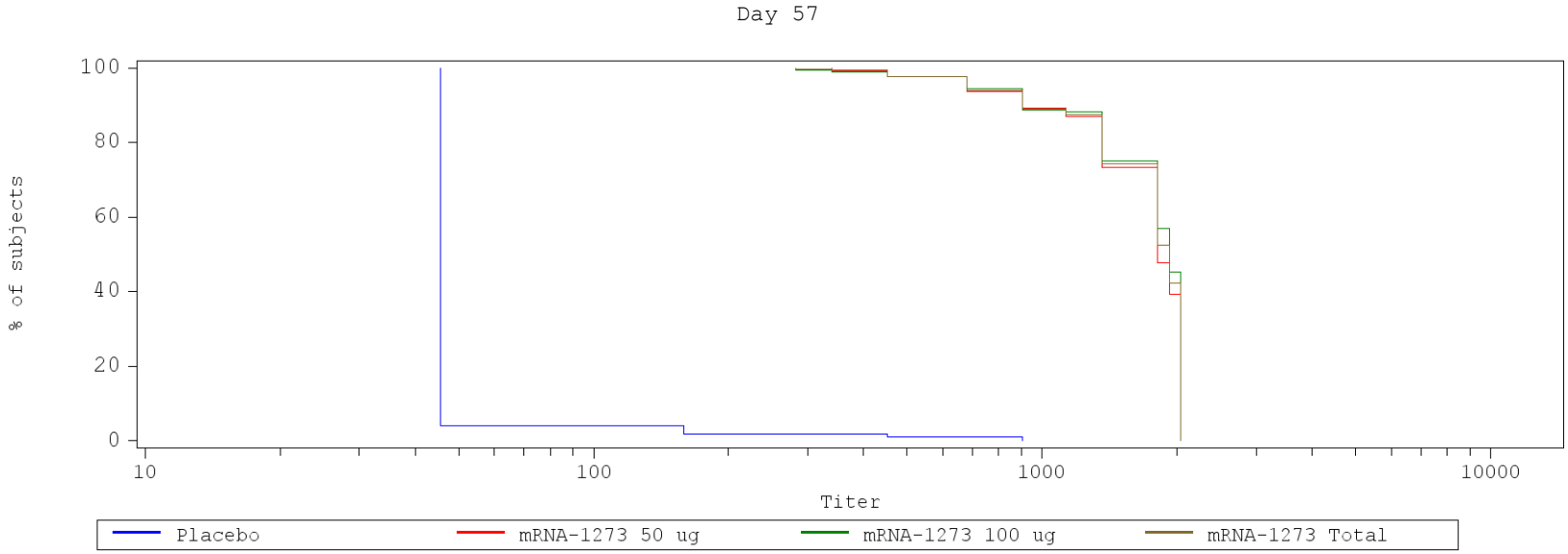


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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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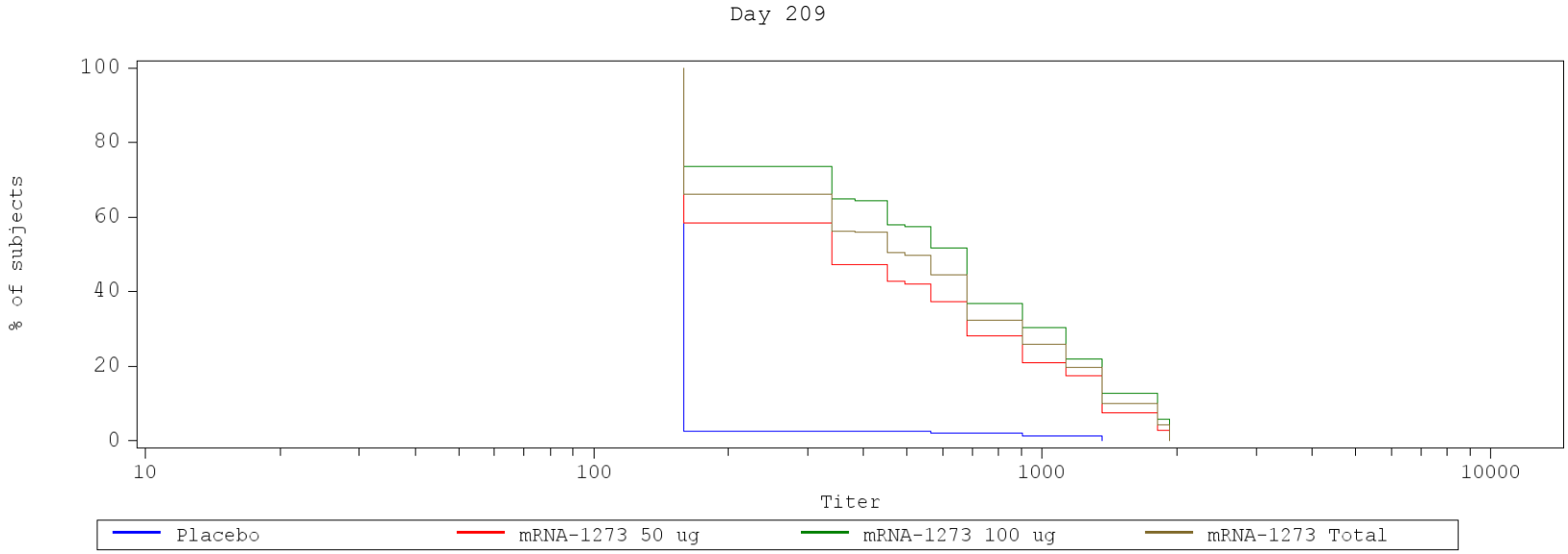
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort Overall
Antibody: MN50

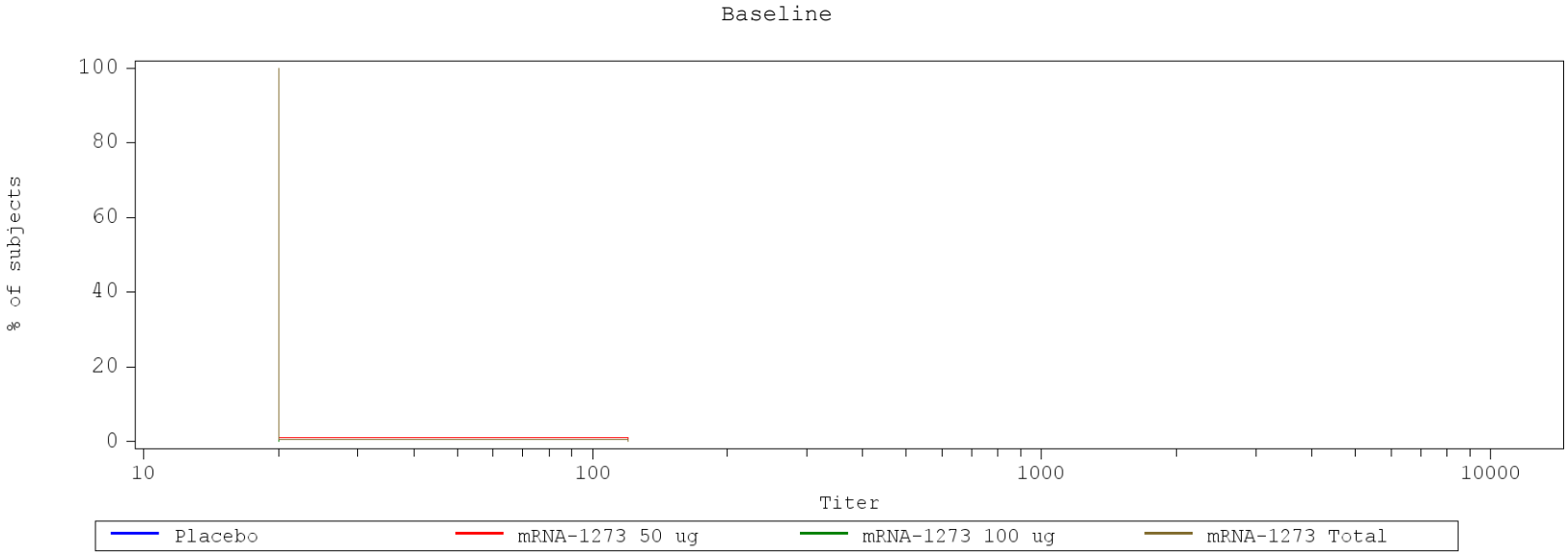


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



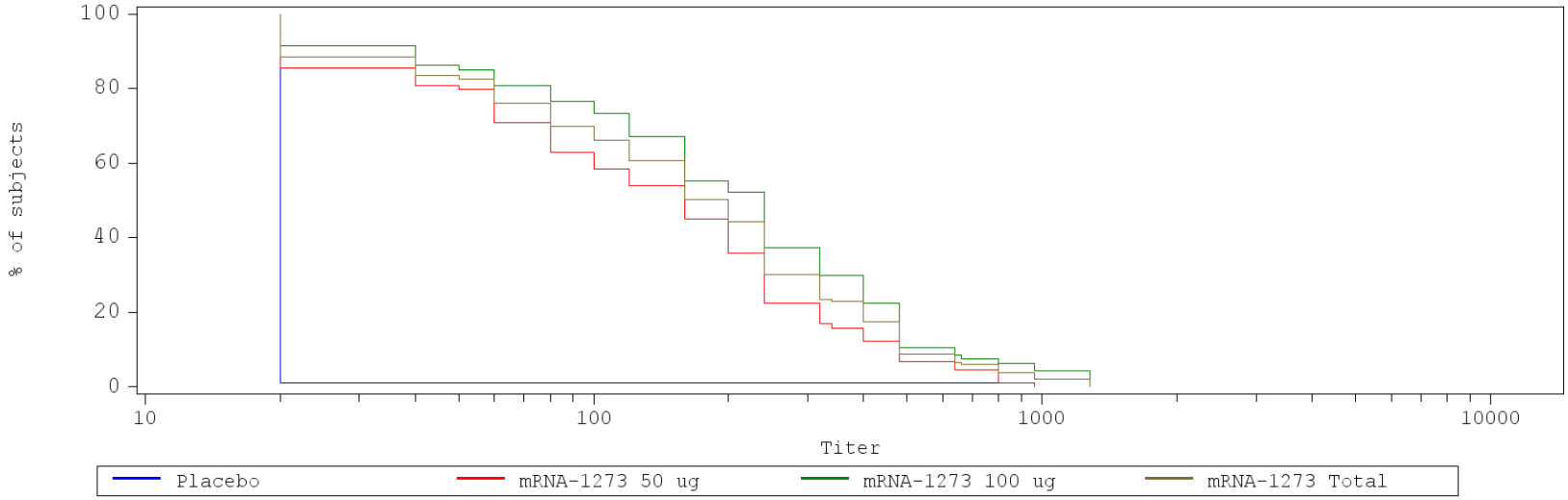
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 29



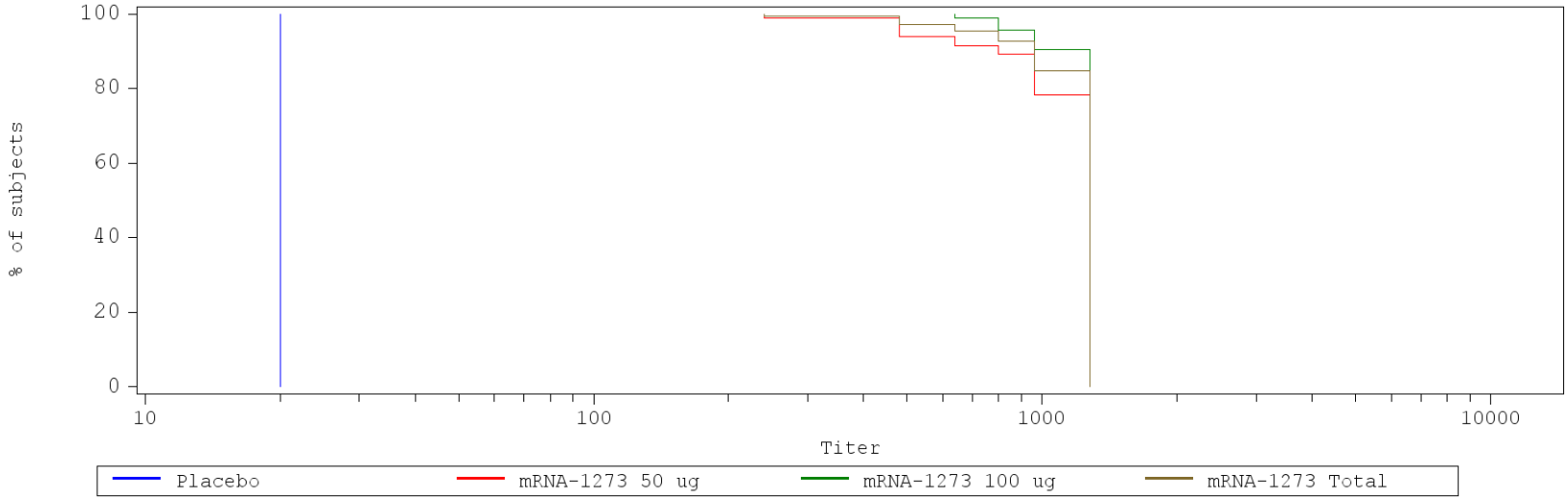
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 43

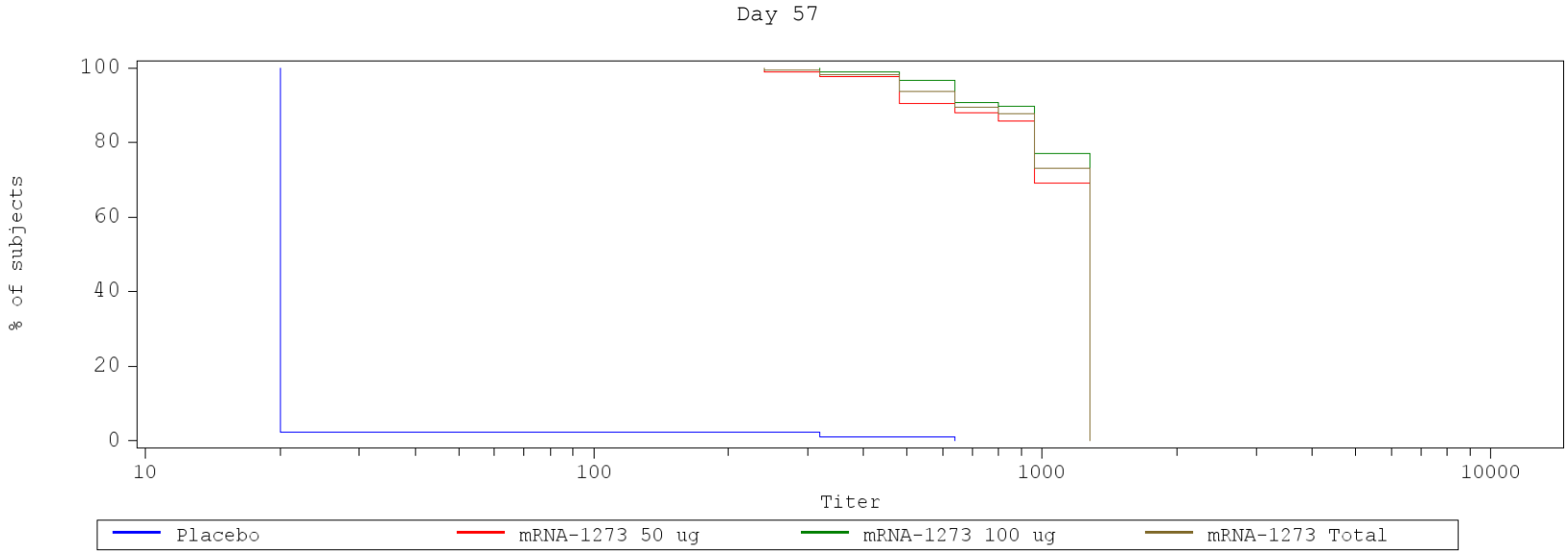


nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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



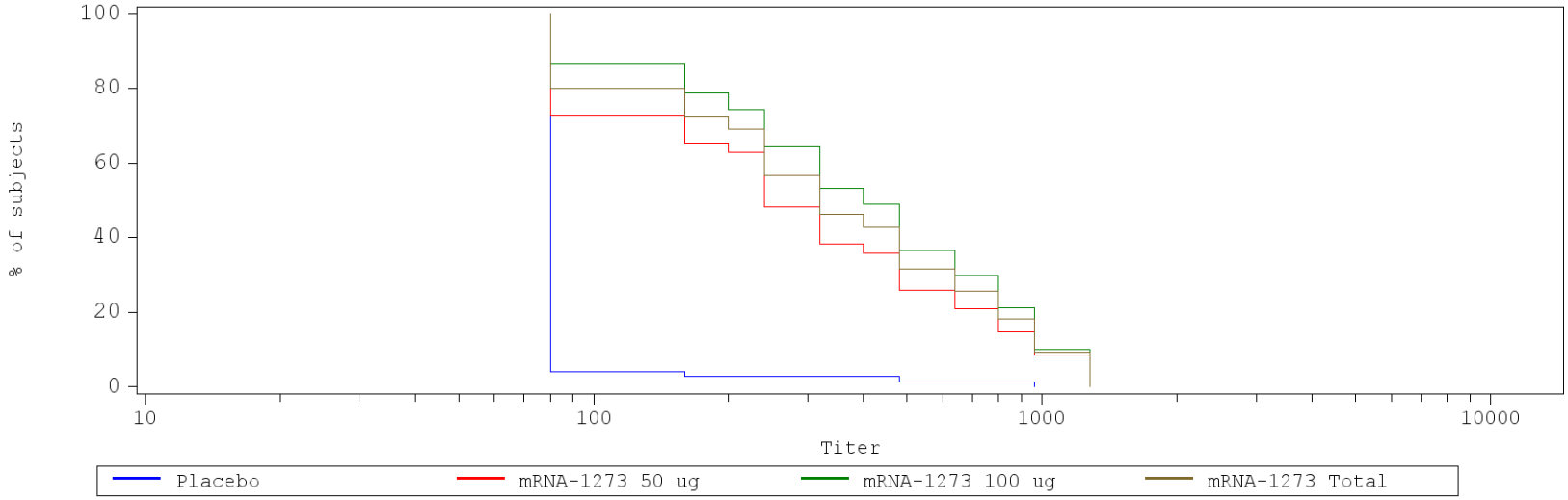
nAb = Neutralizing antibody.
Note: Percentages are based on the number of subjects in the Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots with non-missing data at each visit.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that 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\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 209



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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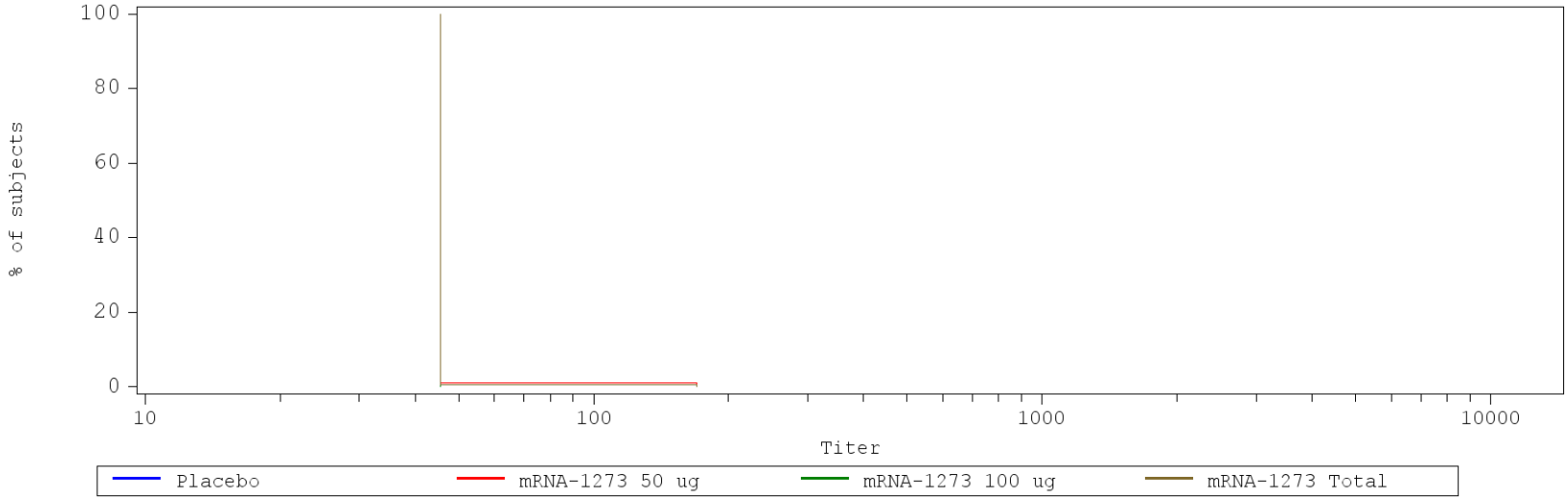
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: MN50

Baseline



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.
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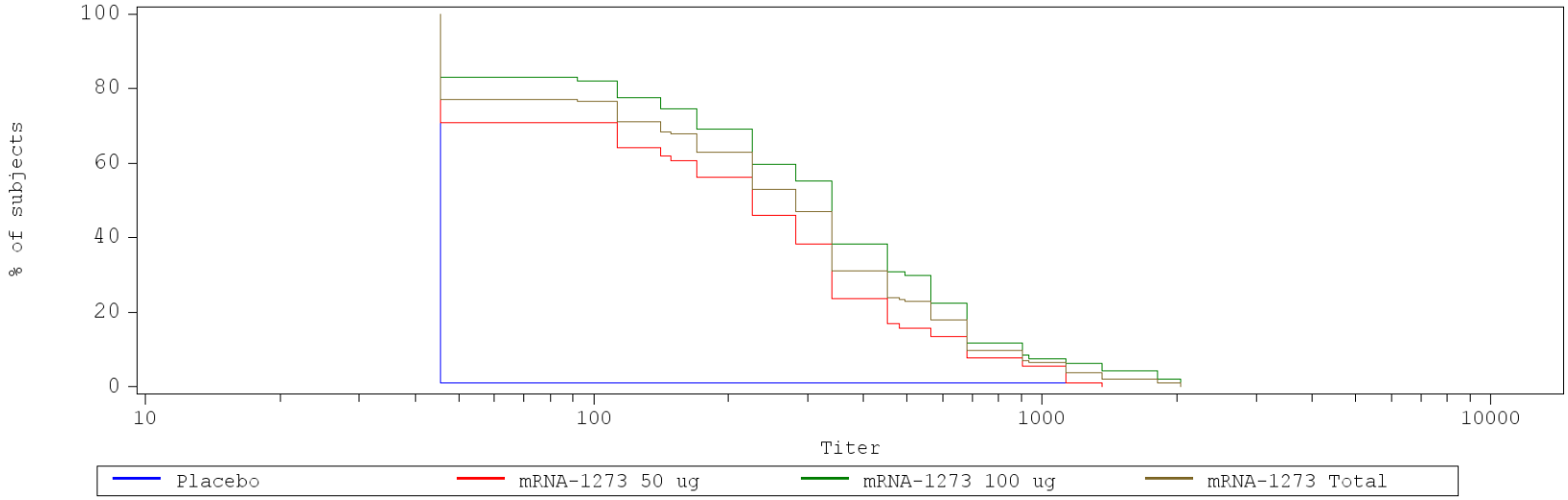
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: MN50

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 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.
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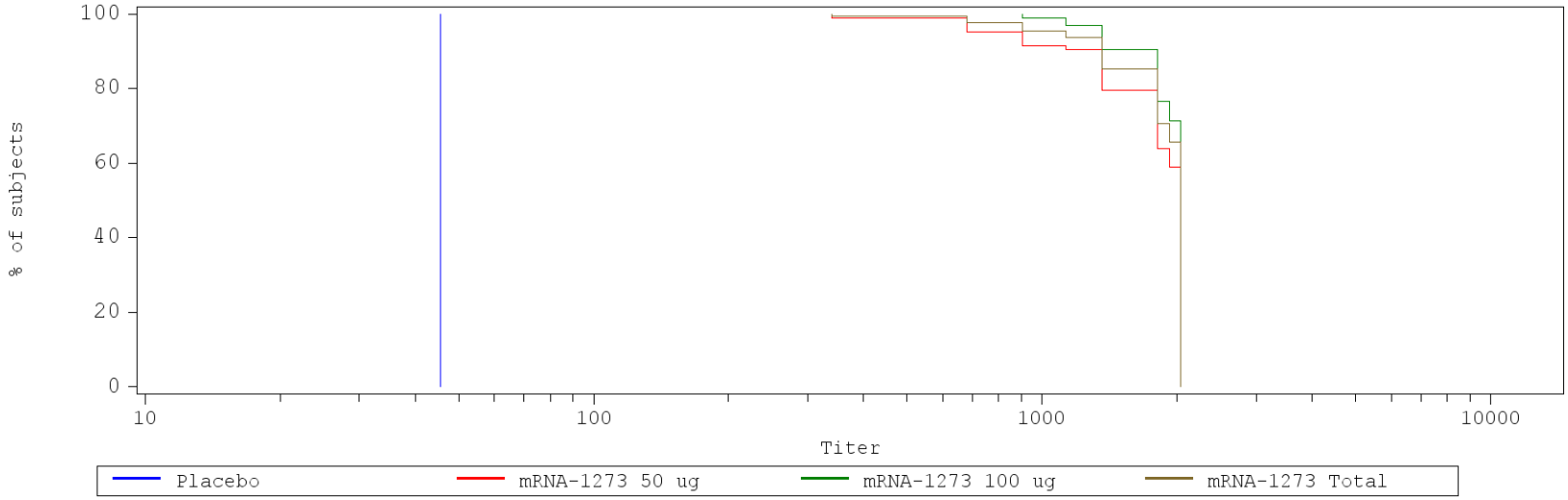
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: MN50

Day 43



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.
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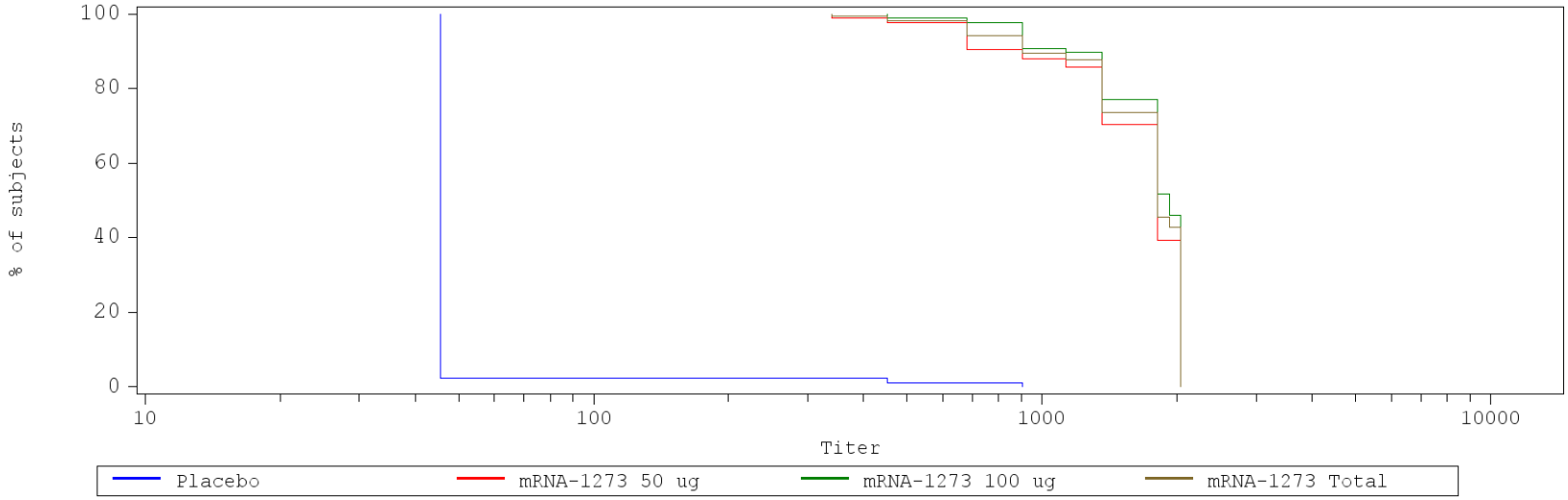
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: MN50

Day 57



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.
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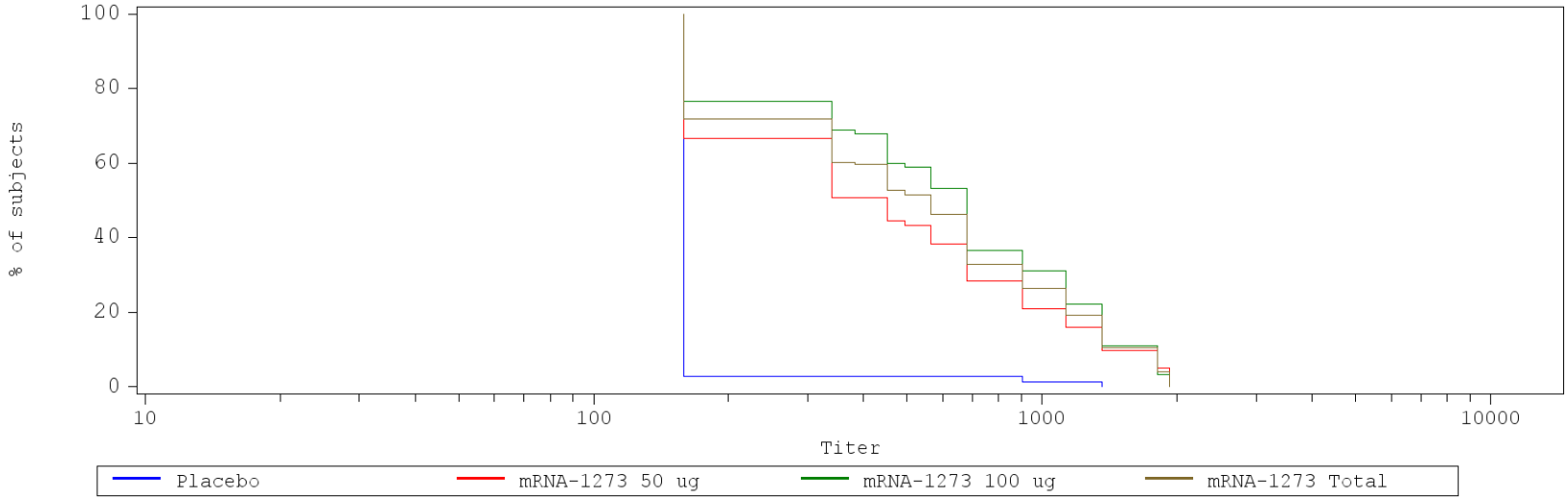
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 1 (>=18 and <55 Years)
Antibody: MN50

Day 209



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.
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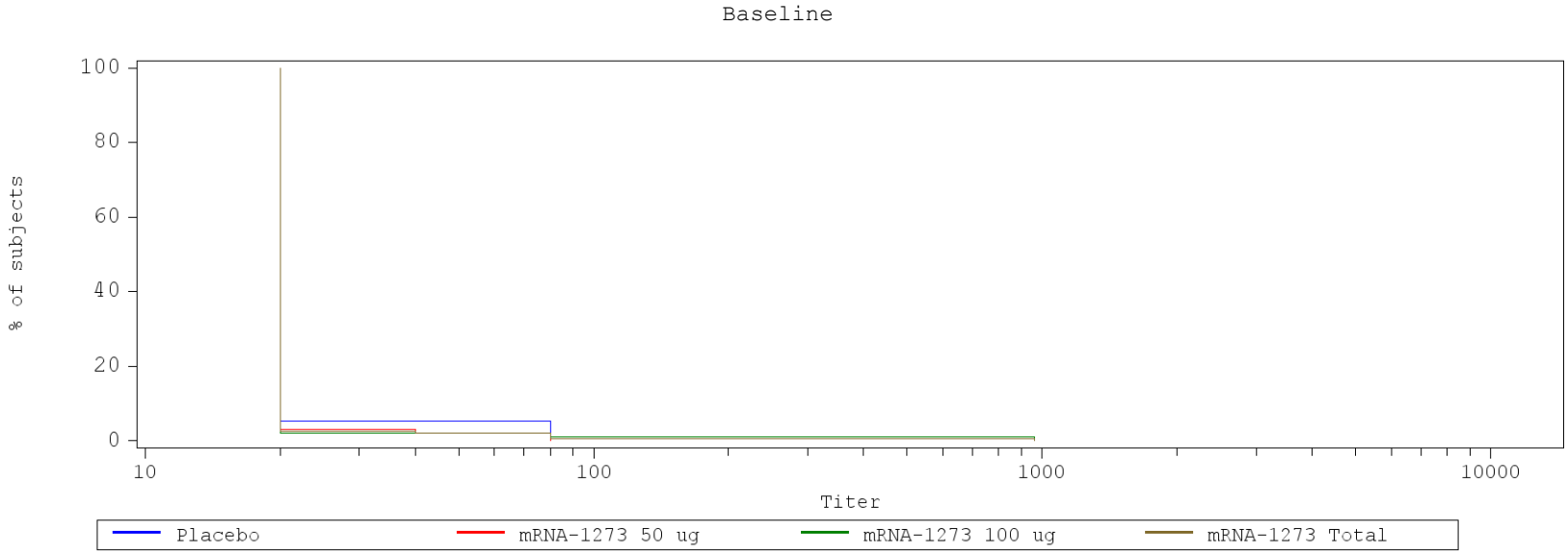
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
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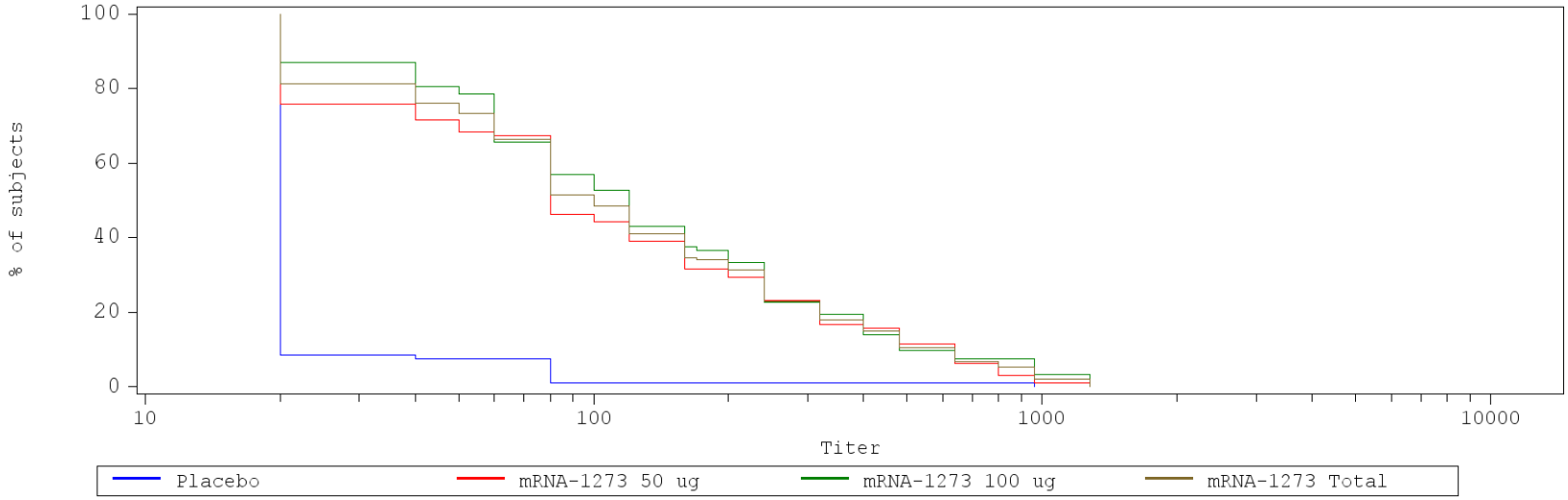
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (>=55 Years)
Antibody: MN Endpoint Titer

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 All Lots with non-missing data at each visit.
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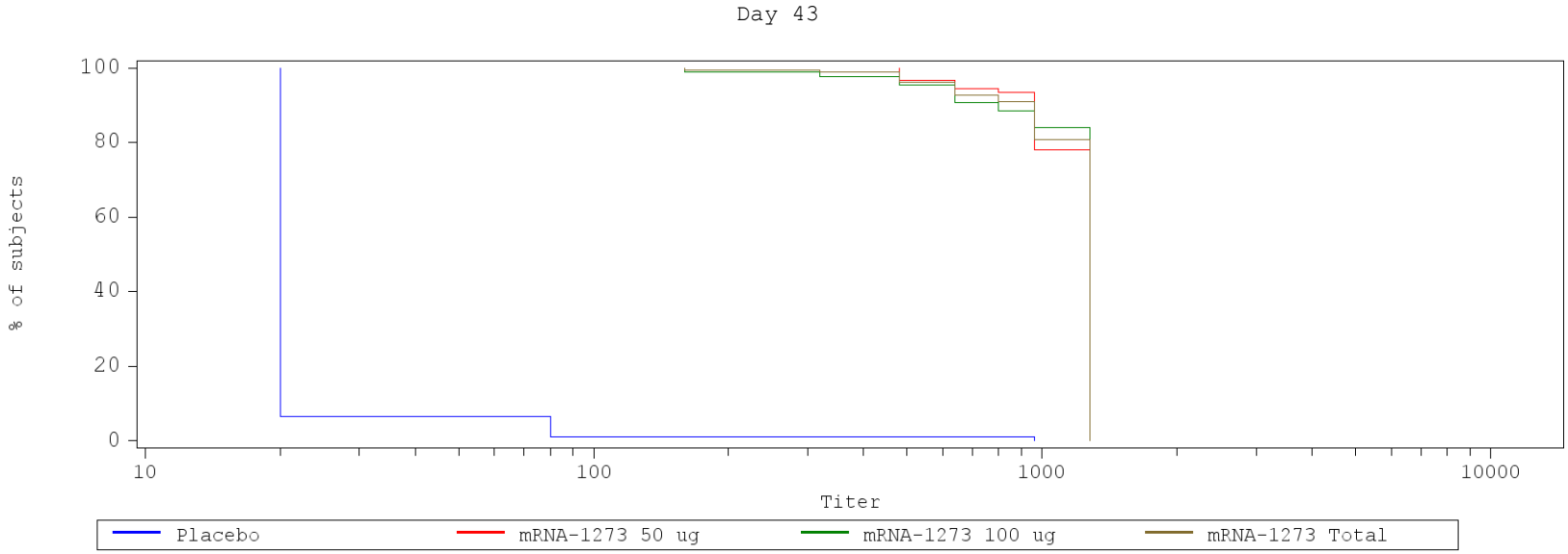
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
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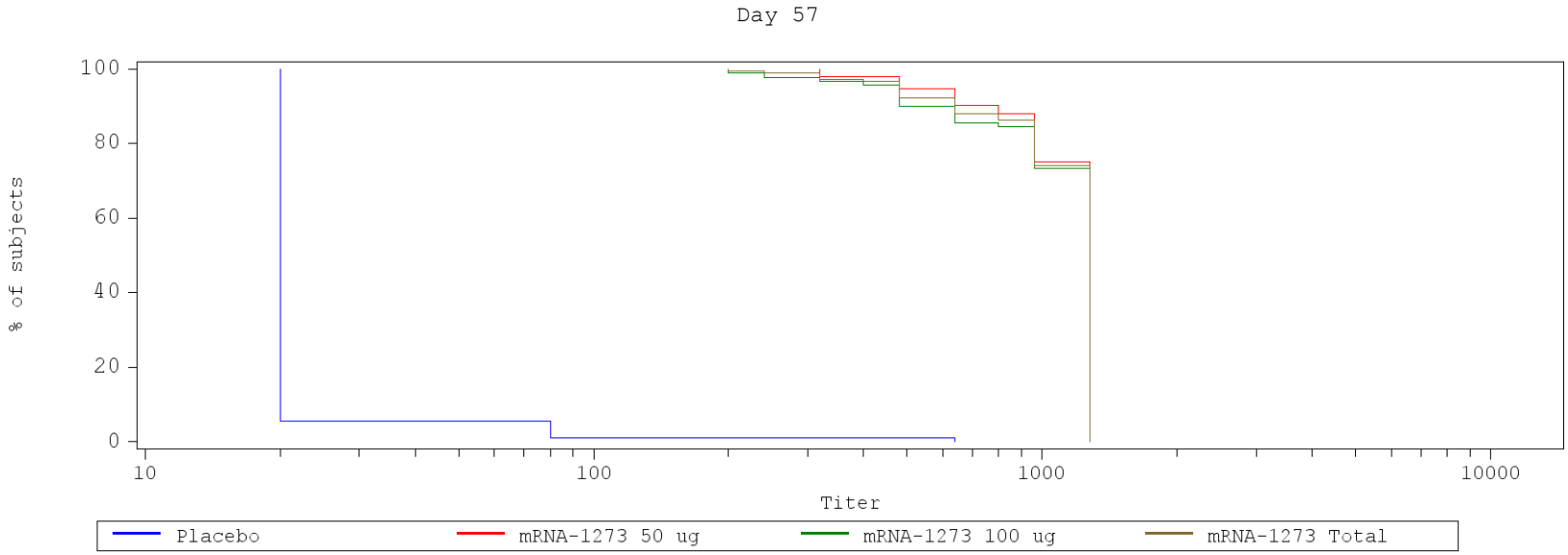
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
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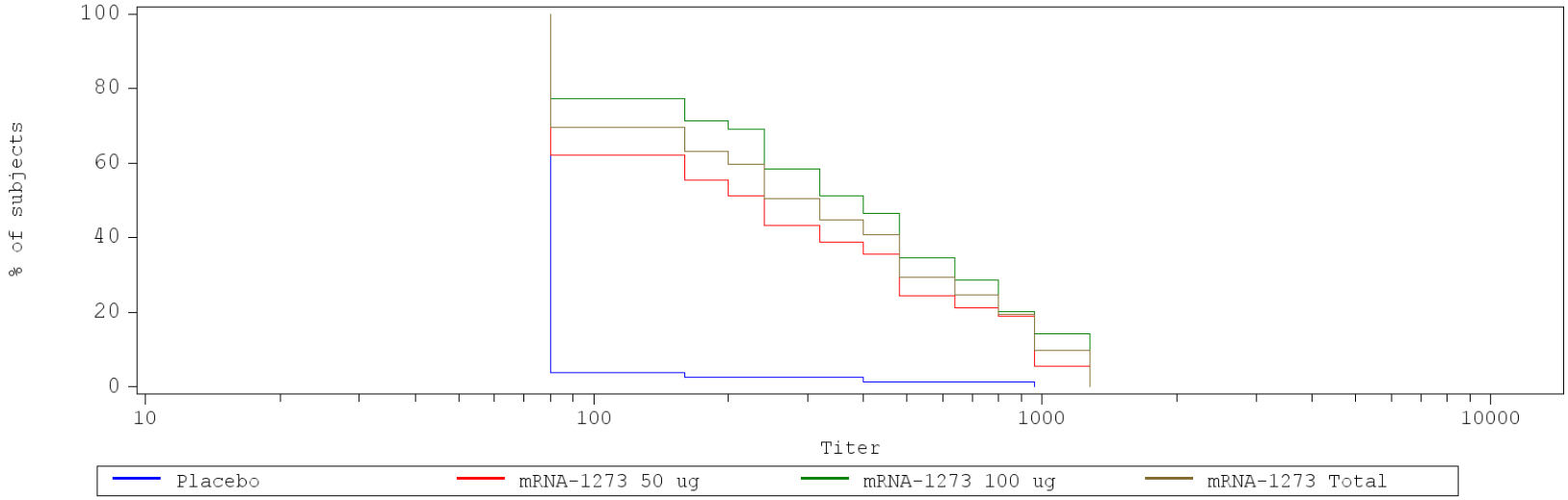
Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

Day 209



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.
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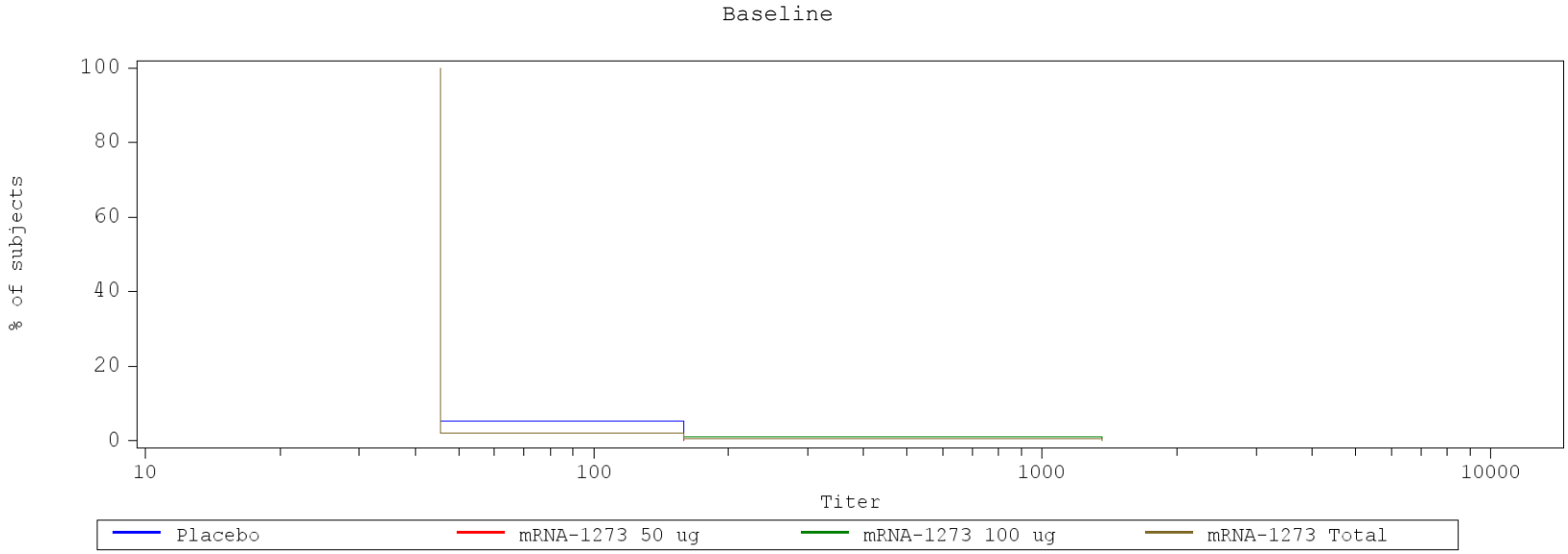
Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
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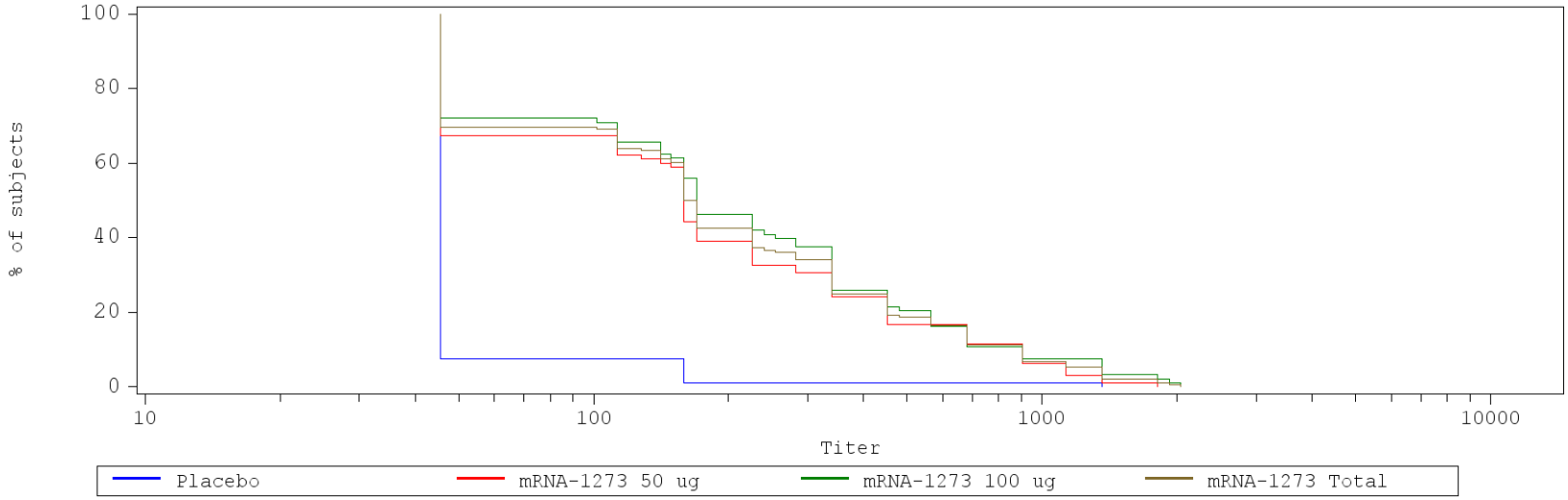
Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f1402060102.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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

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 All Lots with non-missing data at each visit.
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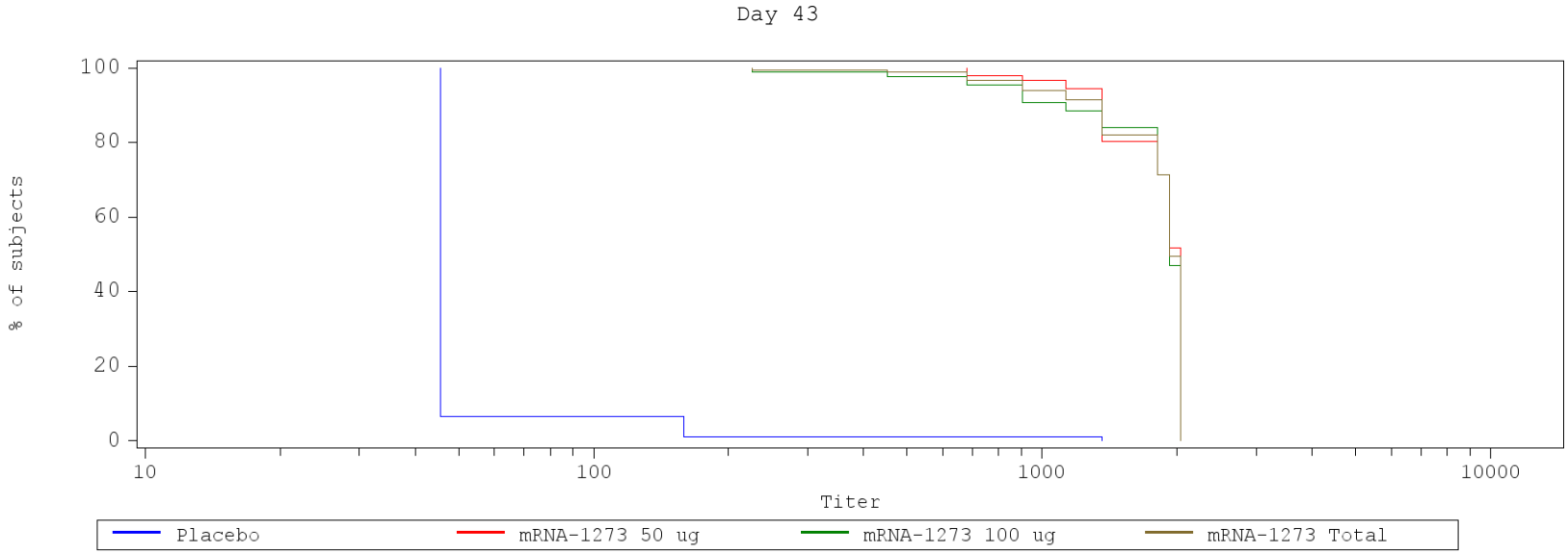
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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.
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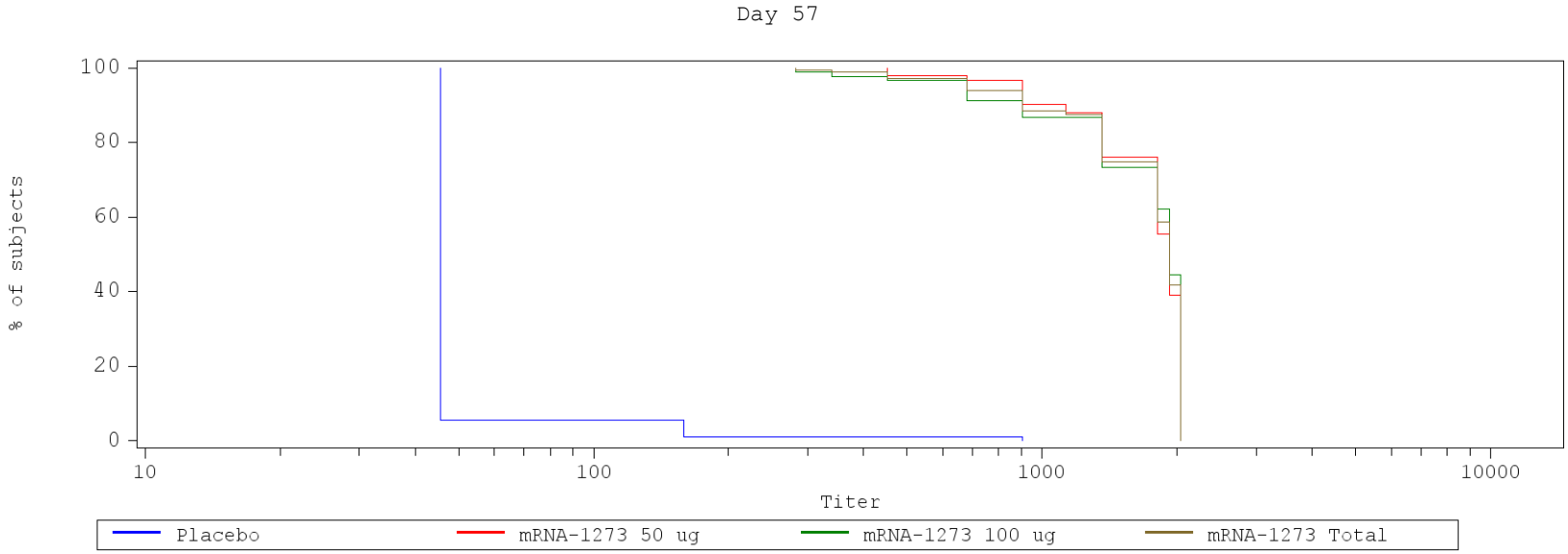
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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.
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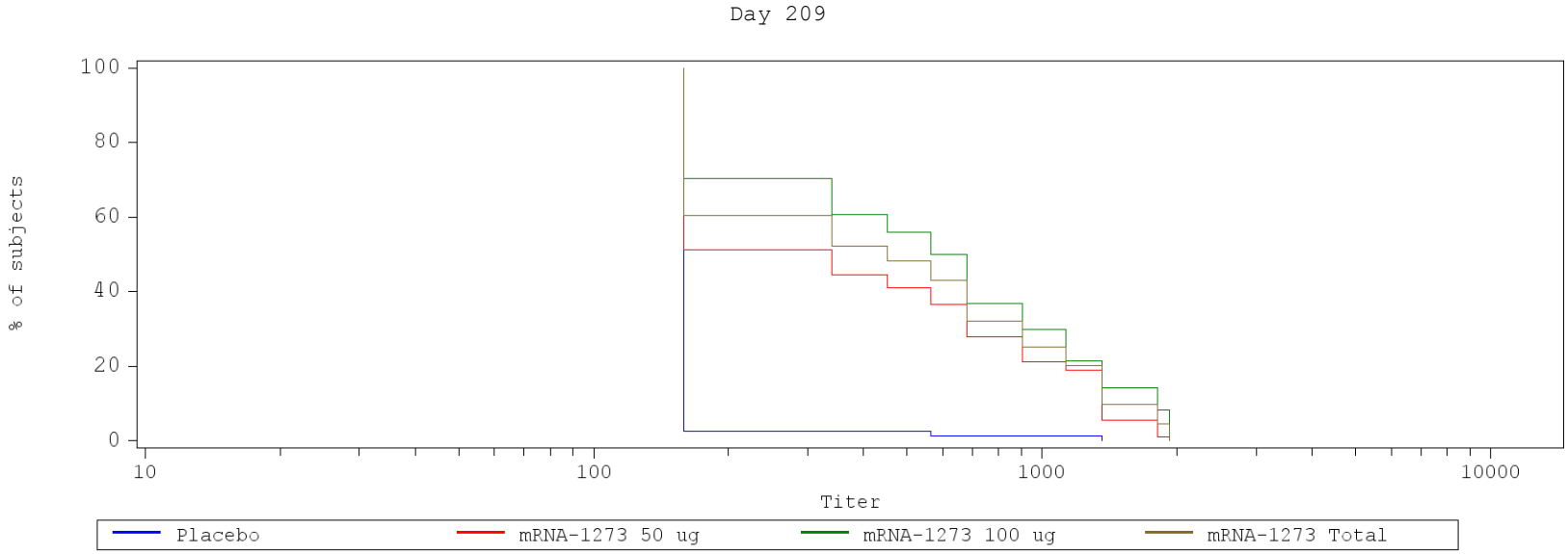
Figure 14.2.6.1.2
Reverse Cumulative Distribution Function of Neutralizing Antibody Immunogenicity Results
Per-Protocol Set for SARS-CoV-2-specific nAb from All Lots

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 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ.
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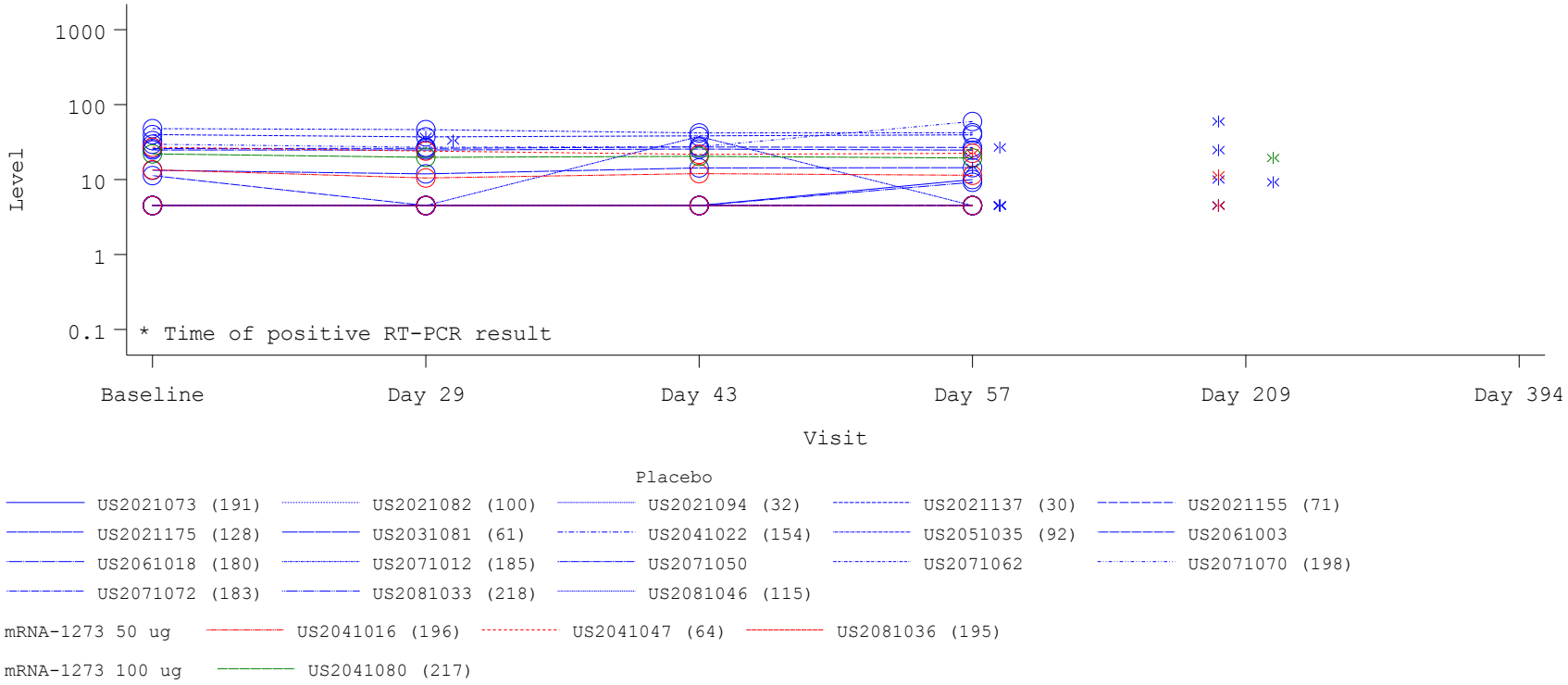
Figure 14.2.7.1
Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (Age >= 18 and age < 55)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) by ELISA (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 if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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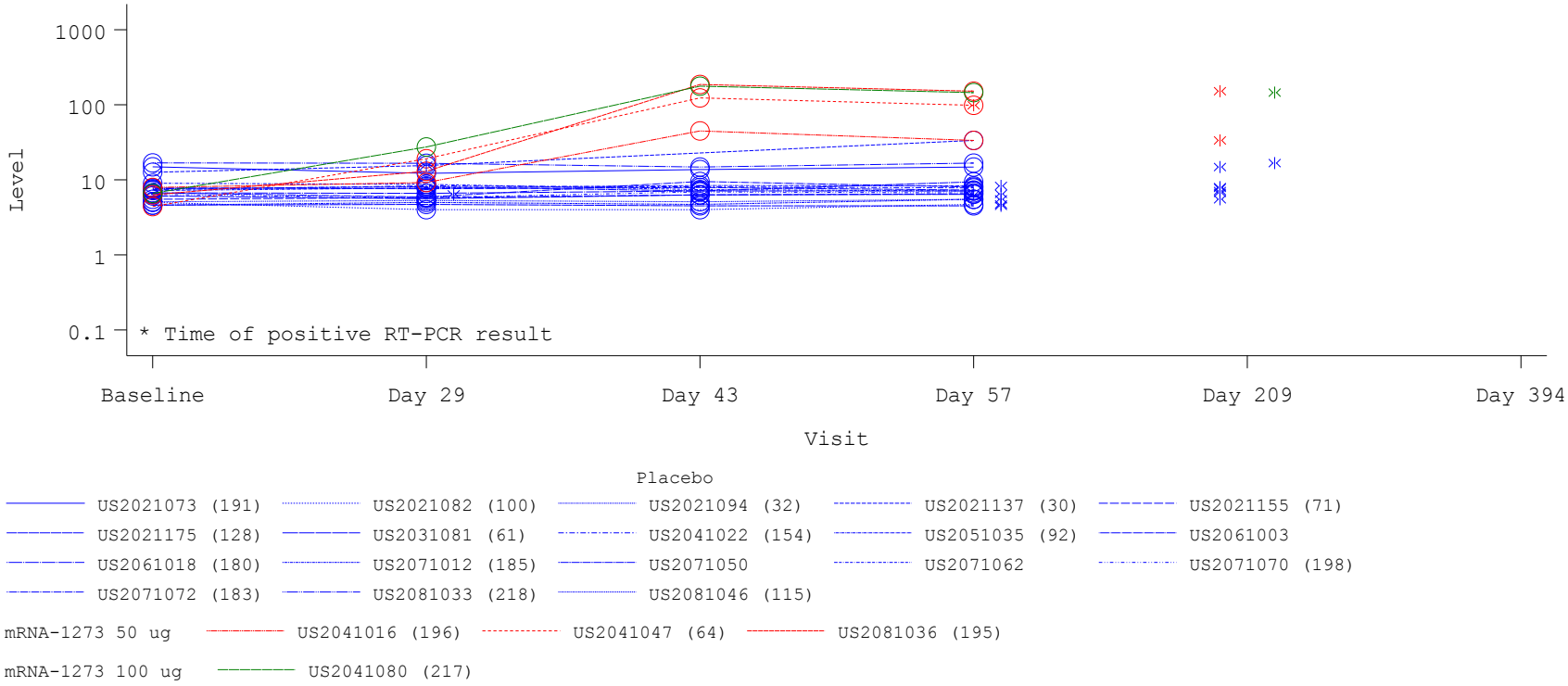
Figure 14.2.7.1
Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (Age >= 18 and age < 55)
Antibody: VAC58 Spike IgG Antibody (ug/mL) by ELISA (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 if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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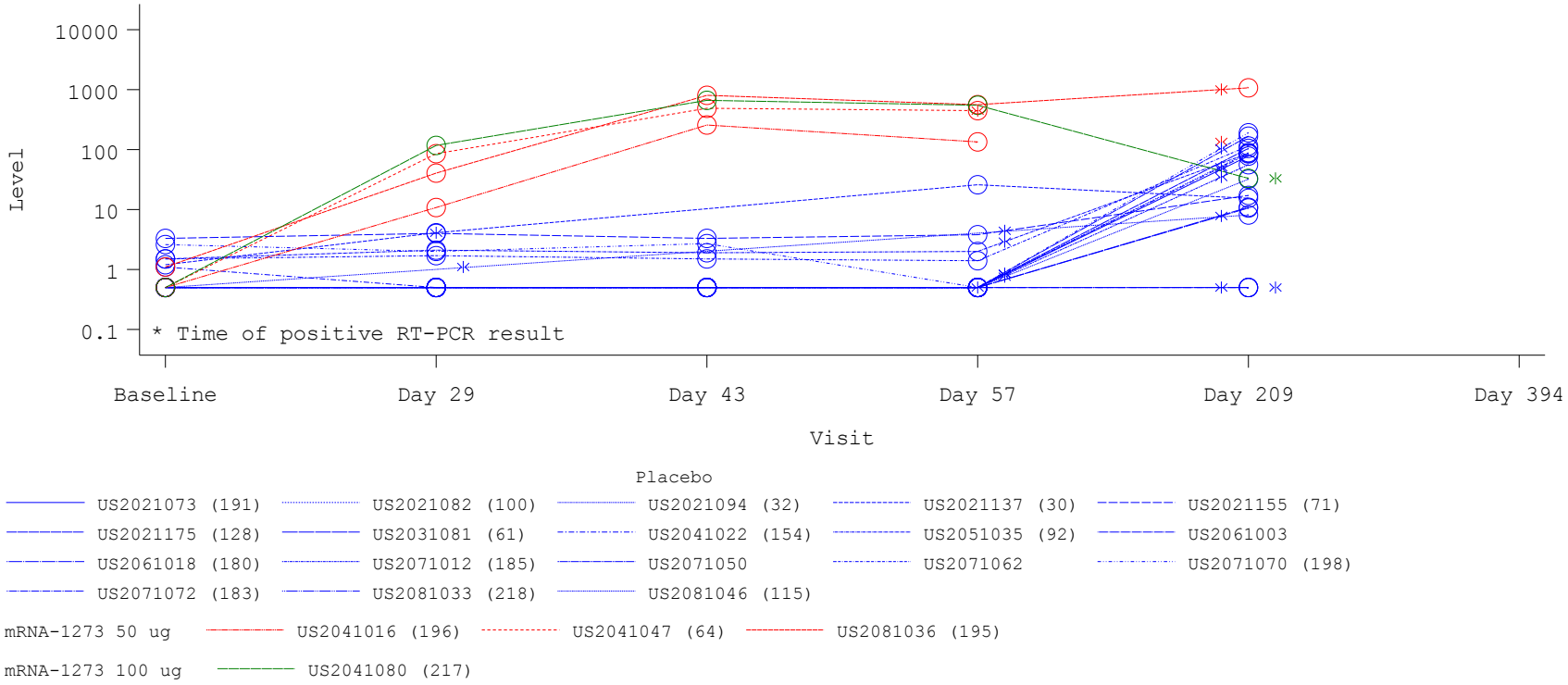
Figure 14.2.7.1
Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 1 (Age >= 18 and age < 55)
Antibody: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



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 if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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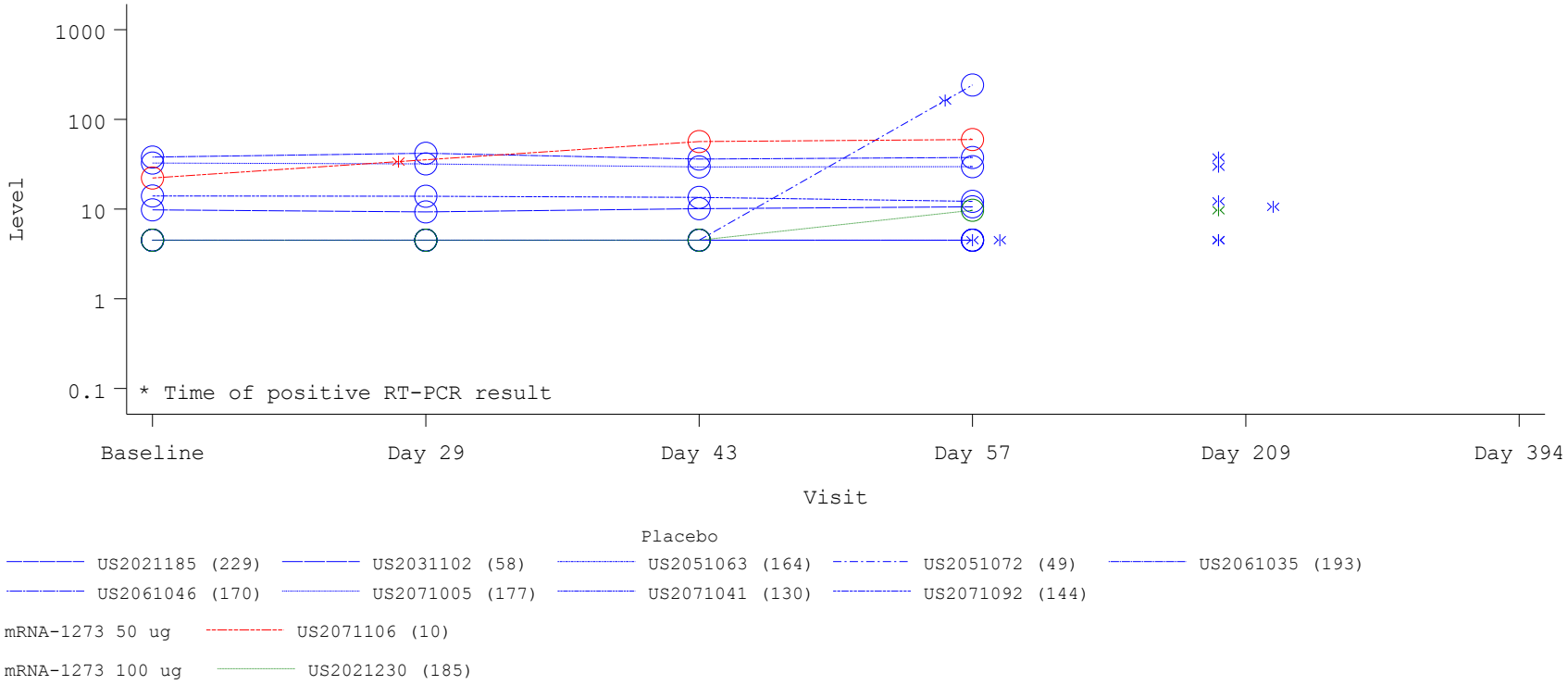
Figure 14.2.7.1
Binding Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific bAb

Cohort 2 (Age >= 55)
Antibody: VAC58 Nucleocapsid IgG Antibody (AU/mL) by ELISA (LLOQ: 9, ULOQ: 33000)

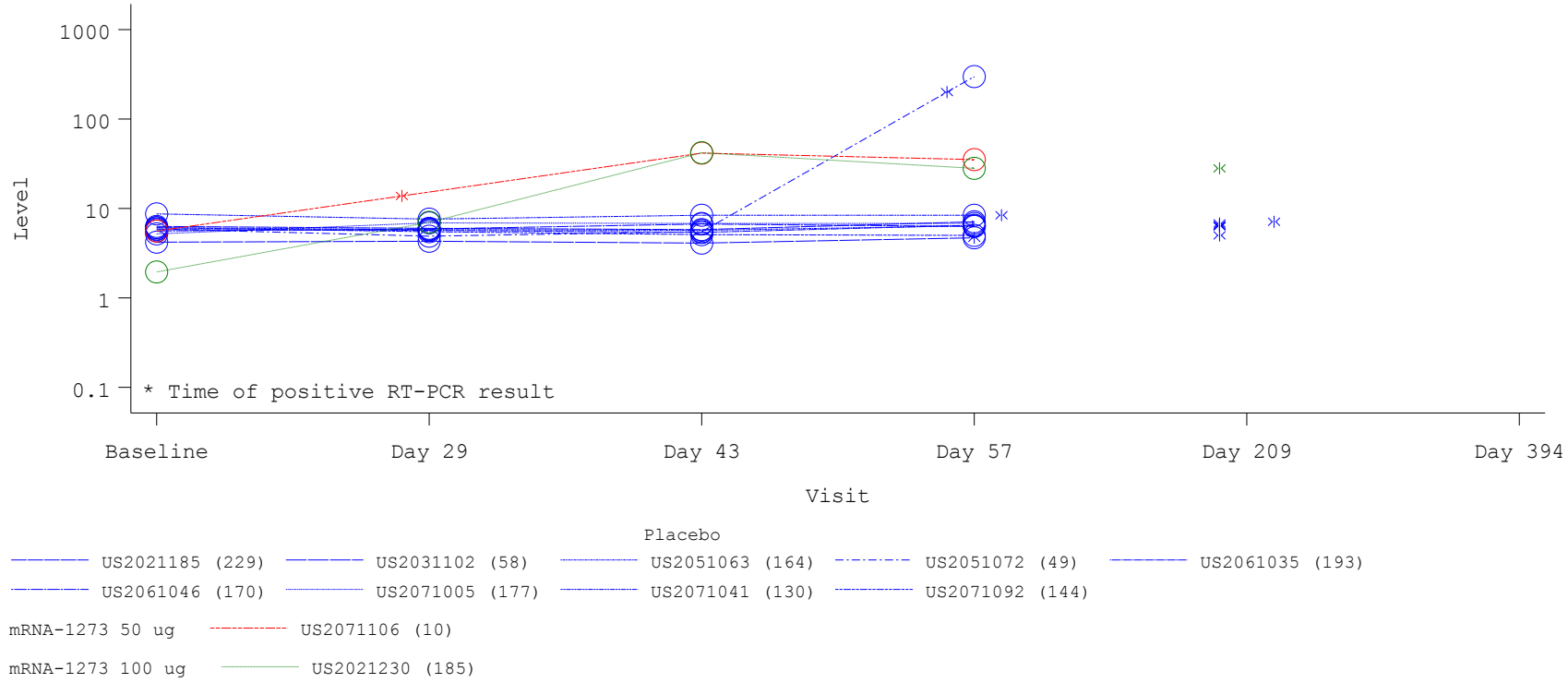


bAb = Binding antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f14020701.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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) by ELISA (LLOQ: 3.9, ULOQ: 487)

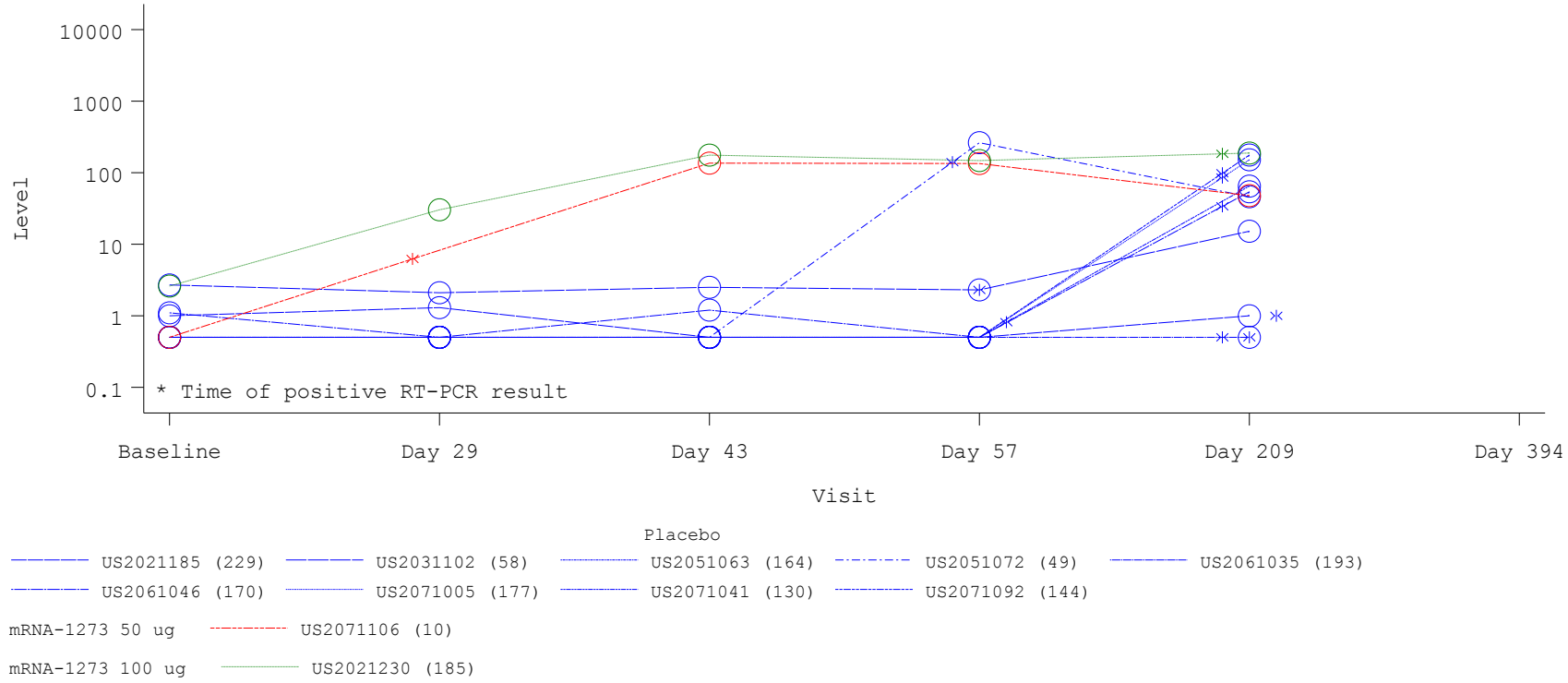


bAb = Binding antibody.
Antibody values reported as below the lower limit of quantification (LLOQ) are replaced by 0.5 x LLOQ. Values that are greater than the upper limit of quantification (ULOQ) are converted to the ULOQ if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

Program: \Moderna MODMRNA1273P201\Part A end of Part A\TLF\f14020701.sas 19JUL2021 22:58 Database Lock Date: 10JUN2021

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: VAC65 Spike IgG Antibody (AU/mL) by ELISA (LLOQ: 1, ULOQ: 2052)



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 if actual values are not available.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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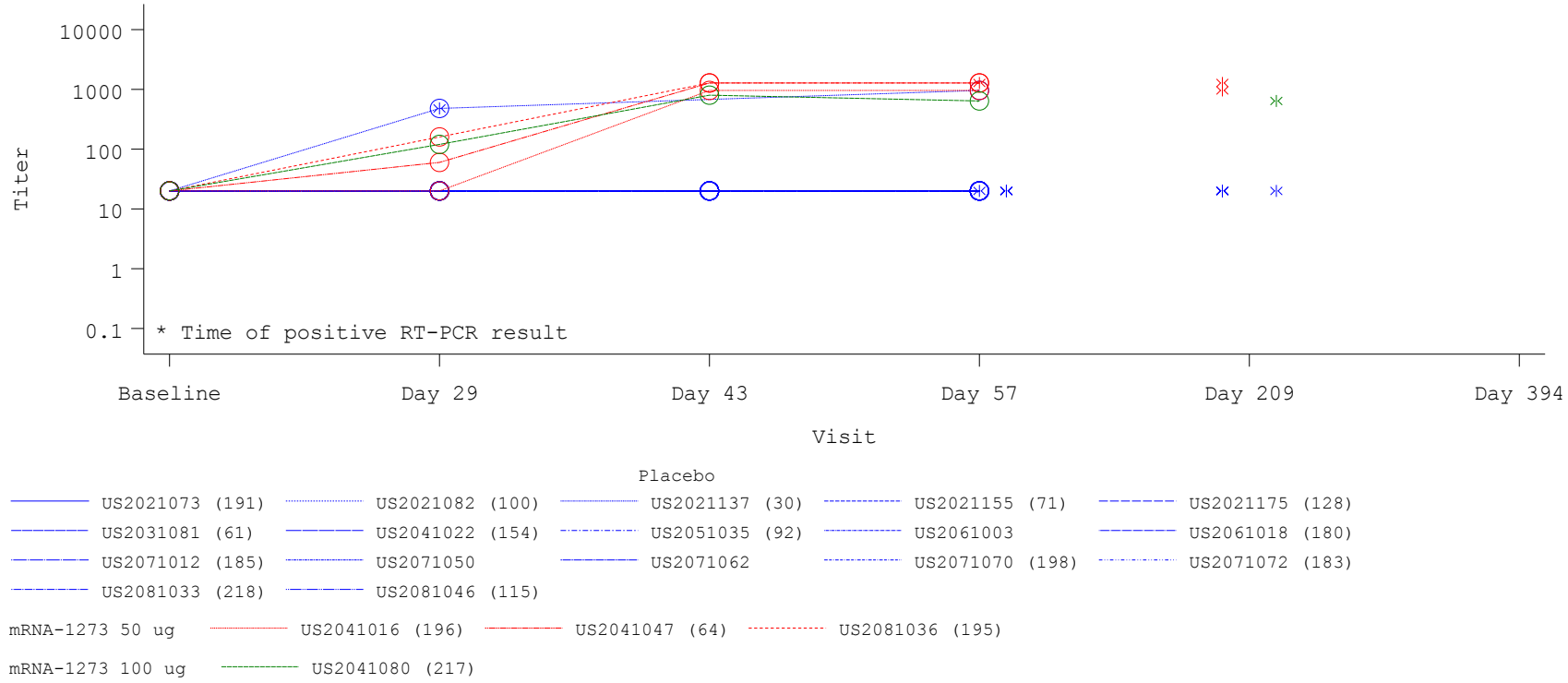
Figure 14.2.7.2.1
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot
Cohort 1 (Age >= 18 and age < 55)
Antibody: MN Endpoint Titer



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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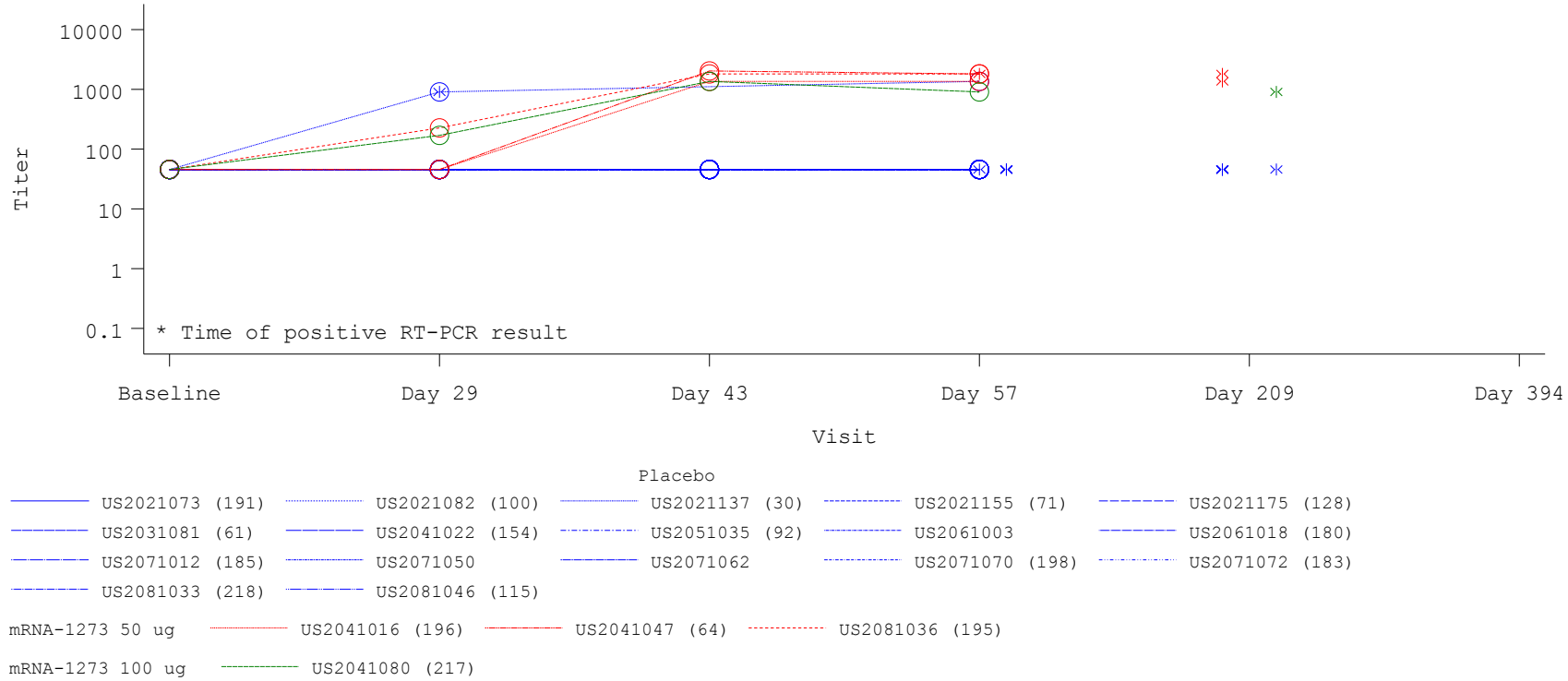
Figure 14.2.7.2.1
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot
Cohort 1 (Age >= 18 and age < 55)
Antibody: MN50



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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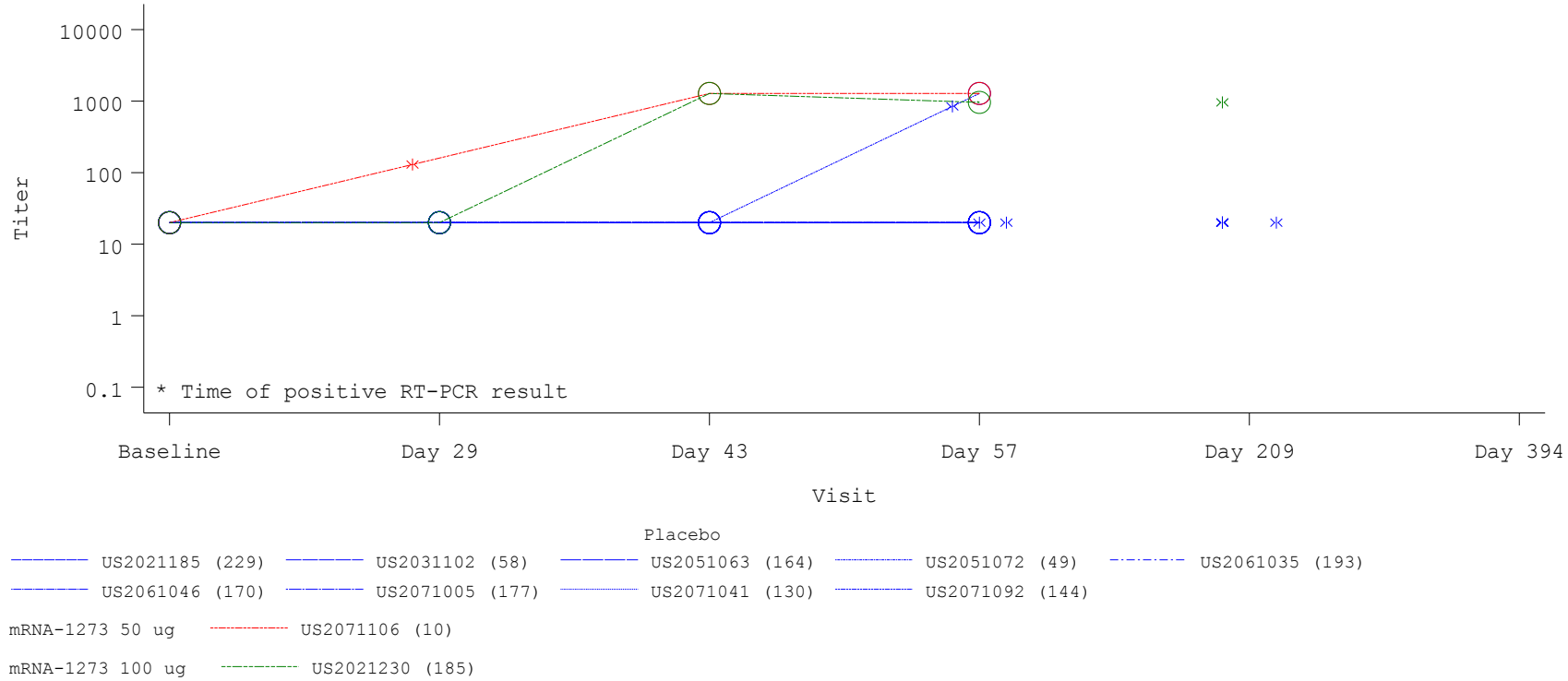
Figure 14.2.7.2.1
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot
Cohort 2 (Age >= 55)
Antibody: MN Endpoint Titer



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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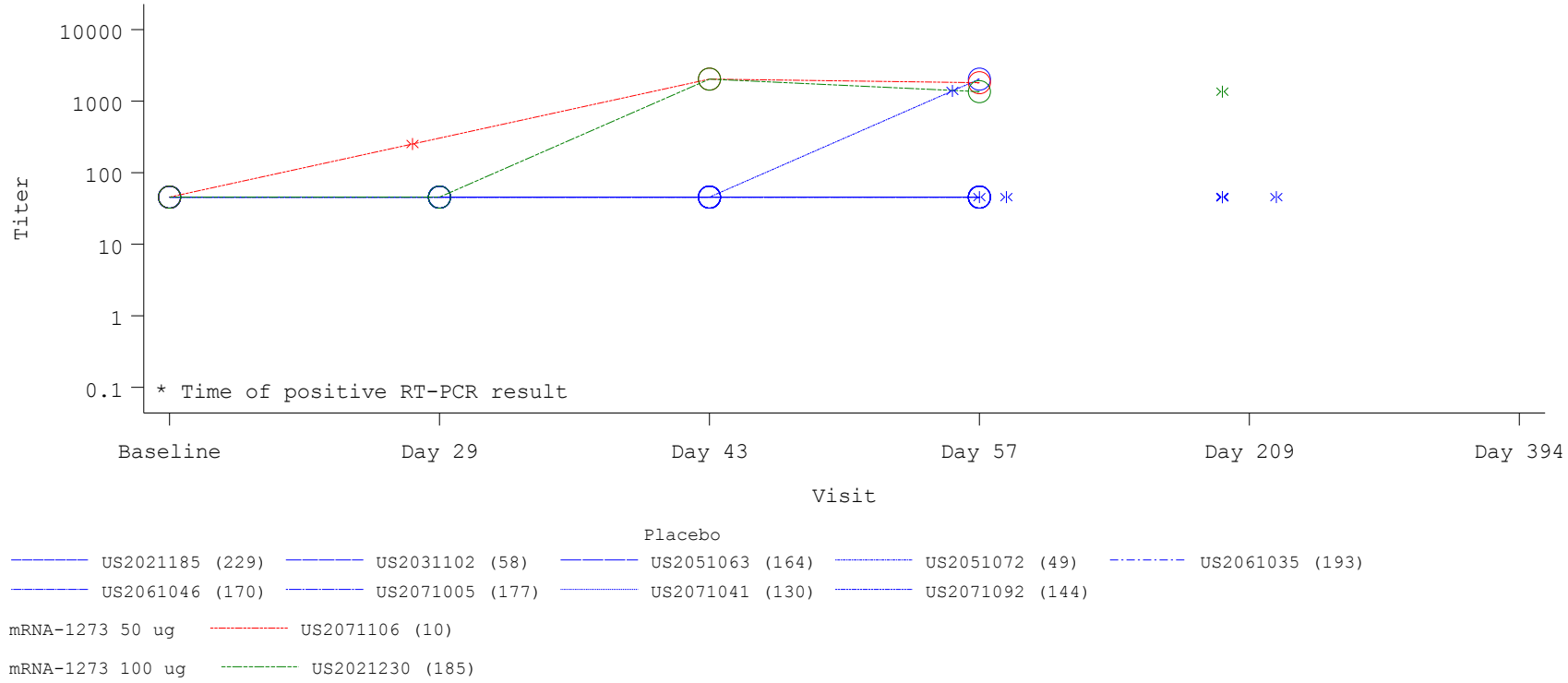
Figure 14.2.7.2.1
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from the First Lot

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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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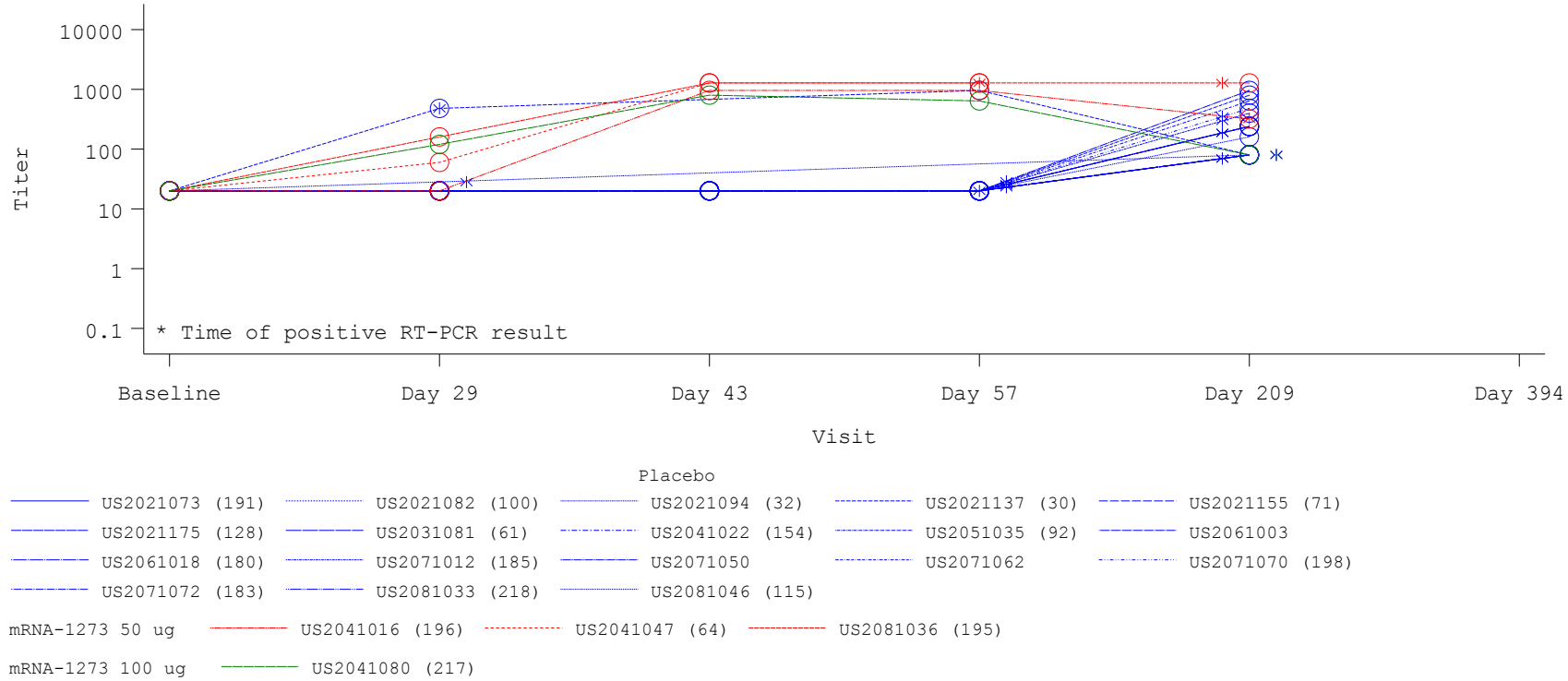
Figure 14.2.7.2.2
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots
Cohort 1 (Age >= 18 and age < 55)
Antibody: MN Endpoint Titer



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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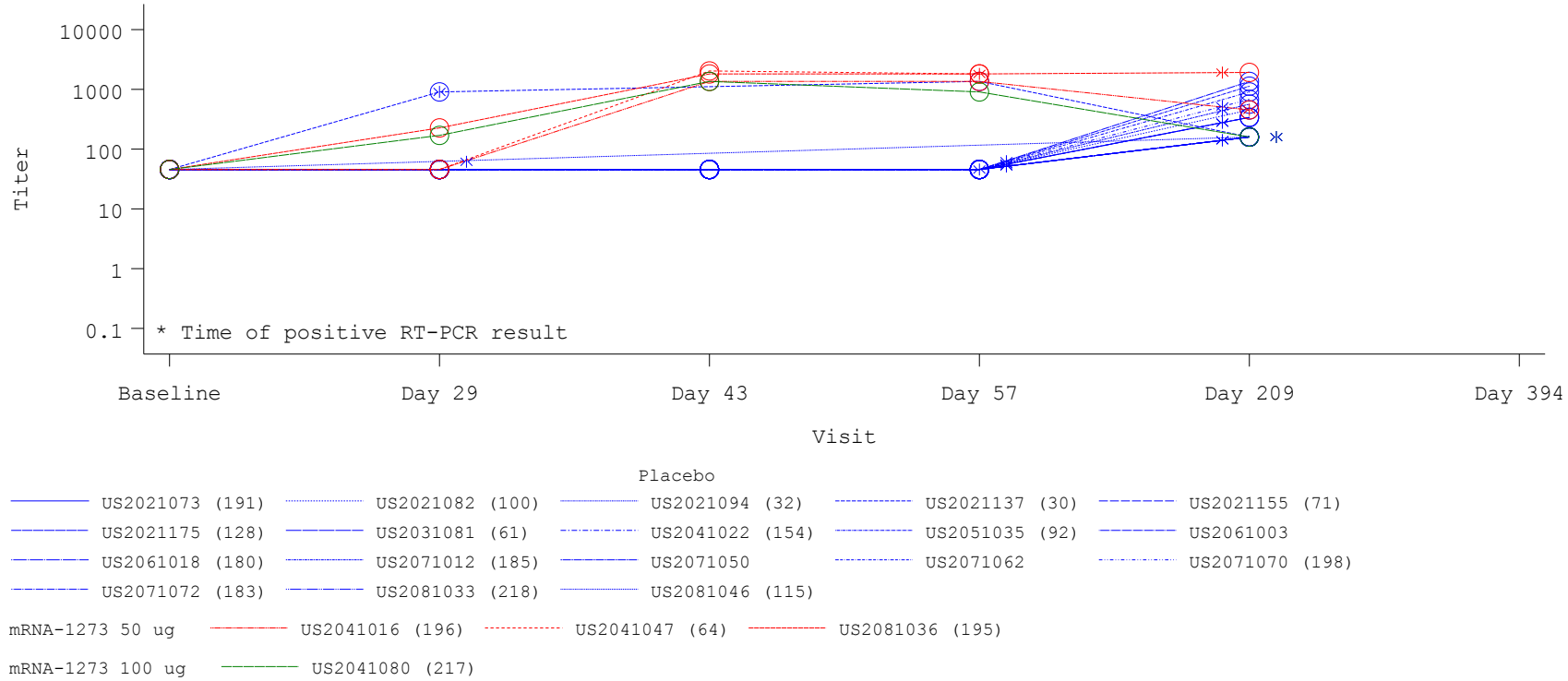
Figure 14.2.7.2.2
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots
Cohort 1 (Age >= 18 and age < 55)
Antibody: MN50



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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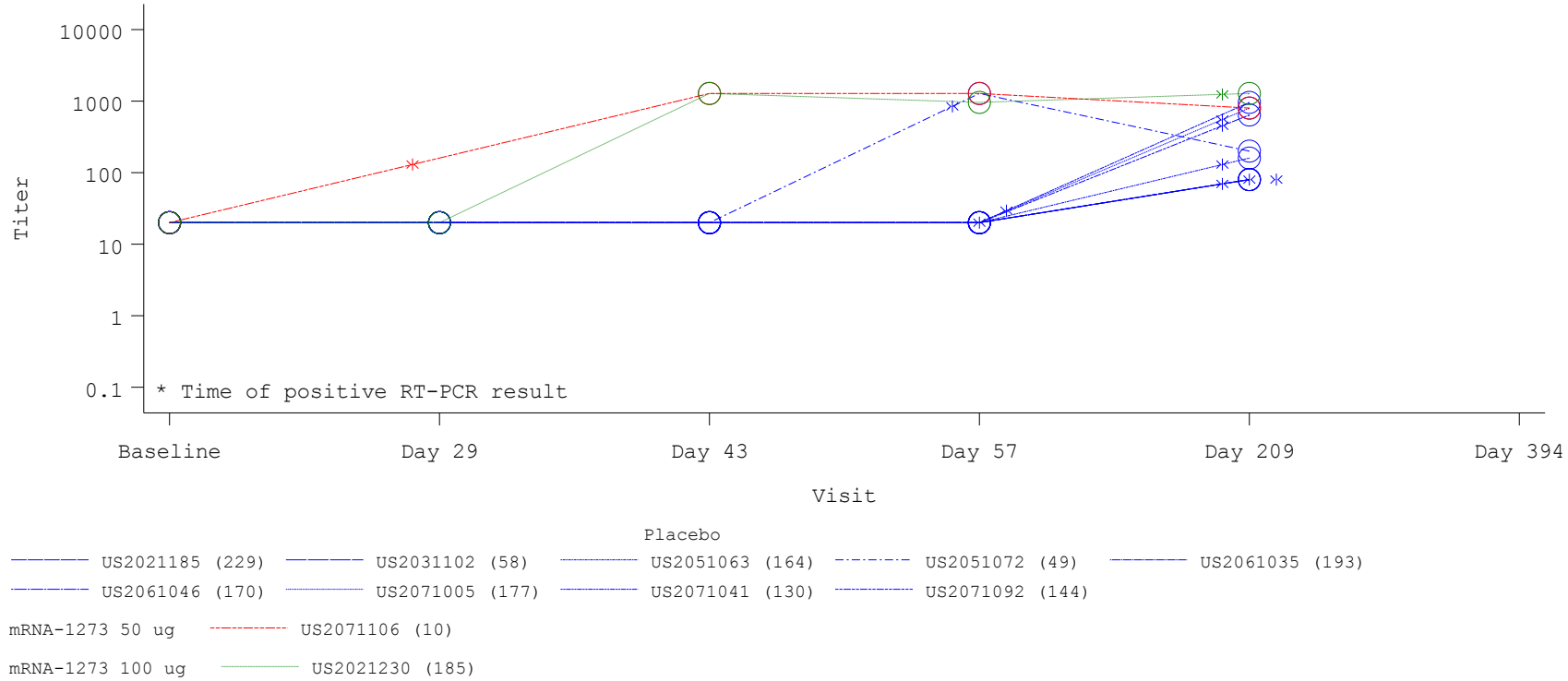
Figure 14.2.7.2.2
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (Age >= 55)
Antibody: MN Endpoint Titer



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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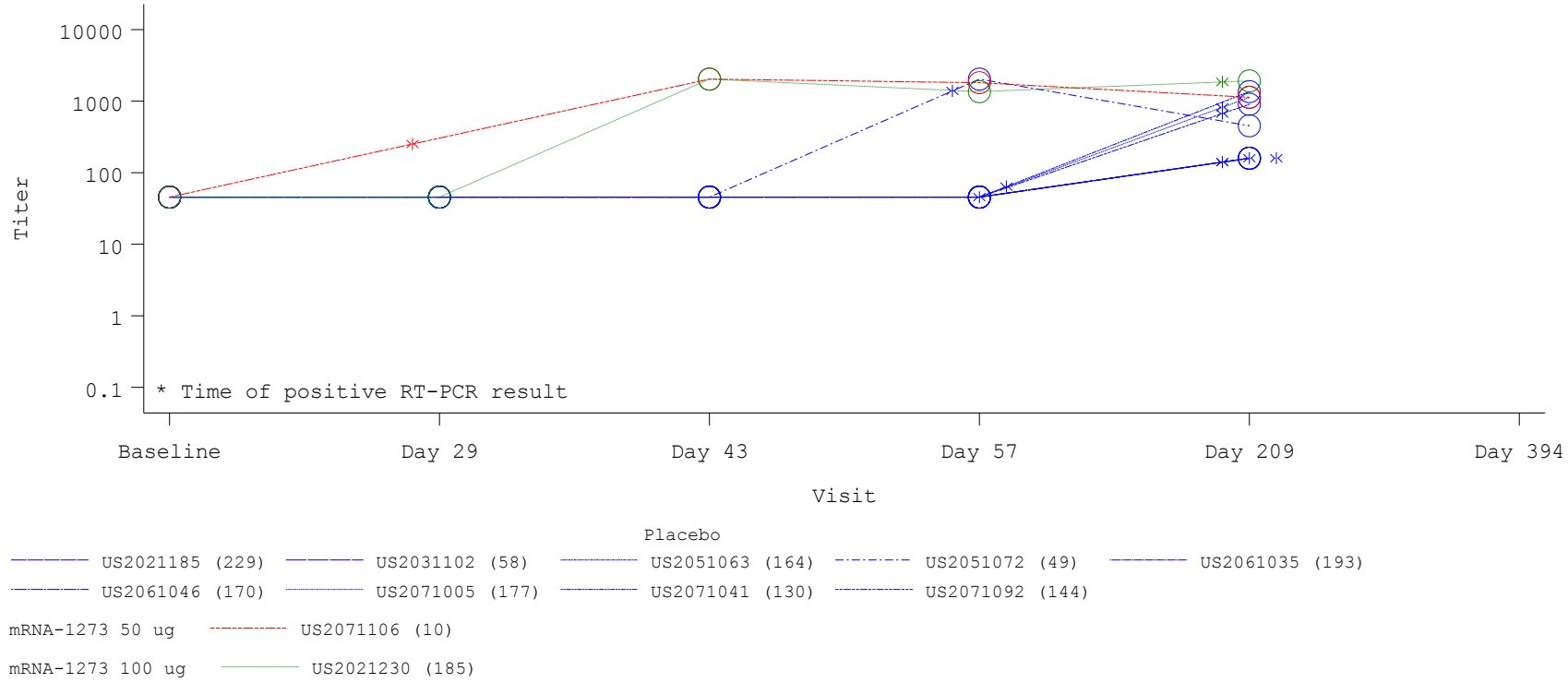
Figure 14.2.7.2.2
Neutralizing Antibody Immunogenicity Results Overtime for Subjects with SARS-CoV-2 Infection or COVID-19
Full Analysis Set for SARS-CoV-2-specific nAb from All Lots

Cohort 2 (Age >= 55)
Antibody: MN50



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.
Subject US2061003, US2071050 and US2071062 do not have positive PCR but have AE reported as SARS-CoV-2 Infection or COVID-19.

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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
US2011089		X		X
US2021031		X		
US2031097		X		
US2041007		X		X
US2041119		X		
US2071083		X		
US2081123		X		

Abbreviations: AE=adverse event; SAE= serious adverse event; TEAE=treatment-emergent adverse event.

Participant Number:	**US2011089**
Vaccination Cohort:	Cohort 1 (≥18 to < 55 years)
Vaccination Group:	100 µg mRNA-1273
First Dose of Vaccine:	05 Jun 2020
Second Dose of Vaccine:	10 Jul 2020
Reason for Narrative:	Serious adverse event, Pregnancy

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abortion missed	Grade 2/ moderate	Not related	26 Feb 2021 – 10 Mar 2021	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2011089 was a 32-year old white female who signed the informed consent form on 01 Jun 2020 and was randomly assigned to Cohort 1 on 05 Jun 2020. The participant received the first dose of 100 µg mRNA-1273 in the left arm on 05 Jun 2020 (Day 1). The second dose was administered in the left arm on 10 Jul 2020 (Day 36). 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: headache (2006-ongoing) and seasonal allergy (2019-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: ibuprofen and cetirizine hydrochloride.

Event Details

On 26 Feb 2021, the participant experienced a Grade 2 moderate serious adverse event of abortion missed. According to the safety database, the participant had a positive pregnancy test on 01 Feb 2021 at her primary care physician's office. The participant reported using condoms with spermicide since 05 Dec 2020 as contraceptive. The first day of the participant's last menstrual period was on 28 Dec 2020. The estimated date of conception and estimated due date were not provided. On 26 Feb 2021, the participant experienced miscarriage with no fetal heartbeat detected via ultrasound. A second ultrasound on 08 Mar 2021 confirmed no fetal heartbeat was detected. On 10 Mar 2021, a dilation and curettage were performed.

Action taken with the IP was not applicable.

The event of abortion missed was considered to be resolved on 10 Mar 2021. The outcome of the event was unknown. The Investigator assessed the event of abortion missed to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2021031**
Vaccination Cohort:	Cohort 2 (≥55 years)
Vaccination Group:	100 µg mRNA-1273
First Dose of Vaccine:	01 Jun 2020
Second Dose of Vaccine:	29 Jun 2020
Reason for Narrative:	Serious adverse event

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Arrhythmia	Grade 4	Not related	28 Jul 2020 – 30 Jul 2020	Recovered/ resolved
Struck by lightning	Grade 3/ severe	Not related	28 Jul 2020 – 30 Jul 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2021031 was a 72-year old white male who signed the informed consent form on 26 May 2020 and was randomly assigned to Cohort 2 on 01 Jun 2020. The participant received the first dose of 100 µg mRNA-1273 in the right arm on 01 Jun 2020 (Day 1). The second dose was administered in the right arm on 29 Jun 2020 (Day 29). The participant was 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: food allergies (fish and seafood; 1966-ongoing), hyperlipidemia (1976-ongoing), anxiety and depression (1985-ongoing), and blood testosterone decreased (2015-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: simvastatin, buspirone hydrochloride, sertraline, and testosterone.

Event Details

On 28 Jul 2020, the participant experienced a Grade 4 serious adverse event of arrhythmia and a Grade 3 severe serious adverse event of being struck by lightning. According to the safety database, the participant was struck by lightning on 28 Jul 2020 resulting in arrhythmia. The participant experienced atrial fibrillation while en route to the hospital. Echocardiogram showed ejection fraction of 60%, aortic valve with trace regurgitation and mild sclerosis, and mitral valve with mild annular calcification. Electrocardiogram showed sinus bradycardia, left axis deviation, and minor nonspecific T-wave abnormality.

Action taken with the IP was not applicable.

The events of arrhythmia and being struck by lightning were considered to be resolved on 30 Jul 2020 and the participant was discharged from the hospital on the same day. The Investigator assessed the events of arrhythmia and struck by lightning to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2031097**
Vaccination Cohort:	Cohort 2 (≥55 years)
Vaccination Group:	50 µg mRNA-1273
First Dose of Vaccine:	30 Jun 2020
Second Dose of Vaccine:	03 Aug 2020
Reason for Narrative:	Serious adverse event

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Acute myocardial infarction	Grade 2/ moderate	Not related	25 Nov 2020 – 25 Nov 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2031097 was an 86-year old white female who signed the informed consent form on 09 Jun 2020 and was randomly assigned to Cohort 2 on 30 Jun 2020. The participant received the first dose of 50 µg mRNA-1273 in the left arm on 30 Jun 2020 (Day 1). The second dose was administered in the left arm on 03 Aug 2020 (Day 35). 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: drug hypersensitivity (sulfa; 1970-ongoing), postmenopause (1988-ongoing), hypercholesterolaemia (2015-ongoing), glaucoma (2016-ongoing), musculoskeletal pain (chronic right shoulder; 2018-ongoing), and osteoarthritis (generalized; 2018-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: simvastatin, meloxicam, and brimonidine tartrate/timolol maleate.

Event Details

On 25 Nov 2020, the participant experienced a Grade 2 moderate serious adverse event of acute myocardial infarction. According to the safety database, the participant was hospitalized due to non-ST elevation myocardial infarction on 25 Nov 2020. The participant felt unwell, dizzy, fell from her chair, and lost consciousness for several minutes. She was taken to the emergency room and continued to experience chest pain and heaviness. She had elevated cardiac enzymes with a high troponin of 343 (reference range less than 34 unit not reported). Repeat troponin values of 327 and 225 (units not reported) were reported on 26 Nov 2020 and 27 Nov 2020, respectively. During the hospitalization at unknown dates, laboratory results were reported for D-dimer at 2306 and brain natriuretic peptide at 143.9 (reference ranges and units not reported). On 30 Nov 2020,

the participant saw her ophthalmologist for acute vision loss. It appeared at that time; the participant was experiencing acute vision loss due to right inferior homonymous quadrantanopia indicating the participant had experienced a stroke. On 01 Dec 2020. she saw her neurologist. A magnetic resonance imaging (MRI) scan was performed, and she was diagnosed with a cerebrovascular accident due to embolism of the left posterior cerebral artery (reported as non-serious event). The vision loss appeared to be the only lasting effect. On 07 Dec 2020, a repeat head MRI showed late subacute infarct in the medial left occipital lobe. Treatments included subcutaneous enoxaparin, apixaban, rosuvastatin/calcium, losartan potassium, and bisoprolol/hydrochlorothiazide.

Action taken with the IP was not applicable.

The event of acute myocardial infarction was considered to be resolved on 25 Nov 2020. On 27 Nov 2020, the participant was discharged from the hospital. The Investigator assessed the event of acute myocardial infarction to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2041007**
Vaccination Cohort:	Cohort 1 (≥18 to < 55 years)
Vaccination Group:	50 µg mRNA-1273
First Dose of Vaccine:	01 Jun 2020
Second Dose of Vaccine:	29 Jun 2020
Reason for Narrative:	Serious adverse event, Pregnancy

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Abortion spontaneous	Grade 1/ mild	Not related	17 Dec 2020 – 17 Dec 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2041007 was a 33-year old white female who signed the informed consent form on 26 May 2020 and was randomly assigned to Cohort 1 on 01 Jun 2020. The participant received the first dose of 50 µg mRNA-1273 in the left arm on 01 Jun 2020 (Day 1). The second dose was administered in the left arm on 29 Jun 2020 (Day 29). 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: otitis media chronic and ear tube insertion (1987), ear tube removal (1988), fibroadenoma of breast (2006-ongoing), benign breast lump removal (2006, 2008, 2010, and 2014), caesarean section (16 Oct 2007), appendicitis and appendicectomy (2013), and polycystic ovaries (2014-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, no concomitant medications were reported.

Event Details

On 17 Dec 2020, the participant experienced a Grade 1 mild serious adverse event of abortion spontaneous. According to the safety database, the participant had a positive urine pregnancy test on 15 Dec 2020. The first day of the participant's last menstrual period was on 01 Oct 2020. The estimated date of conception was reported as 16 Oct 2020 and the due date was estimated as 07 Jul 2021. The participant reported that she was using condoms with spermicide for contraception. On 16 Dec 2020, the pregnancy was confirmed with her primary care physician. On 17 Dec 2020, at 8 weeks gestation, the participant experienced a medically significant event of spontaneous abortion. A medical provider confirmed both the pregnancy and the spontaneous abortion by human chorionic gonadotropin tests (dates and results not reported). The participant did not take any medications for miscarriage and let it happen naturally.

Action taken with the IP was not applicable.

The event of abortion spontaneous was considered to be resolved on 17 Dec 2020. The Investigator assessed the event of abortion spontaneous to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2041119**
Vaccination Cohort:	Cohort 2 (≥55 years)
Vaccination Group:	50 µg mRNA-1273
First Dose of Vaccine:	06 Jul 2020
Second Dose of Vaccine:	04 Aug 2020
Reason for Narrative:	Serious adverse event

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Nervous system cyst	Grade 1/ mild	Not related	10 Aug 2020 – 16 Nov 2020	Recovered/ resolved
Spondylolisthesis	Grade 1/ mild	Not related	10 Aug 2020 – 16 Nov 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2041119 was a 68-year old white male who signed the informed consent form on 11 Jun 2020 and was randomly assigned to Cohort 2 on 06 Jul 2020. The participant received the first dose of 50 µg mRNA-1273 in the left arm on 06 Jul 2020 (Day 1). The second dose was administered in the left arm on 04 Aug 2020 (Day 30). 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: seasonal allergy (1980-2010), hiatus hernia and oesophagogastric fundoplasty (1998), anxiety (2000-ongoing), osteoarthritis (2000-2013), hip arthroplasty (2013), hypercholesterolemia (2015-ongoing), back pain (2017-ongoing), prostatomegaly (2019-ongoing), and basal cell carcinoma and skin neoplasm excision (01 Apr 2020).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: tamsulosin, atorvastatin, acetylsalicylic acid, vitamins, plantago ovata, and epidural.

Event Details

On 10 Aug 2020, the participant experienced a Grade 1 mild serious adverse events of nervous system cyst and spondylolisthesis. According to the safety database, the participant experienced a cyst on the spinal nerve and spondylolisthesis on 10 Aug 2020. On 16 Nov 2020, the participant was admitted and underwent a spinal laminectomy and fusion of lumbar spines 4-5, with spinal cyst removal. Treatment included paracetamol.

Action taken with the IP was not applicable.

The events of nervous system cyst and spondylolisthesis were considered to be resolved on 16 Nov 2020. On 17 Nov 2020, the participant was discharged from the hospital. The Investigator assessed the event of nervous system cyst and spondylolisthesis to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2071083**
Vaccination Cohort:	Cohort 2 (≥55 years)
Vaccination Group:	50 µg mRNA-1273
First Dose of Vaccine:	26 Jun 2020
Second Dose of Vaccine:	21 Jul 2020
Reason for Narrative:	Serious adverse events

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Bradycardia	Grade 2/ moderate	Not related	03 Sep 2020 – 31 Oct 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2071083 was an 87-year old white female who signed the informed consent form on 15 Jun 2020 and was randomly assigned to Cohort 2 on 26 Jun 2020. The participant received the first dose of 50 µg mRNA-1273 in the left arm on 26 Jun 2020 (Day 1). The second dose was administered in the left arm on 21 Jul 2020 (Day 26). 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: postmenopause (1980-ongoing), osteoarthritis and hypercholesterolemia (2015-ongoing), and hypothyroidism (13 May 2019-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: calcium carbonate/colecalciferol, acetylsalicylic acid, gemfibrozil, lovastatin, and levothyroxine.

Event Details

On 03 Sep 2020, the participant experienced a Grade 2 moderate serious adverse event of bradycardia. According to the safety database, an electrocardiogram on 17 Aug 2020 showed ventricular rate of 51 beats per minute and minor intraventricular conduction delay in the ventricles. On 18 Aug 2020, laboratory results included calcium of 10.2 mg/dl (reference range: 8.4-10.2), chloride of 103 mmol/L (reference range: 98-107), glucose of 96 mg/dl (reference range: 74-106), potassium of 4.6 mmol/L (reference range: 3.5-5.1), sodium of 140 mmol/L (reference range: 137-145), blood thyroid stimulating hormone of 0.07 mIU/ml (reference range: 0.47-4.68), blood urea nitrogen of 18 mg/dl (reference range: 7-17), carbon dioxide of 30 mmol/L (reference range: 22-30), free thyroxine of 1.54 ng/dL (reference range: 0.78-2.19), and free tri-iodothyronine

of 3.5 pg/ml (reference range: 2.8-5.3). On 03 Sep 2020, the participant experienced worsening of chronic bradycardia. On 30 Oct 2020, the participant was admitted to the hospital for observation for planned pacemaker insertion for the diagnosis of bradycardia. On 31 Oct 2020, the participant underwent pacemaker placement insertion. On 03 Nov 2020, transthoracic echocardiogram revealed Grade 1 diastolic dysfunction.

Action taken with the IP was not applicable.

The event of bradycardia was considered to be resolved on 31 Oct 2020 and the participant was discharged from the hospital on the same day. The Investigator assessed the event of bradycardia to be not related to the IP. The participant's participation is ongoing at the time of database lock.

Participant Number:	**US2081123**
Vaccination Cohort:	Cohort 2 (≥55 years)
Vaccination Group:	50 µg mRNA-1273
First Dose of Vaccine:	30 Jun 2020
Second Dose of Vaccine:	Not administered
Reason for Narrative:	Serious adverse event

MedDRA Preferred Term	Severity	Relationship to IP	Start Date – Stop Date	Outcome
Pneumonia	Grade 3/ severe	Not related	01 Aug 2020 – 26 Aug 2020	Recovered/ resolved

Abbreviations: IP = investigational product; MedDRA = Medical Dictionary for Regulatory Activities Version 23.0.

Participant US2081123 was a 65-year old white male who signed the informed consent form on 25 Jun 2020 and was randomly assigned to Cohort 2 on 30 Jun 2020. The participant received the first dose of 50 µg 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 and spinal stenosis (2000-ongoing), attention deficit hyperactivity disorder (2003-ongoing), depression (2008-ongoing), and erectile dysfunction (2018-ongoing).

Prior/Concomitant Medications and Procedures

According to the safety database, the participant was taking the following concomitant medications: methylphenidate, duloxetine hydrochloride, and multivitamin.

Event Details

On 01 Aug 2020, the participant experienced a Grade 3 severe serious adverse event of pneumonia. According to the safety database, on 25 Jul 2020, the participant was experiencing headache, cough, body aches all over, weakness, and fever. A nasal swab for COVID-19 was negative. Acetaminophen and ibuprofen were given for pain associated with bilateral pneumonia. On 29 Jul 2020, the participant attended an unscheduled site visit because he was not feeling well, with a continuation of the prior symptoms. Vital signs included blood pressure (BP) 114/64 mmHg, 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. A second nasal swab for COVID-19 was negative.

On 01 Aug 2020, the participant experienced worsening symptoms including cough with some productive sputum, elevated fevers, urinary issues, body aches, joint pains, and generalized weakness. He had increasing ongoing confusion for 2 days and reported being sick for 10 days. Physical examination revealed that he was alert and oriented to person, place, and time; however, he appeared distressed and somewhat confused with altered mental status. His breathing was normal, without wheezing, rhonchi, or respiratory distress. Vital signs included body temperature of 97.8°F, BP of 116/96 mmHg, pulse rate of 67 beats per minute, respiratory rate of 21 breaths per minute, and oxygen saturation of 95%. Laboratory results included white blood cell (WBC) count of 13.4 K/uL (reference range: 4.0-10.0), absolute lymphocyte count of 0.94 K/uL (reference range: 1.20-3.70), absolute monocyte count of 0.94 K/uL (reference range: 0.20-0.80), absolute basophil count of 0.13 K/uL (reference range: 0.00-0.10), red blood cell (RBC) count of 3.52 M/uL (reference range:4.63-6.08), hemoglobin (HGB) of 11.0 g/dL (reference range: 13.7-17.5), and hematocrit (HCT) of 33.7 % (reference range: 40.1-51.0). Urinalysis and blood cultures were negative. A nasopharyngeal rapid polymerase chain reaction 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 chest x-ray results, the participant was considered to be septic secondary to the life-threatening event of double pneumonia (community acquired) and was hospitalized. Treatment for pneumonia included azithromycin and ceftriaxone, with a bolus of intravenous fluids. The participant was also treated with oral loperamide for diarrhea related to pneumonia. The participant's BP reassessment revealed systolic pressure of 98 mmHg. Additional IV fluids were administered with noted improvement in BP (116/96 mmHg). On 02 Aug 2020, blood cultures were drawn, and were negative for growth after 2 days. Blood glucose was 114 mg/dL (74-106). On 03 Aug 2020, laboratory results included WBC count of 11.1 K/uL, RBC count of 3.15 M/uL, HGB of 10.1 g/dL, and HCT of 29.8 %. On 04 Aug 2020, the participant was treated with butalbital-acetaminophen-caffeine for tension headaches related to pneumonia. On 05 Aug 2020, vital signs included BP of 107/51 mmHg, pulse rate of 48 beats per minute, body temperature of 98.6°F, respiratory rate of 17 breaths per minute, and oxygen saturation of 94%. Physical examination revealed bilateral diminished breath sounds without respiratory distress. Laboratory results included WBC count of 12.6 K/uL, RBC count of 3.27 M/uL, HGB of 10.3 g/dL, HCT of 31.4 %, absolute neutrophil count of 9.90 K/uL (reference range: 1.60-6.10), absolute lymphocyte count of 1.06 K/uL, absolute monocyte count of 0.90 K/uL, and absolute immature granulocyte count of 0.46 K/uL (reference range: 0.00-0.03). Blood cultures remained negative. The participant was treated with levofloxacin for sepsis related to pneumonia, and guaifenesin and benzonatate for pneumonia. On 11 Aug 2020, at Study Visit 4, Day 29, central laboratory results included platelet count of 901×10^3/uL (140-400) and alkaline phosphatase (ALP) of 477 U/L (reference range: 35-144). On 17 Aug 2020, local laboratory results

revealed gamma-glutamyl transferase (GGT) of 244 U/L (reference range: 3-70), ALP of 249 U/L, creatinine kinase of 41 U/L (reference range: 44-196), blood urea nitrogen 29 mg/dL (reference range: 7-25), creatinine of 0.69 mg/dL (reference range: 0.70-1.25), RBC count of 3.79 million/uL (reference range: 4.20-5.80), HGB of 12.1 g/dL (reference range: 13.2-17.1), HCT of 37.0% (reference range: 38.5-50.0), platelet (PLT) count 618×10^3/uL, Epstein Barr viral (EBV) capsid antigen antibody (immunoglobulin [Ig] G) of 508 U/mL (high), EBV capsid antigen antibody (IgM) of <30 U/ml, EBV nuclear antigen antibody (IgG) of 46.8 U/mL (high), and a negative cytomegalovirus antibody IgG and IgM. EBV results (ranges not reported) were consistent with prior exposure. On 19 Aug 2020, a right upper quadrant ultrasound revealed borderline hepatomegaly with increased echogenicity likely due to fatty replacement; no focal intrahepatic lesions were seen; gallbladder sludge layering dependently in the gallbladder; no definite calculi, wall thickening or pericholecystic fluid were seen; normal bile ducts; and mild aortic ectasia with maximum dimension of 34 mL in the proximal segment.

On 20 Aug 2020, a 2-view chest x-ray revealed persistent right lower lobe airspace disease compatible with pneumonia, slightly decreased from prior study. On 24 Aug 2020, laboratory results revealed GGT of 155 U/L, creatinine of 0.68 mg/dL, ALP of 160 U/L, RBC count of 3.91 million/uL, HGB of 12.3 g/dL, HCT of 38.1% and PLT of 311×10^3/uL. On 26 Aug 2020, the participant was seen in follow-up via virtual visit with primary provider for abnormal laboratory results. At this time, PLT was within normal limits, elevated ALP had fallen from 477 U/L to 160 U/L and was almost back to normal, and GGT had decreased from 244 U/L to 155 U/L. Aspartate aminotransferase, alanine aminotransferase, and bilirubin were normal throughout. The participant reported feeling back to baseline, and the weakness and fatigue had resolved. He had started an exercise program and reported that he was doing well. He was educated to report any new or unusual symptoms and to return to the clinic for follow-up in two months.

Action taken with the IP was withdrawn.

The event of pneumonia was considered to be resolved on 26 Aug 2020. On 05 Aug 2020, the participant was discharged from the hospital. The Investigator assessed the event of pneumonia to be not related to the IP. On 11 Aug 2020, the participant discontinued from the study due to adverse event.

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
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16.2 Participant Data Listings

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16.3 Case Report Forms (CRFs)